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RTC Research Toxicology Centre

[redacted]

13 WEEK ORAL TOXICITY STUDY IN RATS

FOLLOWED BY A 8 WEEK RECOVERY PERIOD

AUDITED DRAFT REPORT

RTC STUDY NO. A1474

a9 - DRAFT - 14th December 2016

Sponsor:
SOLVAY SPECIALTY POLYMERS ITALY S.p.A.
Viale Lombardia, 20
20021 Bollate (MI)
Italy

COMPLIANCE STATEMENT

I, the undersigned, was responsible for the preparation of this report and hereby declare that it constitutes a true and faithful account of the procedures adopted and of the results obtained in the performance of the study. The aspects of the study conducted by Research Toxicology Centre S.p.A. were performed in accordance with:

1. Decreto Legislativo 2 March 2007 n. 50, Attuazione delle direttive 2004/9/CE e 2004/10/CE, concernenti l'ispezione e la verifica della Buona Pratica di Laboratorio (BPL) ed il ravvicinamento delle disposizioni legislative, regolamentari ed amministrative relative all'applicazione dei principi di Buona Pratica di Laboratorio ed al controllo della loro applicazione per le prove sulle sostanze chimiche (G.U. 13 Aprile 2007, Serie generale n. 86) and subsequent revisions.
2. Directive 2004/10/EC of European Parliament and of the Council of 11 February 2004, on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of Good Laboratory Practice and the verification of their applications for tests on chemical substances.
3. ENV/MC/CHEM(98)17 OECD principles on Good Laboratory Practice (as revised in 1997).

C. Longobardi, Biol.D. — *Date*
STUDY DIRECTOR

KEY STUDY STAFF

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Test Facility Management

G. Oberto, DVM, ERT	General Manager & Scientific Director
S. Villa, Chem.D.	General Manager & Operational Director

Management authorization:

GENERAL MANAGER *Date*

QUALITY ASSURANCE STATEMENT

Study phases	Inspection dates[a]	Report to SD[b]	Report to CM[c]
Protocol			
Protocol check	17.09.2015	17.09.2015	17.09.2015
Protocol amendment (1)	01.03.2016	01.03.2016	01.03.2016
Protocol amendment (2)	07.04.2016	07.04.2016	07.04.2016
Protocol amendment (3)	14.12.2016	14.12.2016	14.12.2016
Study based inspections related to this study			
Dose praparation	07.10.2015	13.11.2015	20.11.2015
Dose preparation	24.12.2015	15.01.2016	22.01.2016
Dosing (oral)	05.10.2015	12.10.2015	12.10.2015
Dosing (oral)	30.12.2015	08.01.2016	08.01.2016
Functional observation battery	24.11.2015	30.11.2015	30.11.2015
Motor activity	21.12.2015	08.01.2016	08.01.2016
Sensory reactivity to stimuli	24.12.2015	08.01.2016	08.01.2016
Grip strength	24.12.2015	08.01.2016	08.01.2016
Blood sampling at necropsy	05.01.2016	08.01.2016	08.01.2016
Blood sampling (Biomarkers)	09.10.2015	12.10.2015	12.10.2015
Process based inspections related to this type of study			
Allocation	15.07.2015	-	23.07.2015
Body weight	25.08.2015	-	11.09.2015
Clinical signs	26.08.2015	-	28.08.2015
Food consumption	09.11.2015	-	13.11.2015
Blood sampling	09.02.2016	-	12.02.2016
Despatch to necropsy	04.01.2016	-	08.01.2016
Necropsy	09.02.2016	-	12.02.2016
Final Report (end of review)	*date of QA Statement signature*		

[a] *For Final Report - date of end of review*
[b] *SD = Study Director only for protocol check and study based inspections*
[c] *CM = Company Management*

Other QA process based inspections were carried out on departments or laboratories performing routine activities (e.g. Analytical Chemistry, Histopathology, Veterinary Services and Clinical Pathology) as well as on other routine activities not directly related to this type of study. The relevant documentation is kept on file although specific inspection dates are not reported here. Involved departments or laboratories and support functions are also subject to regular facility inspections.

Review of this report by RTC QA found the reported methods and procedures to describe those used and the results to constitute an accurate representation of the recorded raw data.

M. M. Brunetti, Biol. D.
Spec. General Pathology
HEAD OF QA AND GXP COMPLIANCE

Date

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1 SUMMARY

1.1 Study design

The oral toxicity of [redacted] in rats, following daily oral administration for 13 consecutive weeks and recovery from any treatment-related effect during a period of 8 weeks, were investigated in this study.

Three groups, each of 10 male and 10 female Sprague Dawley rats, received the test item by gavage at dosages of 0.05, 0.1 and 0.3 mg/kg/day for 13 consecutive weeks. A fourth, similarly constituted group received the vehicle alone (sterile water) and acted as a control. Each dose group included 5 additional animals per sex which were sacrificed after 8 weeks of recovery.

The following investigations were performed: daily clinical signs, weekly detailed clinical signs (removal from cage and open field observations), evaluation of sensory reactivity to stimuli and motor activity, body weight, food consumption, ophthalmoscopy, clinical pathology investigations, terminal body weight, organ weights, macroscopic observations and histopathological examination.

1.2 Mortality and clinical signs

No mortality occurred during the study. No clinical signs of toxicological significance were observed.

1.3 Weekly detailed clinical signs (Removal from cage and Open field measurements)

No changes of note were found at the weekly clinical examination which included an evaluation of neurotoxicity during treatment and recovery periods.

1.4 Neurotoxicity assessment (Functional Tests and Motor activity)

No differences between treated animals and controls, which could be considered treatment-related, were observed at functional tests (sensory reactivity, landing footsplay, grip strength) and motor activity measurements performed at the end of treatment and recovery periods.

1.5 Body weight

No changes of toxicological significance were observed in body weight during treatment and recovery periods.

Body weight gain was comparable between treatment and control groups.

1.6 Food consumption

No treatment-related changes were observed in food consumption in either sex during the experimental period.

1.7 Ophthalmoscopy

No significant findings were detected at the ophthalmoscopic examinations performed during the study.

1.8 Haematology

Dosing phase
Some statistically significant differences between control and treated animals were recorded for red series parameters at all dose levels investigated. These were from 2% to 9%. In addition neutrophils in females from the low and mid-dose groups were increased by 66%. Due to the minimal severity and/or the absence of dose-relation, the above changes were considered of no toxicological relevance.

Coagulation

Dosing phase
No changes of toxicological importance were observed.

1.9 Clinical chemistry

Dosing phase
Fluctuations of some biochemical markers were recorded in treated animals, males being more sensitive than females. In general, changes comprised liver/metabolic parameters and were of low severity, therefore they could reflect mainly metabolic / adaptive changes rather than tissue/organ injury. Increases of both transaminases enzymes were recorded in a number of animals, including controls. Degenerative hepatic changes were described at histopathological examination for few high dose males; however, no correlation was recorded with these findings, therefore no clear conclusions could be drawn.

Recovery phase
Some of the fluctuations recorded during the dosing phase were still present or showed partial reversibility. In particular, triglycerides and creatinine were lower than controls in all treated males and glucose was higher than controls in females dosed at 0.3 mg/kg/day. As for the dosing phase, changes were mainly indicative of adaptive changes.

1.10 Organ weights

Dose-related, statistically significant increases in liver weights were noted in mid- and high dose males and in the high dose females at the end of the treatment period.

These increases were still present at the end of the recovery period in the high dose animals.

1.11 Macroscopic observations

Final sacrifice

Treatment-related changes were noted at *post mortem* examination in the liver of most males and in one female receiving 0.3 mg/kg/day. Enlarged and/or swollen liver was the only macroscopic change observed in such treated animals. Reduced size of the thymus was noted in 2 out of 10 high dose females.

Recovery sacrifice

No treatment-related changes were noted at *post mortem* in the animals sacrificed after 8 weeks of recovery period.

1.12 Microscopic examination

Final sacrifice

Hepatocytic hypertrophy, associated with cytoplasmic eosinophilia, was seen in the liver of males and females receiving 0.3 mg/kg/day. This was seen in high dose males with an increased severity degree and a major extention in the hepatic lobule when compared with that observed in males dosed at 0.1 mg/kg/day or in high dose females (0.3 mg/kg/day). Hepatocytic degenerative changes such as necrosis were also reported in few high dose males. Micro and/or macrovescicular hepatocytic vacuolation, most like consistent with fatty change (steatosis), was noted in most males dosed at 0.05 and 0.1 mg/kg/day, as well as in few high dose females.

In addition, males receiving [redacted] at 0.1 mg/kg/day also showed follicular cell hypertrophy in the thyroid, associated only in males dosed at 0.3 mg/kg/day with basophilic cell hypertrophy in the pars distalis of the pituitary.

Recovery sacrifice

Hepatocytic hypertrophy, associated with cytoplasmic eosinophilia, sporadic hepatocytic necrosis and/or micro and/or macrovescicular hepatocytic vacuolation was observed in the liver of high dose males, dosed at 0.3 mg/kg/day. Micro and/or macrovescicular hepatocytic vacuolation was the only relevant liver change noted in the remaining treated males (low and medium dosages) sacrificed after 8 weeks of recovery period.

1.13 Conclusions

On the basis of the above results, signs of possible treatment-related effects of the test item, [redacted] were observed in male rats at the dose level of 0.3 mg/kg/day and, with minor extent, in females dosed at 0.3 mg/kg/day and males and females at the dosage of 0.1 mg/kg/day, when administered by oral gavage for 13 consecutive weeks at the dosages of 0.05, 0.1 and 0.3 mg/kg/day.

These effects were demonstrated by the slight changes in clinical pathology parameters and the *post mortem* findings. A main target organ, the liver, was identified on the basis of the organ weights data and histopathological findings. A second target organ appeared to be the thyroid, whose changes were considered to be a secondary effect of the liver toxicity. The above effects showed a dose-related trend and appeared to be only partially reversible after the 8-week recovery period.

No changes that could be considered adverse were observed in male animals dosed at 0.05 mg/kg/day and in female animals dosed at 0.05 and 0.1 mg/kg/day, indicating that females were less sensitive than males.

Therefore, the test item [redacted] when administered daily to rats for 13 consecutive weeks to both sexes, showed a No Observed Adverse Effect Level (NOAEL) of 0.1 mg/kg/day in the females and 0.05 mg/kg/day in the males.

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2 INTRODUCTION

2.1 Purpose

The purpose of this study was to investigate the toxicity of [redacted] in rats after daily oral administration for 13 weeks and recovery from any treatment-related effects during a recovery period of 8 weeks. In addition, supplemental analyses should be conducted to investigate parameters that could be used as liver injury biomarkers.

2.2 Regulatory compliance

Experimental procedures were based on the following guidelines:

- OECD Guideline no. 408 'Repeated Dose 90-day Oral Toxicity Study in Rodents' adopted 21 September 1998.
- Test method B.26. "Sub-chronic Oral Toxicity Test repeated Dose 90-Day Oral Toxicity Study in Rodents " described in Council Regulation (EC) No. 440/2008 and subsequent revisions.

The Sponsor has affirmed that the test item is a chemical product and that the study was performed to comply with the relevant legislation for safety assessment, for notification or for submission to Regulatory Authorities.

2.3 Choice of the species, administration route and dose levels

The Sprague Dawley SD rat was the species and strain of choice because it is accepted by many regulatory authorities and there is ample experience and background data on this species and strain.

The test item was administered orally, by gavage. The oral route was selected as it is a suitable route of testing generally considered appropriate for assessing potential adverse effects and perform risk assessment in man.

Dose levels of 0.05, 0.1 and 0.3 mg/kg/day were selected in consultation with the Sponsor, based on information from other studies.

2.4 Animal welfare

Procedures and facilities were compliant with the requirements of the Directive 2010/63/EU on the protection of animals used for scientific purposes. The national transposition of the Directive is defined in *Decreto Legislativo 26/2014.*

RTC test facility is fully accredited by AAALAC. Aspects of the protocol concerning animal welfare have been approved by RTC animal-welfare body.

2.5 Sponsor and Test Facility

The study was performed at:

Research Toxicology Centre S.p.A.
Via Tito Speri, 12/14
00071 Pomezia
Italy

On behalf of the Sponsor:

SOLVAY SPECIALTY POLYMERS ITALY S.p.A.
Viale Lombardia, 20
20021 Bollate (MI)
Italy

2.6 Study schedule

Procedure	**Date**
Protocol approved by: Study Director	14 September 2015
Start of experimental phase Allocation of animals	28 September 2015
End of experimental phase Last day of necropsy	1 March 2016
Study completion	Date of Study Director's signature on this report

3 TEST ITEM

3.1 Identity

Details of the test item received at RTC were as follows:

Identity	[redacted]
Batch no.	90409/86-11
CAS Number	330809-92-2
Expiry date	July 2020
Storage conditions	Ambient
Appearance	White solid
RTC number	14663

The determination of the identity, strength, purity, composition and stability of the test item was the responsibility of the Sponsor. The certificate of analysis is presented in Addendum 3 of this report. A sample of test item was taken and will be stored in the archives of RTC for 10 years prior to disposal.

3.2 Vehicle

The vehicle was sterile water.

3.3 Formulation procedure

The required amount of [redacted] was dissolved in the vehicle. On a weekly basis, a sufficient amount of the test item was dissolved in purified water, to obtain a concentration 0.3 mg/mL (stock solution). Then further independent solutions were prepared with the same vehicle from the stock solution to give the required concentrations of 0.005, 0.01 and 0.03 mg/mL. The dilutions were prepared daily (concentrations of 0.005, 0.01 and 0.03 mg/mL) for the first 2 weeks of the study, then weekly thereafter when the stability at room temperature was assessed for the dilutions. Concentrations were calculated and expressed in terms of test item as supplied.

3.4 Formulation analysis

The analytical method was validated in the present study in the range from 0.005 to 0.3 mg/mL. Linearity, accuracy and precision were within the limits stated in RTC SOPs for solutions ($r > 0.98$; accuracy 95-105%; precision CV < 5%).

In this study a 24 hour and 8 day stability at room temperature and at +4°C was verified in the range from 0.005 to 0.3 mg/mL. According to RTC SOPs, solutions are considered to be stable if concentration after the defined period of storage, is still acceptable (90-110%).

The proposed formulation procedure for the test item was checked in the range from 0.005 to 0.3 mg/mL by chemical analysis (concentration) during the pre-treatment period to confirm that the method was suitable. Final results for all levels were within the acceptability limits stated in RTC SOPs for concentration (90-110%). Chemical analysis was carried out by the Analytical Chemistry Department at RTC. The software used for this activity was Analyst 1.6.2.

Samples of the formulations prepared on Day 1 and Week 13 were analysed to check the concentration. On Day 1, results of the analyses were within the acceptability limits stated in RTC SOPs for concentration of solutions (90-110%). On Week 13, in the first instance analysis of the dilutions was out of acceptance limits for all concentrations, although the stock solution was within the acceptance limits. The analysis was repeated and the results were within the acceptability limits.

Results of formulation analyses are presented in Addendum 4 of this report.

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4 METHODS

4.1 Animal management

4.1.1 Animal supply and acclimatisation

A total of 140 Hsd: Sprague Dawley SD rats (70 males and 70 females), 27-29 days old and with body weight of approximately 75-99 g, were ordered from and supplied by Harlan Italy s.r.l., San Pietro al Natisone (UD), Italy.

After arrival, on 17 September 2015, the weight range for each sex was determined and the animals were temporarily identified within the cage by means of a coloured mark on the tail. A health check was then performed by a veterinarian. An acclimatisation period of 18 days was allowed before the start of treatment, during which time the health status of the animals was assessed by thorough observations.

4.1.2 Animal husbandry

The animals were housed in a limited access rodent facility. Animal room controls were set to maintain temperature and relative humidity at 22°C ± 2°C and 55% ± 15% respectively; actual conditions were monitored, recorded and the records retained. No relevant deviations from these ranges were recorded during the study. There were approximately 15 to 20 air changes per hour and the rooms were lit by artificial light for 12 hours each day.

The animals were housed up to 5 of one sex to a cage, in clear polysulphone solid bottomed cages as indicated in the relevant SOP. Nesting material was provided inside suitable bedding bags and changed at least twice a week.

Drinking water was supplied *ad libitum* to each cage via water bottles, except as noted in section 4.4.

A commercially available laboratory rodent diet (4 RF 21, Mucedola S.r.l., Via G. Galilei, 4, 20019 Settimo Milanese (MI), Italy) was offered *ad libitum* throughout the study, except as noted in section 4.4.

There was no information available to indicate that any non-nutrient substance likely to influence the effect of the test item was present in the drinking water or the diet. Records of analyses of water and diet are kept on file at RTC.

Dated and signed records of activities relating to the day to day running and maintenance of the study in the animal house were recorded.

4.1.3 Allocation to groups

On the day of allocation (7 days prior to the start of treatment) all animals were weighed. Animals at the extremes of the weight distribution and one animal showing signs of ill health were excluded to leave the required number of animals.

The rats were allocated to groups by computerised stratified randomisation to give approximately equal initial group mean body weights. Individuals were uniquely identified within the study by sex, tattoo on the hind feet and ear notch and housed up to 5 of one sex per cage.

The cages were identified by a label recording the study number, animal numbers and details of treatment. The arrangement of cages in batteries was such that cages from each treatment group were evenly distributed across the battery (Figure 1) to minimise possible environmental effects.

After allocation, 1 animal showing signs at ophthalmoscopy carried out during the period between allocation and the start of treatment was replaced with a spare animal showing no ocular abnormality.

4.2 Treatment

4.2.1 Dose levels, group size and identification

Each main group comprised 10 male and 10 female rats.

Each dose groups included 5 additional animals per sex which were sacrificed after 8 weeks of recovery.

The group identification and animal numbers assigned to the treatment are summarised below:

Group	Treatment (mg/kg/day)[a]	Level	Rat Numbers			
			Main phase		Recovery phase	
			M (even)	F (odd)	M (even)	F (odd)
1	0	Control	2-20	1-19	22-30	21-29
2	0.05	Low	32-50	31-49	52-60	51-59
3	0.1	Medium	62-80	61-79	82-90	81-89
4	0.3	High	92-110	91-109	112-120	111-119

[a]in terms of test item as supplied

The rat numbers listed above formed the last digits of a computer generated 8 figure animal number (the remaining digits of the animal number were different for each concurrent study and served to ensure unique animal numbering for any study employing computerised data collection). The computerised system used in this study was Pristima, Version 6.3.2.

4.2.2 Administration of test item

The test item was administered orally by gavage at a dose volume of 10 mL/kg body weight. Control animals received the vehicle alone at the same dose volume. The dose was administered to each animal on the basis of the most recently recorded body weight and the volume administered was recorded for each animal.

4.2.3 Duration of treatment

All animals were dosed once a day, 7 days a week, for a minimum of 13 consecutive weeks. Animals in the main phase were dosed up until the day before necropsy. Following end of treatment, recovery group animals (5 males and 5 females per group) were observed for a recovery period of 8 weeks.

4.3 *In vivo* observations

Full records were maintained for all measurements and observations.

4.3.1 Mortality

Throughout the study, all animals were checked early in each working day and again in the afternoon. At weekends and Public Holiday a similar procedure was followed except that the final check was carried out at approximately mid-day.

4.3.2 Clinical signs and neurotoxicity assessment

All clinical signs were recorded for individual animals. Once before commencement of treatment and once daily during the study, each animal was observed and any clinical signs were recorded. Observations were performed at the same time interval each day, the interval was selected taking into consideration the presence of post-dose reactions.

Once before commencement of treatment and at least once per week from the start of treatment, each animal was given a detailed clinical examination.

Each animal was observed in an open arena. The test included observation of changes in gait and posture, reactivity to handling, presence of clonic or tonic movements, stereotypies or bizarre behaviour and effects on the autonomic nervous system (e.g. lachrymation, piloerection, unusual respiratory pattern). Changes in fur, skin, eyes, mucous membranes, occurrences of secretions and excretions were also recorded.

Once during Weeks 12 or 13 of treatment and once during Week 8 of recovery an evaluation of sensory reactivity to stimuli of different modalities (e.g. auditory, visual and proprioceptive stimuli) and an assessment of grip strength were also performed.

4.3.3 Motor activity assessment (MA)

The motor activity (MA) of all animals was measured once during Week 12 or 13 of treatment and once during Week 8 of recovery by an automated activity recording. Measurements were performed using a computer generated random order.

4.3.4 Body weight

Each animal was weighed on the day of allocation to treatment group, on the day that treatment commenced, weekly thereafter and just prior to necropsy.

4.3.5 Food consumption

The weight of food consumed by each cage of rats was recorded at weekly intervals following allocation. The group mean daily intake per rat was calculated.

4.3.6 Ophthalmoscopy

Both eyes of all animals assigned to the study were examined just prior to the commencement of treatment by means of an ophthalmoscope, and by a slit-lamp microscope, after the instillation of 0.5% Tropicamide (Visumidriatic®, Visufarma, Rome, Italy). One animal with non-resolving lesions was replaced with a spare animal showing no ocular abnormality, from the batch initially ordered for the study. The eyes of all animals from high dose and control groups were re-examined during Week 13 of treatment.

4.4 Clinical pathology investigations

Prior to necropsy of main phase animals, blood samples were taken in fasting conditions from the abdominal vena cava under isofluorane anaesthesia. At the end of week 8 of the recovery period blood samples were also taken (in agreement with the Sponsor) from all surviving animals under identical conditions in order to re-evaluate clinical chemistry parameters, since potential treatment-related changes were observed at measurements performed at the end of treatment period.

Blood samples were collected and analysed in the same order. The blood samples collected were divided into tubes as follows:

- EDTA anticoagulant for haematological investigations
- Heparin anticoagulant for biochemical tests
- Citrate anticoagulant for coagulation tests

The measurements to be performed on blood samples are listed below:

4.4.1 Haematology

- Haematocrit
- Haemoglobin
- Red blood cell count
- Reticulocyte count
- Mean red blood cell volume
- Mean corpuscular haemoglobin
- Mean corpuscular haemoglobin concentration
- White blood cell count
- Differential leucocyte count
    - Neutrophils
    - Lymphocytes
    - Eosinophils
    - Basophils
    - Monocytes
    - Large unstained cells
- Platelets

These parameters were analysed by Siemens Advia 120.

Coagulation

- Prothrombin time

This parameter was analysed by Instrumentation Laboratory ACL 3000 PLUS.

4.4.2 Clinical chemistry

- Alkaline phosphatase
- Alanine aminotransferase
- Aspartate aminotransferase
- Gamma-glutamyltransferase
- Urea
- Creatinine
- Glucose
- Triglycerides
- Phosphorus
- Total bilirubin
- Total cholesterol
- Total protein
- Albumin
- Globulin
- A/G Ratio

- Sodium
- Potassium
- Calcium
- Chloride

These parameters were analysed by Siemens Advia 1200.

4.4.3 Additional investigations (Liver injury panel biomarkers determination and miRNA-122)

Once pre-dose and at the end of Weeks 1, 4, 8 of and 13 treatment, additional blood samples were withdrawn from the tail vein or, under isofluorane anaesthesia, from the abdominal vena cava of all main phase animals. The collected blood samples were divided in two 0.5 mL aliquots with no anticoagulant and one 0.4 mL aliquot with Heparin anticoagulant.

At the end of Week 8 of the recovery period, blood samples were also taken (in agreement with the Sponsor) from all surviving animals under identical conditions. Animals were under food deprivation prior to Week 13 of treatment and Week 8 of recovery bleeds only.

Blood samples were collected into tubes as indicated above, centrifuged and serum or plasma samples were frozen at approximately -80°C until analysis.

No analyses were performed as they were not requested by the Sponsor. The samples will be eliminated within 3 months after the issue of the Final Report.

4.5 Terminal studies

4.5.1 Euthanasia

Animals that had completed the scheduled test period were killed by exsanguination under isofluorane anaesthesia. All animals were subjected to necropsy, supervised by a pathologist, as detailed below.

4.5.2 Necropsy

The clinical history of the animals was studied and a detailed *post mortem* examination was conducted (including examination of the external surface and orifices). Changes were noted, the requisite organs weighed and the required tissue samples preserved in fixative and processed for histopathological examination (see sections 4.5.3 to 4.5.5).

4.5.3 Organ weights

From all animals completing the scheduled test period, the organs indicated in Annex 1 of Study Protocol (section 4.5.6) were dissected free of fat and weighed.

The ratios of organ weight to body weight were calculated for each animal.

4.5.4 Tissues fixed and preserved

Samples of all the tissues listed in Annex 1 of Study Protocol (section 4.5.6) were fixed and preserved in 10% neutral buffered formalin (except eyes, testes and epididymides which were fixed in Modified Davidson's fluid and preserved in 70% ethyl alcohol).

A small liver sample was processed as follows for possible further investigations. Tissue samples were rinsed with cold saline solution, divided into two aliquots, weighed, flash frozen in liquid nitrogen and stored at approximately -80°C pending analysis.

4.5.5 Histopathological examination

The tissues required for histopathological examination are listed in Annex 1 of Study Protocol (section 4.5.6). After dehydration and embedding in paraffin wax, sections of the tissues were cut at 5 micrometre thickness and stained with haematoxylin and eosin.

The examination was performed as detailed below:

i Tissues specified in Annex 1 of Study Protocol (section 4.5.6) from all animals in the control and high dose groups killed at the end of the 13 weeks of treatment.
ii All abnormalities in all main phase groups

The examination was extended to include the liver from female animals killed after 13 weeks of treatment (main phase groups 2 and 3) and 8 weeks of recovery (recovery phase groups 1, 2, 3 and 4) and the liver, thyroid gland and pituitary gland from male animals of the same groups, since there was a suspicion of treatment-related changes at the high dose level.

4.5.6 Annex 1 of Study Protocol

Organs / Tissues	Weight	Fixation Preservation	Microscopic Examination
Abnormalities		✓	✓
Adrenal glands	✓	✓	✓
Aorta		✓	✓
Bone marrow (from sternum)		✓	✓
Brain (cerebrum, cerebellum, medulla/pons)	✓	✓	✓
Caecum		✓	✓
Colon		✓	✓
Duodenum		✓	✓
Epididymides	✓	✓	✓
Eyes		✓	✓
Femur with joint		✓	✓
Heart	✓	✓	✓
Ileum		✓	✓
Jejunum (including Peyer's patches)		✓	✓
Kidneys	✓	✓	✓
Larynx		✓	✓
Liver	✓	✓	✓
Lungs (including mainstem bronchi)		✓	✓
Lymph nodes – cervical		✓	✓
Lymph nodes – mesenteric		✓	✓
Mammary area		✓	✓
Nasopharynx		✓	✓
Oesophagus		✓	✓
Optic nerves		✓	✓
Ovaries	✓	✓	✓
Oviducts[1]		✓	✓
Pancreas		✓	✓
Parathyroid glands[2]		✓	✓
Pituitary gland		✓	✓
Prostate gland		✓	✓
Rectum		✓	✓
Salivary glands		✓	✓
Sciatic nerve		✓	✓
Seminal vesicles		✓	✓

continued on next page

[1]weighed and preserved with ovaries
[2]weighed and preserved with thyroid gland

Organs / Tissues	Weight	Fixation Preservation	Microscopic Examination
Skeletal muscle		✓	✓
Skin		✓	✓
Spinal column		✓	
Spinal cord (cervical, mid-thoracic, lumbar)		✓	✓
Spleen	✓	✓	✓
Stomach		✓	✓
Testes	✓	✓	✓
Thymus (where present)	✓	✓	✓
Thyroid gland		✓	✓
Trachea		✓	✓
Urinary bladder		✓	✓
Uterus – cervix	✓	✓	✓
Vagina		✓	✓

4.6 Statistical analysis

Standard deviations were calculated as considered appropriate. For continuous variables the significance of the differences amongst groups was assessed by analysis of variance. Differences between each treated group and the control group were assessed by Dunnett's test using a pooled error variance. The homogeneity of the data was verified by Bartlett's test before Dunnett's test. If the data were found to be inhomogeneous a Modified t test (Cochran and Cox) was applied.

The mean values, standard deviations and statistical analysis were calculated from the actual values in the computer without rounding off. Statistical analysis of histopathological finding was carried out by means of a nonparametric Kolmogorov-Smirnov test.

4.7 Protocol deviations

In order to avoid excessive stress to the animals, they were not subjected to food deprivation prior to the bleeds for liver injury panel (pre-dose, Weeks 1, 4 and 8, as indicated in the study protocol. Since the food deprivation was not required for those evaluations, this deviation is not considered to have comprised the purpose of the study.

There were no other deviations from the protocol.

4.8 Archives

Full records of all aspects of the study conduct were maintained together with the results of all measurements and observations. All specimens, raw data, records and documentation generated during the course of this study will be retained within RTC archives. The data will be kept for a period of 3 years after which the Sponsor will be contacted for instructions regarding despatch or disposal of the material. The Final Protocol, the Final Report and, where applicable, electronic raw data generated by RTC main validated systems (Pristima, Analyst, Empower), will be archived at RTC.

FINAL - DRAFT - 14th December 2016

5 RESULTS

5.1 Mortality and daily clinical signs (Table 1; Appendices 1, 2)

No mortality occurred during the study.

No clinical signs which could be considered treatment-related were observed during treatment and recovery periods.

5.2 Weekly detailed clinical signs (removal from cage and open field measurements) (Table 2; Appendices 3, 4)

No changes of toxicological significance were found at the weekly clinical examination, which included an evaluation of neurotoxicity. The reduction occasionally observed of the mean number of rearing in males or females of the high dose group was not considered to be of toxicological relevance.

5.3 Neurotoxicity assessment (Functional Tests and Motor activity) (Tables 3, 4, 5; Appendices 5, 6, 7)

No differences between treated animals and controls, which could be considered treatment-related were observed at evaluations of sensory reaction performed at the end of treatment and recovery periods. Motor activity measurements performed at the end of the treatment period did not show any statistically significant differences between treated animals and controls.

5.4 Body weight (Figure 2; Table 6; Appendix 8) and body weight gain (Table 7; Appendix 9

No significant differences in body weights and body weight changes were noted between treated animals and controls during treatment and recovery periods.

5.5 Food consumption (Table 8; Appendix 10)

No treatment-related changes were observed in food consumption in either sex during the experimental period.

5.6 Ophthalmoscopy (Table 9; Appendix 11; Addendum 5)

Animals with no ocular abnormality were selected for the study by an ophthalmoscopic examination performed before the start of treatment.

No findings were detected in both eyes of all surviving animals, from high-dose and control groups, when they were re-examined during Week 13 of treatment.

5.7 Haematology (Tables 10, 11; Appendices 12, 14, 13; Addendum 6)

Some statistically significant differences between control and treated animals were recorded, such as: decrease of erythrocytes, haemoglobin, haematocrit in males dosed at 0.05 and 0.3 mg/kg/day, increase of mean corpuscular haemoglobin concentration in animals of both sexes dosed at 0.05 and 0.3 mg/kg/day, increase of mean corpuscular haemoglobin in males receiving 0.3 mg/kg/day, increase of erythrocytes in females dosed at 0.1 mg/kg, increase of neutrophils in females treated with 0.05 and 0.1 mg/kg/day. Changes of the red series parameters were 2% to 9%, while neutrophils in females were increased by 66%. Due to the minimal severity and/or the absence of dose-relation, the above changes were considered of no toxicological relevance.

Coagulation

Dosing phase
Prothrombin time was slightly decreased in animals dosed at 0.1 and 0.3 mg/kg/day. Due to the minimal severity (up to 8%) and the direction of changes, this finding was considered of no toxicological importance.

5.8 Clinical chemistry (Table 12; Appendix 15; Addendum 6)

Dosing phase
Fluctuations of some biochemical markers were recorded in treated animals, males being more sensitive than females. In general, changes comprised liver / metabolic parameters and were of low severity, therefore they could reflect mainly metabolic / adaptive changes rather than tissue / organ injury. Increases of both transaminases enzymes were recorded in a number of animals, including controls. Degenerative hepatic changes were described at histopathological examination for few high dose males; however, no correlation was recorded with these findings, therefore no clear conclusions could be drawn. Data are reported in the following table. Control data are expressed in absolute values and data from treated groups as percentage differences with controls:

	1M	2M	3M	4M	1F	2F	3F	4F
ALP	163.27	-4	0	42*C	112.05	7	-13	-16
ALT	70.64	-5	-15	41	40.66	31	1	-15
AST	100.79	-21	-21	-13	72.58	38	-5	-20+C
GGT	0	NA	NA	NA	0.88	-17	-42	-18
TBIL	0.024	-46	-46	-79	0.082	10	-21	-61+C
CHOL	64.91	-20+D	-26+D	-13*D	81.64	-12	-11	-10
TRIG	64.88	-31	-54+C	-53*C	42.74	4	-11	28*D
GLU	168.98	-30*C	-22	6	113.34	-12	-7	18*D
UREA	42.42	-19+C	3	24+C	41.29	-5	1	0
CREA	0.387	-27	-15	-10	0.443	-14*D	-19+D	-22+D
Cl	106.3	-1	-2	-1	106.79	1	0	0
Ca	2.455	0	1	3*C	2.410	1	5+C	3*C
Na	142.39	1	1	1	143.35	-1	0	0
K	4.392	-19	-13	-12	3.374	33	0	3
IP	6.208	-10	0	4	5.736	5	-3	1
PROT	6.23	-2	-2	-3	5.81	3	6+D	4*D
ALB	3.69	-1	-3	-3	3.55	3	6+D	5*D
GLO	2.54	-3	-1	-2	2.26	2	5	4

*C = Cochran and Cox Test significant at 0.05 level, +C = Cochran and Cox Test significant at 0.01 level

*D = Dunnett LSD Test significant at 0.05 level, +D = Dunnett LSD Test significant at 0.01 level

Recovery phase

Some of the fluctuations recorded during the dosing phase were still present or showed partial reversibility. In particular, triglycerides and creatinine were lower than controls in all treated males and glucose was higher than controls in females dosed at 0.3 mg/kg/day. As for the dosing phase, changes were mainly indicative of adaptive changes. Animal no. A1474116 showed moderate increases of both transaminases enzymes. Since this finding was not recorded during the dosing phase, it cannot be conclusively attributed to treatment. The other statistically significant changes recorded (calcium, protein and albumin in males, bilirubin, creatinine, chloride and potassium in females) were of low severity and/or not dose-related, therefore considered of no toxicological significance.

Data are reported in the following table. Control data are expressed in absolute values and data from treated groups as percentage differences with controls:

	1M	2M	3M	4M	1F	2F	3F	4F
ALP	190.56	-12	-15	-2	104.18	-8	-15	-5
ALT	41.46	20	77	159	44.16	-12	-12	-17
AST	64.00	9	30	27	65.96	-2	7	-3
GGT	0.50	NA	-48	-30	1.80	-92	NA	-86
TBIL	0.022	-36	45	-45	0.046	161+D	61	-35
CHOL	80.28	-20	-11	-10	94.66	-12	-17	-4
TRIG	82.16	-27*D	-29*D	-59+D	72.86	-31	-23	-22
GLU	158.88	-16	-29	-6	80.94	23	33*D	49+D
UREA	43.38	-16	9	1	37.78	-9	16	9
CREA	0.474	-19*D	-20+D	-19*D	0.514	-12*D	3	-11
Cl	101.80	4	2	2	108.70	-7+D	-5	-3
Ca	2.394	3	2	6+D	2.350	3	4	3
Na	141.66	-1	0	0	141.14	-1	0	-1
K	4.110	-9	-8	-9	3.562	-6	-15+D	-11
IP	4.478	5	14	22	4.264	-6	11	9
PROT	6.30	-2	-5*D	1	6.30	0	-1	-2
ALB	3.72	-2	-6+D	1	3.74	3	0	-1
GLO	2.58	-2	-2	1	2.56	-5	-3	-5

*D = Dunnett LSD Test significant at 0.05 level, +D = Dunnett LSD Test significant at 0.01 level

5.9 Terminal body weight and organ weights (Tables 13, 14, 15; Appendices 16, 17)

No significant differences in terminal body weights were observed between treated animals and controls of the treatment and recovery periods.

Dose-related, statistically significant increases in liver weights were noted in mid- and high dose males (17% and 79% in mid- and high dose groups for absolute weights, 18% and 78% greater than controls for relative weights) and in the high dose females (28% for absolute, 29% for relative weight) at the end of the treatment period.

These increases were still present at the end of the recovery period in the high dose animals (in the males 36% and 33% and in the females 21% and 29% for absolute and relative weights, respectively).

No other significant changes were observed at the end of treatment or recovery periods.

5.10 Macroscopic observations (Table 16; Appendix 18; Addendum 7)

Final sacrifice

Treatment-related changes were noted at *post mortem* examination in the liver of most males and in one female receiving 0.3 mg/kg/day. Enlarged and/or swollen liver was the only macroscopic change observed in such treated animals. Reduced size of the thymus was only noted in 2 out of 10 high dose females.

Recovery sacrifice

No treatment-related changes were noted at *post mortem* in the animals sacrificed after 8 weeks of recovery period.

5.11 Microscopic observations (Table 17; Appendix 18; Addendum 7)

Final sacrifice

Hepatocytic hypertrophy, associated with cytoplasmic eosinophilia, was seen in the liver of males and females receiving 0.3 mg/kg/day. In addition, males receiving [redacted] at ≥ 0.1 mg/kg/day also showed follicular cell hypertrophy in the thyroid, associated only in males dosed at 0.3 mg/kg/day with basophilic cell hypertrophy in the pars distalis of the pituitary. The pathogenesis seen in males dosed at ≥ 0.1 mg/kg/day is a well-known mechanism, which initiates with the hepatic microsomal enzyme induction (hepatocytic hypertrophy), then subsequently with an increased clearance of the thyroid hormone and consequently the activation of the hypothalamus-pituitary-thyroid axis with the thyroid-releasing hormone (TRH) secretion, which develops the hypertrophy of thyrotrophs/basophilic cells in the pituitary gland (high dose males only), and then stimulates the hypertrophy of the follicular cell in the thyroid gland (increased synthesis and release of T3 and T4) [3] [4]. Hepatocytic hypertrophy was seen in high dose males with an increased severity degree and a major extention in the hepatic lobule (centrilobular/midzonal and in some occasions panlobular), when compared with that observed in males dosed at 0.1 mg/kg/day or in high dose females (0.3 mg/kg/day). Hepatocytic degenerative changes such as necrosis were also reported in few high dose males. Micro and/or macrovescicular hepatocytic vacuolation, most like consistent with fatty change (steatosis), was noted in most males dosed at 0.05 and 0.1 mg/kg/day, as well as in few high dose females.

[3] Liver Hypertrophy: A Review of Adaptive (Adverse and Non-adverse) Changes—Conclusions from the 3rd International ESTP Expert Workshop - Toxicologic Pathology, 40: 971-994, 2012

[4] Characterization of Xenobiotic-Induced Hepatocellular Enzyme Induction in Rats: Anticipated Thyroid Effects and Unique Pituitary Gland Findings - Toxicologic Pathology, 39: 664-677, 2011

Recovery sacrifice

Hepatocytic hypertrophy, associated with cytoplasmic eosinophilia, sporadic hepatocytic necrosis and/or micro and/or macrovescicular hepatocytic vacuolation was observed in the liver of high dose males. Micro and/or macrovescicular hepatocytic vacuolation was the only relevant liver change noted in the remaining treated males (low and medium dosages) sacrificed after 8 weeks of recovery period.

The remanining lesions reported in control and treated animals, in final and recovery sacrifice, were considered to be an expression of spontaneous and/or incidental pathology commonly seen in this species and age under our experimental conditions.

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6 DISCUSSION AND CONCLUSION

The oral toxicity of [redacted] in rats, following daily oral administration at dose levels of 0.05, 0.1 and 0.3 mg/kg/day for 13 consecutive weeks and recovery from any treatment-related effect during a period of 8 weeks, were investigated in this study.

No mortality occurred during the study. No clinical signs were observed at any of the dose levels investigated at daily observations carried out during the *in vivo* phase of the study. No lesions were recorded at ophthalmological examination. Body weight and food consumption were not affected by treatment with the test item.

Statistically significant differences between control and treated animals were recorded for red series parameters at all dose levels investigated. In addition neutrophils in females were reduced. Due to the minimal severity and/or the absence of dose-relation, the above changes were considered of no toxicological relevance.

Fluctuations of some biochemical markers were recorded in treated animals, males being more sensitive than females. In general, changes comprised liver / metabolic parameters and were of low severity, therefore they could reflect mainly metabolic / adaptive changes rather than tissue / organ injury. Increases of both transaminases enzymes were recorded in a number of animals, including controls. Degenerative hepatic changes were described at histopathological examination for few high dose males; however, no correlation was recorded with these findings, therefore no clear conclusions could be drawn.

Dose-related, statistically significant increases in liver weights were noted in mid- and high dose males (0.1 and 0.3 mg/kg/day) and in the high dose females (0.3 mg/kg/day) at the end of the treatment period. These increases were still present at the end of the recovery period in the high dose animals.

Treatment-related changes were noted at *post mortem* examination in the liver of most males and in one female receiving 0.3 mg/kg/day. Enlarged and/or swelling liver was the only macroscopic change observed in such treated animals. Reduced size of the thymus was only noted in 2 out of 10 high dose females.

At microscopc examination, the observed hepatocellular hypertrophy could be considered an adaptive and reversible change that does not compromise functional integrity, in particular in all treated females and probably in males dosed at 0.05 and 0.1 mg/kg/day.

On the other hand, in the presence of some hepatic degenerative changes observed in the high dose males at the end of treatment and still present after 8 weeks of recovery period, the liver pathology was be considered adverse at this dose level.

Follicular cell hypertrophy in the thyroid, associated only in males dosed at 0.3 mg/kg/day with basophilic cell hypertrophy in the pars distalis of the pituitary was also observed. This change was considered to be a secondary effect of the liver toxicity.

On the basis of the above results, signs of possible treatment-related effects of the test item, [redacted] were observed in male rats at the dose level of 0.3 mg/kg/day and, with minor extent, in females dosed 0.3 mg/kg/day and males and females at the dosage of 0.1 mg/kg/day, when administered by oral gavage for 13 consecutive weeks at the dosages of 0.05, 0.1 and 0.3 mg/kg/day.

These effects were demonstrated by the slight changes in clinical pathology parameters and the *post mortem* findings. A main target organ, the liver, was identified on the basis of the organ weights data and histopathological findings. A second target organ appeared to be the thyroid, whose changes were considered to be a secondary effect of the liver toxicity. The above effects showed a dose-related trend and appeared to be only partially reversible after the 8-week recovery period.

No changes that could be considered adverse were observed in male animals dosed at 0.05 mg/kg/day and in female animals dosed at 0.05 and 0.1 mg/kg/day, indicating that females were less sensitive than males.

Therefore, the test item [redacted] when administered daily to rats for 13 consecutive weeks to both sexes, showed a No Observed Adverse Effect Level (NOAEL) of 0.1 mg/kg/day in the females and 0.05 mg/kg/day in the males.

7 FIGURES

FIGURE 1 - Group and cage arrangement on battery

[redacted] 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

GROUP AND CAGE ARRANGEMENT ON BATTERY

STUDY NO.: A1474

MAIN PHASE						
Group Number	Treatment (mg/kg/day)+	Level	Rat numbers		Cage numbers	
			M (even)	F (odd)	M	F
1	0	Control	2-20	1-19	1-2	13-14
2	0.05	Low	32-50	31-49	4-5	16-17
3	0.1	Medium	62-80	61-79	7-8	19-20
4	0.3	High	92-110	91-109	10-11	22-23
RECOVERY PHASE°						
Group Number	Treatment (mg/kg/day)+	Level	Rat numbers		Cage numbers	
			M (even)	F (odd)	M	F
1	0	Control	22-30	21-29	3	15
2	0.05	Low	52-60	51-59	6	18
3	0.1	Medium	82-90	81-89	9	21
4	0.3	High	112-120	111-119	12	24

+ In terms of test item as supplied.
° No treatment was given during the recovery period.

Group/Sex
Cage no.

Males		Females	
1M	4M	1F	4F
1	11	13	23
2M	1M	2F	1F
4	2	16	14
3M	$1M^R$	3F	$1F^R$
7	3	19	15
4M	$2M^R$	4F	$2F^R$
10	6	22	18
2M	$3M^R$	2F	$3F^R$
5	9	17	21
3M	$4M^R$	3F	$4F^R$
8	12	20	24

^{R} = Recovery

[redacted] 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

BODY WEIGHT (g) - MALES

STUDY NO.: A1474

a9 - DRAFT - 14th December 2016

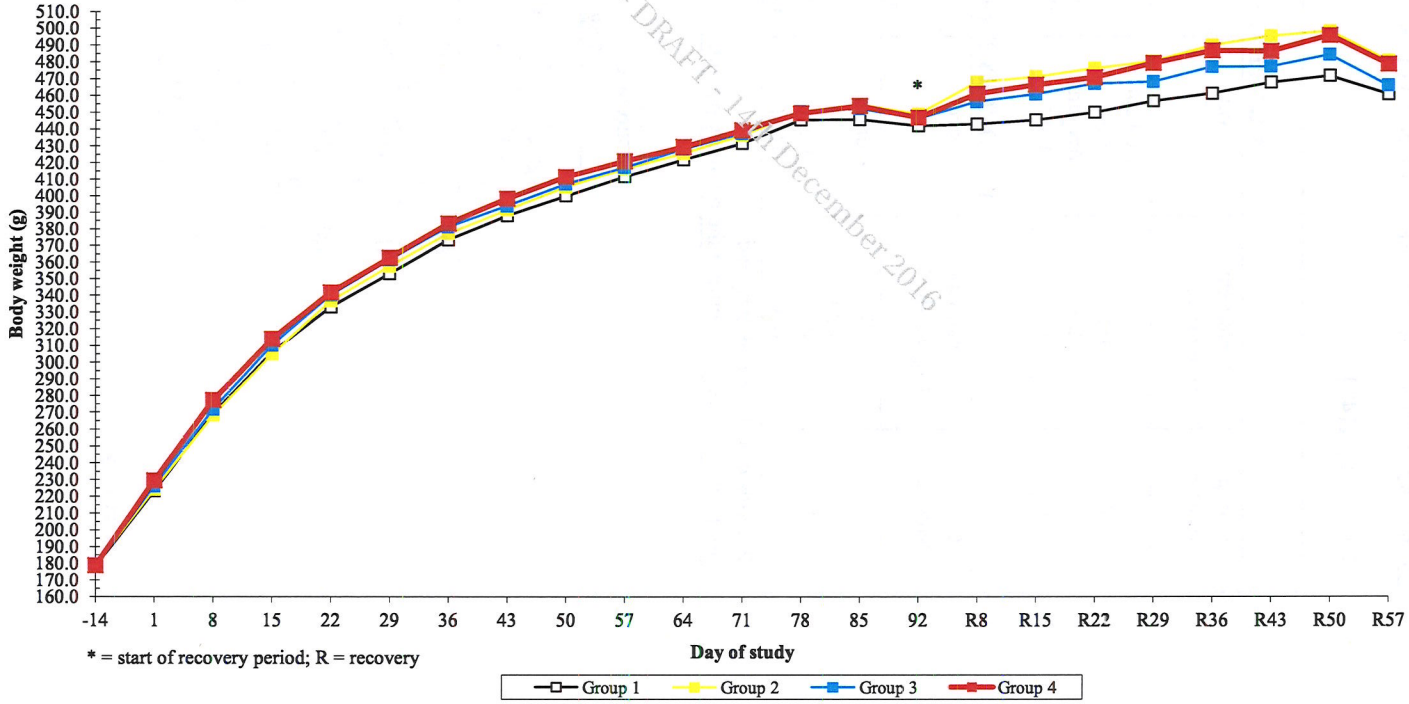

FIGURE 2 - Body weight

[redacted] 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

BODY WEIGHT (g) - FEMALES

STUDY NO.: A1474

a9 - DRAFT - 14th December 2016

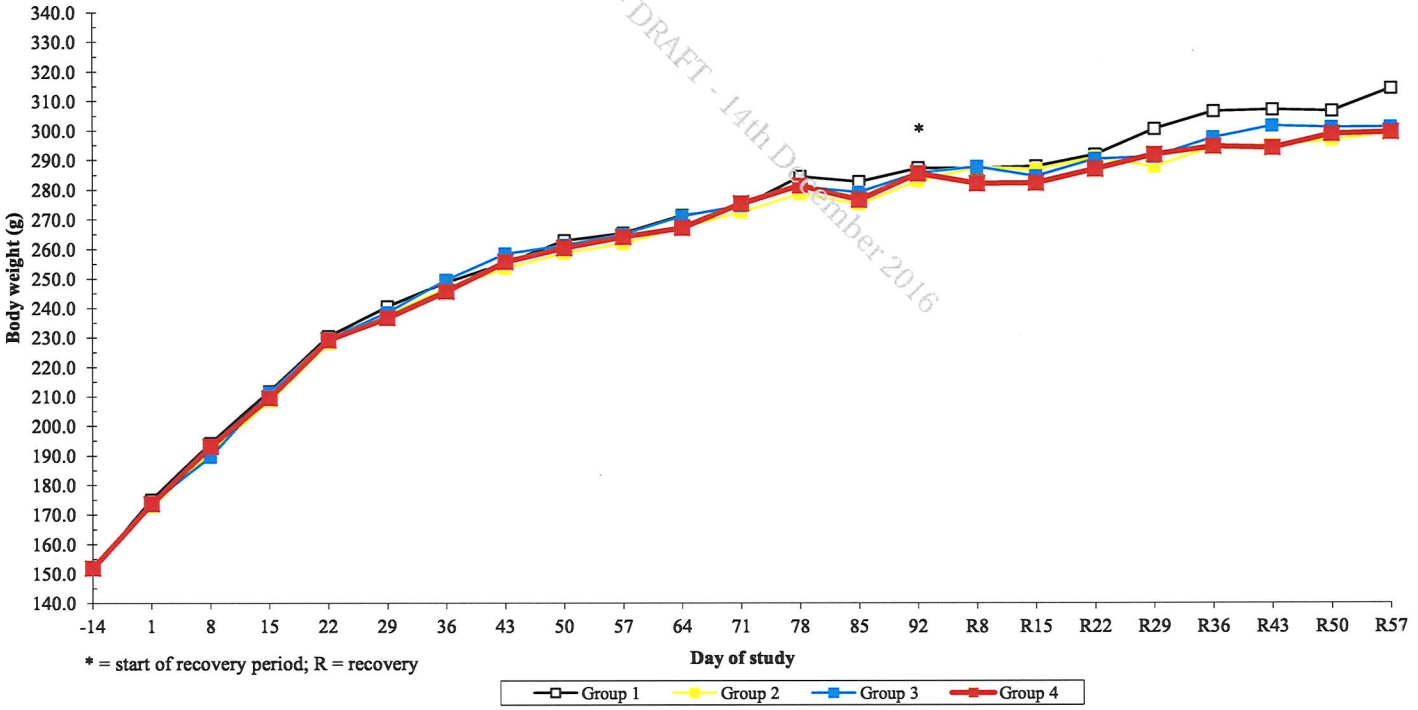

FIGURE 2 - Body weight

REDACTED AS TO TRADE NAMES

8 TABLES

Clinical signs_n/day - Group incidence

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Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Dosing

	Group:	Control		2		3		4	
	Number of Animals:	15		15		15		15	
	Number Examined:	15		15		15		15	
Category	**Observation**	**a**	**b**	**a**	**b**	**a**	**b**	**a**	**b**
No Significant signs									
	No Significant signs	15	91.6	15	91.7	15	92.0	15	92.0
EYE - EAR - MOUTH-NOSE									
	Tooth/teeth broken, Upper	1	6.0	1	5.0	0	0	0	0

Note: a = Number of animals affected

b = Number of days with clinical sign/animal

REDACTED AS TO TRADE NAMES

Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Dosing

	Group:	Control		2		3		4	
	Number of Animals:	15		15		15		15	
	Number Examined:	15		15		15		15	
Category	**Observation**	**a**	**b**	**a**	**b**	**a**	**b**	**a**	**b**
No Significant signs									
	No Significant signs	15	92.0	15	92.0	15	92.0	15	85.4
EYE - EAR - MOUTH-NOSE									
	Damaged ear, Right	0	0	0	0	0	0	2	49.5

Note: a = Number of animals affected
b = Number of days with clinical sign/animal

REDACTED AS TO TRADE NAMES

Clinical signs_n/day - Group incidence

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Recovery

	Group:	Control		2		3		4	
	Number of Animals:	15		15		15		15	
	Number Examined:	5		5		5		5	
Category	**Observation**	**a**	**b**	**a**	**b**	**a**	**b**	**a**	**b**
No Significant signs									
	No Significant signs	5	56.0	5	56.0	5	56.0	5	56.0

Note: a = Number of animals affected
b = Number of days with clinical sign/animal

REDACTED AS TO TRADE NAMES

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Recovery

	Group:	Control		2		3		4	
	Number of Animals:	15		15		15		15	
	Number Examined:	5		5		5		5	
Category	**Observation**	**a**	**b**	**a**	**b**	**a**	**b**	**a**	**b**
No Significant signs									
	No Significant signs	5	50.2	5	56.0	5	56.0	5	56.0
EYE - EAR - MOUTH-NOSE									
	Damaged eye, Right	1	29.0	0	0	0	0	0	0

Note: a = Number of animals affected
b = Number of days with clinical sign/animal

REDACTED AS TO TRADE NAMES

Open Field Measurements - Group mean data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Allocation Day 3

Males

Group		RE	UR	DE
Control	(n)	15	15	15
	Mean	14.3	0.0	0.2
	SD	3.70	0.00	0.77
2	(n)	15	15	15
	Mean	14.3	0.1	0.0
	SD	2.55	0.52	0.00
3	(n)	15	15	15
	Mean	14.3	0.0	0.0
	SD	4.03	0.00	0.00
4	(n)	15	15	15
	Mean	14.5	0.2	0.0
	SD	3.09	0.77	0.00

For Draft - Not Official Data

REDACTED AS TO TRADE NAMES

Open Field Measurements - Group mean data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Allocation Day 4

Females

Group		RE	UR	DE
Control	(n)	15	15	15
	Mean	18.6	0.5	0.0
	SD	1.92	0.99	0.00
2	(n)	15	15	15
	Mean	17.9	0.2	0.0
	SD	2.22	0.56	0.00
3	(n)	15	15	15
	Mean	17.2	0.1	0.0
	SD	2.18	0.52	0.00
4	(n)	15	15	15
	Mean	18.3	0.0	0.0
	SD	3.53	0.00	0.00

REDACTED AS TO TRADE NAMES

Open Field Measurements - Group mean data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 2

Males

Group		RE	UR	DE
Control	(n)	15	15	15
	Mean	19.7	0.0	0.0
	SD	1.54	0.00	0.00
2	(n)	15	15	15
	Mean	15.3+D	0.5	0.3
	SD	1.80	0.92	1.03
3	(n)	15	15	15
	Mean	16.2+D	0.3	0.1
	SD	2.93	0.90	0.52
4	(n)	15	15	15
	Mean	16.7+D	0.0	0.0
	SD	2.50	0.00	0.00

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 9

Males

Group		RE	UR	DE
Control	(n)	15	15	15
	Mean	10.9	0.3	0.0
	SD	3.20	1.05	0.00
2	(n)	15	15	15
	Mean	12.4	0.0	0.0
	SD	3.91	0.00	0.00
3	(n)	15	15	15
	Mean	15.8+D	0.3	0.0
	SD	2.34	0.46	0.00
4	(n)	15	15	15
	Mean	13.1	0.0	0.0
	SD	3.66	0.00	0.00

GLP COMPLIANT - VALIDATED SOFTWARE

TABLE 2 - Open Field Measurements - Group mean data

REDACTED AS TO TRADE NAMES

Open Field Measurements - Group mean data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 16

Males

Group		RE	UR	DE
Control	(n)	15	15	15
	Mean	12.3	0.3	0.0
	SD	2.58	0.62	0.00
2	(n)	15	15	15
	Mean	12.7	0.3	0.0
	SD	2.94	0.72	0.00
3	(n)	15	15	15
	Mean	14.1*C	0.1	0.0
	SD	2.13	0.26	0.00
4	(n)	15	15	15
	Mean	16.0#C	0.0	0.0
	SD	1.20	0.00	0.00

[illegible] - CONFIDENTIAL - AND PROPRIETARY DATA

TABLE 2 - Open Field Measurements - Group mean data

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

TABLE 2 - Open Field Measurements - Group mean data

Dosing Day 23

Males

Group		RE	UR	DE
Control	(n)	15	15	15
	Mean	14.5	0.3	0.0
	SD	1.51	0.59	0.00
2	(n)	15	15	15
	Mean	14.7	0.1	0.0
	SD	2.29	0.35	0.00
3	(n)	15	15	15
	Mean	13.1	0.1	0.0
	SD	2.47	0.35	0.00
4	(n)	15	15	15
	Mean	13.0	0.1	0.0
	SD	2.56	0.26	0.00

REDACTED AS TO TRADE NAMES

Open Field Measurements - Group mean data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 30

Males

Group		RE	UR	DE
Control	(n)	15	15	15
	Mean	14.5	0.1	0.0
	SD	0.99	0.35	0.00
2	(n)	15	15	15
	Mean	14.6	0.1	0.0
	SD	1.40	0.35	0.00
3	(n)	15	15	15
	Mean	13.5	0.0	0.0
	SD	2.20	0.00	0.00
4	(n)	15	15	15
	Mean	13.1*C	0.3	0.0
	SD	2.09	0.59	0.00

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REDACTED AS TO TRADE NAMES

Open Field Measurements - Group mean data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 37

Males

Group		RE	UR	DE
Control	(n)	15	15	15
	Mean	14.7	0.6	0.0
	SD	2.02	0.91	0.00
2	(n)	15	15	15
	Mean	14.6	0.1	0.0
	SD	1.40	0.35	0.00
3	(n)	15	15	15
	Mean	14.7	0.3	0.0
	SD	1.63	0.59	0.00
4	(n)	15	15	15
	Mean	14.3	0.1	0.0
	SD	1.23	0.26	0.00

TABLE 2 - Open Field Measurements - Group mean data

REDACTED AS TO TRADE NAMES

Open Field Measurements - Group mean data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 44

Males

Group		RE	UR	DE
Control	(n)	15	15	15
	Mean	15.7	0.3	0.0
	SD	1.39	0.62	0.00
2	(n)	15	15	15
	Mean	15.1	0.2	0.0
	SD	1.73	0.56	0.00
3	(n)	15	15	15
	Mean	15.1	0.0	0.0
	SD	1.55	0.00	0.00
4	(n)	15	15	15
	Mean	14.0*D	0.3	0.1
	SD	1.93	0.90	0.26

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REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 51

Males

Group		RE	UR	DE
Control	(n)	15	15	15
	Mean	14.6	0.4	0.0
	SD	1.64	0.63	0.00
2	(n)	15	15	15
	Mean	14.5	0.9	0.1
	SD	3.60	1.64	0.52
3	(n)	15	15	15
	Mean	15.5	0.3	0.0
	SD	2.36	0.72	0.00
4	(n)	15	15	15
	Mean	11.5#C	0.4	0.3
	SD	2.17	1.06	1.03

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 58

Males

Group		RE	UR	DE
Control	(n)	15	15	15
	Mean	15.0	0.5	0.0
	SD	1.56	0.64	0.00
2	(n)	15	15	15
	Mean	14.6	0.1	0.0
	SD	2.53	0.35	0.00
3	(n)	15	15	15
	Mean	15.3	0.1	0.0
	SD	1.87	0.35	0.00
4	(n)	15	15	15
	Mean	13.5	0.0	0.0
	SD	2.45	0.00	0.00

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 66

Males

Group		RE	UR	DE
Control	(n)	15	15	15
	Mean	14.6	0.3	0.0
	SD	1.55	0.59	0.00
2	(n)	15	15	15
	Mean	14.3	0.0	0.0
	SD	1.54	0.00	0.00
3	(n)	15	15	15
	Mean	14.7	0.0	0.0
	SD	1.94	0.00	0.00
4	(n)	15	15	15
	Mean	13.5	0.0	0.0
	SD	1.73	0.00	0.00

REDACTED AS TO TRADE NAMES

Open Field Measurements - Group mean data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 72

Males

Group		RE	UR	DE
Control	(n)	15	15	15
	Mean	11.1	0.9	0.0
	SD	5.37	2.59	0.00
2	(n)	15	15	15
	Mean	12.7	0.4	0.0
	SD	5.52	1.30	0.00
3	(n)	15	15	15
	Mean	12.2	0.5	0.0
	SD	4.07	2.07	0.00
4	(n)	15	15	15
	Mean	11.9	0.0	0.0
	SD	3.11	0.00	0.00

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TABLE 2 - Open Field Measurements - Group mean data

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 79

Males

Group		RE	UR	DE
Control	(n)	15	15	15
	Mean	12.7	0.1	0.0
	SD	2.99	0.26	0.00
2	(n)	15	15	15
	Mean	13.9	0.0	0.0
	SD	3.58	0.00	0.00
3	(n)	15	15	15
	Mean	13.3	0.0	0.0
	SD	2.77	0.00	0.00
4	(n)	15	15	15
	Mean	13.1	0.0	0.0
	SD	2.74	0.00	0.00

REDACTED AS TO TRADE NAMES

Open Field Measurements - Group mean data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 86

Males

Group		RE	UR	DE
Control	(n)	15	15	15
	Mean	11.9	0.1	0.0
	SD	4.94	0.26	0.00
2	(n)	15	15	15
	Mean	8.4*C	0.1	0.0
	SD	2.16	0.35	0.00
3	(n)	15	15	15
	Mean	11.1	0.1	0.0
	SD	3.10	0.26	0.00
4	(n)	15	15	15
	Mean	8.3*C	0.0	0.0
	SD	2.12	0.00	0.00

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Open Field Measurements - Group mean data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 3

Females

Group		RE	UR	DE
Control	(n)	15	15	15
	Mean	23.1	0.0	0.2
	SD	2.28	0.00	0.77
2	(n)	15	15	15
	Mean	21.9	0.4	0.1
	SD	3.08	1.06	0.26
3	(n)	15	15	15
	Mean	18.7+D	0.0	0.0
	SD	2.55	0.00	0.00
4	(n)	15	15	15
	Mean	19.7+D	0.0	0.0
	SD	2.23	0.00	0.00

REDACTED AS TO TRADE NAMES

Open Field Measurements - Group mean data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 10

Females

Group		RE	UR	DE
Control	(n)	15	15	15
	Mean	21.1	0.0	0.0
	SD	1.87	0.00	0.00
2	(n)	15	15	15
	Mean	21.0	0.0	0.0
	SD	2.17	0.00	0.00
3	(n)	15	15	15
	Mean	19.0*D	0.2	0.2
	SD	1.77	0.56	0.77
4	(n)	15	15	15
	Mean	19.5	0.7	0.0
	SD	1.85	2.58	0.00

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REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 17

Females

Group		RE	UR	DE
Control	(n)	15	15	15
	Mean	16.7	0.3	0.0
	SD	1.91	0.82	0.00
2	(n)	15	15	15
	Mean	15.7	0.3	0.0
	SD	3.09	0.72	0.00
3	(n)	15	15	15
	Mean	15.9	0.3	0.0
	SD	2.72	0.59	0.00
4	(n)	15	15	15
	Mean	15.8	0.0	0.0
	SD	1.21	0.00	0.00

REDACTED AS TO TRADE NAMES

Open Field Measurements - Group mean data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 24

Females

Group		RE	UR	DE
Control	(n)	15	15	15
	Mean	17.1	0.3	0.0
	SD	1.94	0.59	0.00
2	(n)	15	15	15
	Mean	17.1	0.0	0.0
	SD	1.81	0.00	0.00
3	(n)	15	15	15
	Mean	16.5	0.1	0.0
	SD	2.59	0.26	0.00
4	(n)	15	15	15
	Mean	15.4	0.1	0.0
	SD	1.45	0.26	0.00

REDACTED AS TO TRADE NAMES

Open Field Measurements - Group mean data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 31

Females

Group		RE	UR	DE
Control	(n)	15	15	15
	Mean	17.5	0.1	0.0
	SD	1.68	0.35	0.00
2	(n)	15	15	15
	Mean	17.9	0.1	0.0
	SD	1.85	0.26	0.00
3	(n)	15	15	15
	Mean	17.7	0.0	0.0
	SD	2.25	0.00	0.00
4	(n)	15	15	15
	Mean	15.4*D	0.0	0.0
	SD	2.35	0.00	0.00

TABLE 2 - Open Field Measurements - Group mean data

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Open Field Measurements - Group mean data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 38

Females

Group		RE	UR	DE
Control	(n)	15	15	15
	Mean	17.6	0.3	0.0
	SD	1.45	0.62	0.00
2	(n)	15	15	15
	Mean	17.0	0.3	0.0
	SD	2.00	0.49	0.00
3	(n)	15	15	15
	Mean	17.7	0.3	0.0
	SD	1.91	0.62	0.00
4	(n)	15	15	15
	Mean	16.4	0.2	0.0
	SD	1.99	0.41	0.00

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Open Field Measurements - Group mean data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 45

Females

Group		RE	UR	DE
Control	(n)	15	15	15
	Mean	17.5	0.2	0.0
	SD	1.64	0.41	0.00
2	(n)	15	15	15
	Mean	17.6	0.0	0.0
	SD	1.45	0.00	0.00
3	(n)	15	15	15
	Mean	17.9	0.3	0.0
	SD	1.46	0.59	0.00
4	(n)	15	15	15
	Mean	14.8+C	0.1	0.0
	SD	2.81	0.26	0.00

TABLE 2 - Open Field Measurements - Group mean data

REDACTED AS TO TRADE NAMES

Open Field Measurements - Group mean data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 52

Females

Group		RE	UR	DE
Control	(n)	15	15	15
	Mean	19.3	0.3	0.0
	SD	1.44	0.46	0.00
2	(n)	15	15	15
	Mean	18.3	0.2	0.0
	SD	1.68	0.41	0.00
3	(n)	15	15	15
	Mean	17.7	0.3	0.0
	SD	1.91	0.62	0.00
4	(n)	15	15	15
	Mean	18.3	0.1	0.0
	SD	2.06	0.35	0.00

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REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 59

Females

Group		RE	UR	DE
Control	(n)	15	15	15
	Mean	13.9	0.0	0.0
	SD	2.84	0.00	0.00
2	(n)	15	15	15
	Mean	13.8	0.0	0.0
	SD	2.43	0.00	0.00
3	(n)	15	15	15
	Mean	14.9	0.0	0.0
	SD	2.46	0.00	0.00
4	(n)	15	15	15
	Mean	13.7	0.0	0.0
	SD	2.84	0.00	0.00

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TABLE 2 - Open Field Measurements - Group mean data

REDACTED AS TO TRADE NAMES

Open Field Measurements - Group mean data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 67

Females

Group		RE	UR	DE
Control	(n)	15	15	15
	Mean	16.4	0.3	0.0
	SD	2.20	0.62	0.00
2	(n)	15	15	15
	Mean	16.0	0.1	0.0
	SD	2.33	0.35	0.00
3	(n)	15	15	15
	Mean	15.5	0.0	0.0
	SD	1.81	0.00	0.00
4	(n)	15	15	15
	Mean	13.9+D	0.0	0.0
	SD	1.98	0.00	0.00

TABLE 2 - Open Field Measurements - Group mean data

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 73

Females

Group		RE	UR	DE
Control	(n)	15	15	15
	Mean	16.1	0.2	0.0
	SD	1.67	0.41	0.00
2	(n)	15	15	15
	Mean	16.3	0.1	0.0
	SD	1.95	0.26	0.00
3	(n)	15	15	15
	Mean	16.6	0.0	0.0
	SD	2.16	0.00	0.00
4	(n)	15	15	15
	Mean	16.6	0.0	0.0
	SD	2.20	0.00	0.00

REDACTED AS TO TRADE NAMES

Open Field Measurements - Group mean data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 80

Females

Group		RE	UR	DE
Control	(n)	15	15	15
	Mean	15.7	0.0	0.0
	SD	1.83	0.00	0.00
2	(n)	15	15	15
	Mean	16.9	0.0	0.0
	SD	1.96	0.00	0.00
3	(n)	15	15	15
	Mean	17.0	0.0	0.0
	SD	2.17	0.00	0.00
4	(n)	15	15	15
	Mean	16.4	0.0	0.0
	SD	1.72	0.00	0.00

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TABLE 2 - Open Field Measurements - Group mean data

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 87

Females

Group		RE	UR	DE
Control	(n)	15	15	15
	Mean	13.4	0.3	0.0
	SD	4.08	0.80	0.00
2	(n)	15	15	15
	Mean	13.9	0.3	0.0
	SD	2.84	0.72	0.00
3	(n)	15	15	15
	Mean	13.9	0.1	0.0
	SD	2.96	0.26	0.00
4	(n)	15	15	15
	Mean	12.6	0.1	0.0
	SD	2.85	0.35	0.00

Study Director Initial Inspection Only

TABLE 2 - Open Field Measurements - Group mean data

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

TABLE 2 - Open Field Measurements - Group mean data

Recovery Day 2

Males

Group		RE	UR	DE
Control	(n)	5	5	5
	Mean	11.2	0.0	0.0
	SD	1.79	0.00	0.00
2	(n)	5	5	5
	Mean	11.0	0.0	0.0
	SD	2.24	0.00	0.00
3	(n)	5	5	5
	Mean	10.2	0.0	0.0
	SD	3.19	0.00	0.00
4	(n)	5	5	5
	Mean	10.0	0.0	0.0
	SD	2.24	0.00	0.00

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 9

Males

Group		RE	UR	DE
Control	(n)	5	5	5
	Mean	12.6	0.0	0.0
	SD	2.79	0.00	0.00
2	(n)	5	5	5
	Mean	13.0	0.0	0.0
	SD	3.32	0.00	0.00
3	(n)	5	5	5
	Mean	11.4	0.0	0.0
	SD	3.13	0.00	0.00
4	(n)	5	5	5
	Mean	12.8	0.0	0.0
	SD	1.92	0.00	0.00

REDACTED AS TO TRADE NAMES

Open Field Measurements - Group mean data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 16

Males

Group		RE	UR	DE
Control	(n)	5	5	5
	Mean	13.2	0.0	0.0
	SD	0.84	0.00	0.00
2	(n)	5	5	5
	Mean	14.0	0.0	0.0
	SD	2.92	0.00	0.00
3	(n)	5	5	5
	Mean	12.2	0.0	0.0
	SD	1.79	0.00	0.00
4	(n)	5	5	5
	Mean	13.2	0.0	0.0
	SD	1.92	0.00	0.00

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TABLE 2 - Open Field Measurements - Group mean data

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 23

Males

Group		RE	UR	DE
Control	(n)	5	5	5
	Mean	13.0	0.0	0.0
	SD	2.65	0.00	0.00
2	(n)	5	5	5
	Mean	11.6	0.0	0.0
	SD	3.36	0.00	0.00
3	(n)	5	5	5
	Mean	15.2	0.0	0.0
	SD	0.84	0.00	0.00
4	(n)	5	5	5
	Mean	15.8	0.0	0.0
	SD	1.48	0.00	0.00

REDACTED AS TO TRADE NAMES

Open Field Measurements - Group mean data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 30

Males

Group		RE	UR	DE
Control	(n)	5	5	5
	Mean	15.8	0.0	0.0
	SD	2.17	0.00	0.00
2	(n)	5	5	5
	Mean	14.4	0.0	0.0
	SD	2.70	0.00	0.00
3	(n)	5	5	5
	Mean	12.2	0.0	0.0
	SD	2.28	0.00	0.00
4	(n)	5	5	5
	Mean	12.6	0.0	0.0
	SD	4.28	0.00	0.00

Study - A1474 - IVM Dec 2015

TABLE 2 - Open Field Measurements - Group mean data

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 37

Males

Group		RE	UR	DE
Control	(n)	5	5	5
	Mean	13.4	0.0	0.0
	SD	1.82	0.00	0.00
2	(n)	5	5	5
	Mean	12.8	0.0	0.0
	SD	2.68	0.00	0.00
3	(n)	5	5	5
	Mean	13.0	0.0	0.0
	SD	3.16	0.00	0.00
4	(n)	5	5	5
	Mean	14.4	0.0	0.0
	SD	2.70	0.00	0.00

REDACTED AS TO TRADE NAMES

Open Field Measurements - Group mean data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 44

Males

Group		RE	UR	DE
Control	(n)	5	5	5
	Mean	18.8	0.0	0.0
	SD	2.59	0.00	0.00
2	(n)	5	5	5
	Mean	18.0	0.0	0.0
	SD	5.48	0.00	0.00
3	(n)	5	5	5
	Mean	14.6	0.0	0.0
	SD	3.36	0.00	0.00
4	(n)	5	5	5
	Mean	13.6	0.0	0.0
	SD	3.65	0.00	0.00

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REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 51

Males

Group		RE	UR	DE
Control	(n)	5	5	5
	Mean	14.4	0.2	0.0
	SD	1.52	0.45	0.00
2	(n)	5	5	5
	Mean	10.8	0.0	0.0
	SD	2.17	0.00	0.00
3	(n)	5	5	5
	Mean	13.4	0.0	0.0
	SD	2.41	0.00	0.00
4	(n)	5	5	5
	Mean	13.6	0.0	0.0
	SD	3.65	0.00	0.00

REDACTED AS TO TRADE NAMES

Open Field Measurements - Group mean data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 2

Females

Group		RE	UR	DE
Control	(n)	5	5	5
	Mean	15.8	0.0	0.0
	SD	2.59	0.00	0.00
2	(n)	5	5	5
	Mean	15.0	0.0	0.0
	SD	2.92	0.00	0.00
3	(n)	5	5	5
	Mean	10.2*D	0.0	0.0
	SD	1.92	0.00	0.00
4	(n)	5	5	5
	Mean	15.2	0.0	0.0
	SD	3.42	0.00	0.00

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 9

Females

Group		RE	UR	DE
Control	(n)	5	5	5
	Mean	14.8	0.0	0.0
	SD	3.49	0.00	0.00
2	(n)	5	5	5
	Mean	15.2	0.0	0.0
	SD	2.17	0.00	0.00
3	(n)	5	5	5
	Mean	11.8	0.0	0.0
	SD	1.79	0.00	0.00
4	(n)	5	5	5
	Mean	14.4	0.0	0.0
	SD	2.70	0.00	0.00

REDACTED AS TO TRADE NAMES

Open Field Measurements - Group mean data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 16

Females

Group		RE	UR	DE
Control	(n)	5	5	5
	Mean	15.8	0.0	0.0
	SD	2.59	0.00	0.00
2	(n)	5	5	5
	Mean	16.2	0.0	0.0
	SD	2.68	0.00	0.00
3	(n)	5	5	5
	Mean	13.4	0.0	0.0
	SD	1.82	0.00	0.00
4	(n)	5	5	5
	Mean	14.8	0.0	0.0
	SD	1.64	0.00	0.00

REDACTED AS TO TRADE NAMES

Open Field Measurements - Group mean data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 23

Females

Group		RE	UR	DE
Control	(n)	5	5	5
	Mean	13.4	0.0	0.0
	SD	1.67	0.00	0.00
2	(n)	5	5	5
	Mean	15.8*D	0.0	0.0
	SD	1.48	0.00	0.00
3	(n)	5	5	5
	Mean	17.2+D	0.0	0.0
	SD	1.10	0.00	0.00
4	(n)	5	5	5
	Mean	16.2*D	0.0	0.0
	SD	1.10	0.00	0.00

REDACTED AS TO TRADE NAMES

Open Field Measurements - Group mean data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 30

Females

Group		RE	UR	DE
Control	(n)	5	5	5
	Mean	12.6	0.0	0.0
	SD	1.95	0.00	0.00
2	(n)	5	5	5
	Mean	12.8	0.0	0.0
	SD	3.11	0.00	0.00
3	(n)	5	5	5
	Mean	14.0	0.0	0.0
	SD	2.83	0.00	0.00
4	(n)	5	5	5
	Mean	13.2	0.0	0.0
	SD	2.59	0.00	0.00

REDACTED AS TO TRADE NAMES

Open Field Measurements - Group mean data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 37

Females

Group		RE	UR	DE
Control	(n)	5	5	5
	Mean	14.0	0.0	0.0
	SD	3.39	0.00	0.00
2	(n)	5	5	5
	Mean	15.8	0.0	0.0
	SD	2.59	0.00	0.00
3	(n)	5	5	5
	Mean	15.4	0.0	0.0
	SD	3.36	0.00	0.00
4	(n)	5	5	5
	Mean	13.6	0.0	0.0
	SD	3.05	0.00	0.00

TABLE 2 - Open Field Measurements - Group mean data

REDACTED AS TO TRADE NAMES

Open Field Measurements - Group mean data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 44

Females

Group		RE	UR	DE
Control	(n)	5	5	5
	Mean	19.6	0.0	0.0
	SD	2.97	0.00	0.00
2	(n)	5	5	5
	Mean	17.6	0.0	0.0
	SD	5.27	0.00	0.00
3	(n)	5	5	5
	Mean	15.4	0.0	0.0
	SD	3.13	0.00	0.00
4	(n)	5	5	5
	Mean	15.4	0.0	0.0
	SD	2.07	0.00	0.00

Q/A - DRAFT - Lab Operations 2016

TABLE 2 - Open Field Measurements - Group mean data

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TABLE 2 - Open Field Measurements - Group mean data

Open Field Measurements - Group mean data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 51

Females

Group		RE	UR	DE
Control	(n)	5	5	5
	Mean	17.2	0.2	0.0
	SD	1.30	0.45	0.00
2	(n)	5	5	5
	Mean	16.6	0.2	0.0
	SD	2.07	0.45	0.00
3	(n)	5	5	5
	Mean	15.6	0.0	0.0
	SD	1.82	0.00	0.00
4	(n)	5	5	5
	Mean	15.0	0.0	0.0
	SD	2.65	0.00	0.00

REDACTED AS TO TRADE NAMES

Landing foot splay - Group mean data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 78

Males

Group		LAN1 (cm)	LAN2 (cm)	LAM (cm)
Control	(n)	15	15	15
	Mean	6.74	6.78	6.760
	SD	2.266	1.954	2.0392
2	(n)	15	15	15
	Mean	5.66	5.70	5.680
	SD	1.700	1.437	1.5048
3	(n)	15	15	15
	Mean	5.87	5.21	5.537
	SD	1.343	0.885	1.0029
4	(n)	15	15	15
	Mean	7.01	6.05	6.530
	SD	2.171	2.091	1.8996

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 78

Females

Group		LAN1 (cm)	LAN2 (cm)	LAM (cm)
Control	(n)	15	15	15
	Mean	5.28	5.65	5.467
	SD	1.398	1.551	1.2891
2	(n)	15	15	15
	Mean	5.15	4.57	4.857
	SD	1.455	1.203	1.1715
3	(n)	15	15	15
	Mean	4.33	4.39	4.363
	SD	1.159	1.546	1.2032
4	(n)	15	15	15
	Mean	5.58	5.11	5.347
	SD	1.376	1.130	1.1178

TABLE 3 - Landing foot splay - Group mean data

REDACTED AS TO TRADE NAMES

Landing foot splay - Group mean data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 50

Males

Group		LAN1 (cm)	LAN2 (cm)	LAM (cm)
Control	(n)	5	5	5
	Mean	7.70	7.60	7.650
	SD	2.280	1.673	1.8166
2	(n)	5	5	5
	Mean	6.40	5.50*D	5.950
	SD	1.517	1.414	1.3964
3	(n)	5	5	5
	Mean	6.84	5.40*D	6.120
	SD	1.872	1.140	1.4759
4	(n)	5	5	5
	Mean	5.26	4.60+D	4.930
	SD	1.113	0.652	0.8175

Ex. Quality - 14th December 2010

TABLE 3 - Landing foot splay - Group mean data

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 50

Females

Group		LAN1 (cm)	LAN2 (cm)	LAM (cm)
Control	(n)	5	5	5
	Mean	6.50	6.10	6.300
	SD	1.581	1.517	1.5042
2	(n)	5	5	5
	Mean	5.80	5.60	5.700
	SD	1.037	1.084	0.9747
3	(n)	5	5	5
	Mean	4.00+D	3.80*D	3.900+D
	SD	0.612	1.349	0.9676
4	(n)	5	5	5
	Mean	4.56*D	3.64*D	4.100*D
	SD	0.619	0.586	0.4228

TABLE 3 - Landing foot splay - Group mean data

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Sensory reactivity - Group mean data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 78

Males

Group		GR1 (g)	GR2 (g)	GRM (g)
Control	(n)	15	15	15
	Mean	7.59	6.82	7.207
	SD	3.088	2.604	2.0444
2	(n)	15	15	15
	Mean	7.81	7.49	7.647
	SD	3.344	2.916	2.2929
3	(n)	15	15	15
	Mean	9.93	11.00+D	10.463+D
	SD	2.041	2.771	2.1203
4	(n)	15	15	15
	Mean	9.01	11.97+D	10.490+D
	SD	4.230	4.287	3.4700

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 78

Females

Group		GR1 (g)	GR2 (g)	GRM (g)
Control	(n)	15	15	15
	Mean	11.94	13.10	12.520
	SD	2.109	3.790	2.5409
2	(n)	15	15	15
	Mean	9.33+D	13.16	11.247
	SD	2.325	2.906	1.7536
3	(n)	15	15	15
	Mean	12.28	11.10	11.690
	SD	2.491	2.495	1.6010
4	(n)	15	15	15
	Mean	11.71	10.74*C	11.223
	SD	2.066	1.715	1.4132

REDACTED AS TO TRADE NAMES

Sensory reactivity - Group mean data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 50

Males

Group		GR1 (g)	GR2 (g)	GRM (g)
Control	(n)	5	5	5
	Mean	6.02	5.96	5.990
	SD	5.907	1.205	2.5567
2	(n)	5	5	5
	Mean	3.48	5.28	4.380
	SD	1.722	2.233	1.5849
3	(n)	5	5	5
	Mean	2.46	3.56	3.010
	SD	1.577	1.685	1.3917
4	(n)	5	5	5
	Mean	3.36	3.14	3.250
	SD	2.266	1.704	1.9326

FOR AUDIT - Sufficient Data - October 2010

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 50

Females

Group		GR1 (g)	GR2 (g)	GRM (g)
Control	(n)	5	5	5
	Mean	2.98	4.74	3.860
	SD	1.696	1.184	1.3112
2	(n)	5	5	5
	Mean	4.08	2.82	3.450
	SD	3.009	1.672	2.1855
3	(n)	5	5	5
	Mean	3.44	3.60	3.520
	SD	0.723	1.567	0.6311
4	(n)	5	5	5
	Mean	2.00	3.80	2.900
	SD	0.930	0.797	0.6586

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Motor activity - Group mean data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 78

Males

Group		CD
Control	(n)	15
	Mean	913.5
	SD	322.00
2	(n)	15
	Mean	987.8
	SD	171.78
3	(n)	15
	Mean	980.6
	SD	266.42
4	(n)	15
	Mean	1052.5
	SD	202.46

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TABLE 5 - Motor activity - Group mean data

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 78

Females

Group		CD
Control	(n)	15
	Mean	1022.3
	SD	146.87
2	(n)	15
	Mean	1021.3
	SD	214.36
3	(n)	15
	Mean	981.3
	SD	251.03
4	(n)	15
	Mean	1055.1
	SD	232.97

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Motor activity - Group mean data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 50

Males

Group		CD
Control	(n)	5
	Mean	787.2
	SD	427.76
2	(n)	5
	Mean	1019.2
	SD	253.89
3	(n)	5
	Mean	1007.2
	SD	201.39
4	(n)	5
	Mean	1207.2
	SD	380.50

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REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 50

Females

Group		CD
Control	(n)	5
	Mean	1164.0
	SD	297.45
2	(n)	5
	Mean	1037.0
	SD	193.89
3	(n)	5
	Mean	1034.6
	SD	106.51
4	(n)	5
	Mean	1075.0
	SD	135.75

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TABLE 5 - Motor activity - Group mean data

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Body weight (g) - Group mean data

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No		Quarantine Day: 12	Dosing Day: 1	Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43
Control	(n)	15	15	15	15	15	15	15	15
	Mean	178.18	223.16	269.11	305.83	333.03	353.11	373.26	387.92
	SD	6.630	10.979	12.515	15.653	18.047	20.581	24.474	27.399
2	(n)	15	15	15	15	15	15	15	15
	Mean	178.91	223.92	268.39	304.81	336.61	357.45	377.03	391.27
	SD	5.514	5.454	6.581	10.025	9.876	12.640	11.937	12.618
3	(n)	15	15	15	15	15	15	15	15
	Mean	179.04	226.10	271.87	310.19	340.27	361.49	381.01	393.69
	SD	5.882	7.419	8.163	10.466	12.579	16.207	19.527	19.721
4	(n)	15	15	15	15	15	15	15	15
	Mean	178.91	229.57	277.35	313.86	341.75	362.51	383.18	398.12
	SD	5.516	12.232	13.685	16.798	18.340	17.573	18.740	19.832

REDACTED AS TO TRADE NAMES

Body weight (g) - Group mean data

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No		Dosing Day: 50	Day: 57	Day: 64	Day: 71	Day: 78	Day: 85	Day: 92
Control	(n)	15	15	15	15	15	15	15
	Mean	399.83	411.56	421.76	431.50	445.45	445.64	441.95
	SD	26.898	26.702	27.398	28.076	29.188	29.625	28.096
2	(n)	15	15	15	15	15	15	15
	Mean	405.12	416.25	425.45	436.27	450.24	454.60	448.89
	SD	12.031	14.766	14.798	15.723	15.490	17.210	21.696
3	(n)	15	15	15	15	15	15	15
	Mean	406.97	417.11	428.01	437.35	450.41	452.12	446.09
	SD	21.892	21.911	23.409	23.238	21.287	22.657	22.860
4	(n)	15	15	15	15	15	15	15
	Mean	411.38	420.78	429.27	439.19	449.29	453.76	446.88
	SD	21.703	22.315	24.273	27.032	24.032	24.225	24.470

REDACTED AS TO TRADE NAMES

Body weight (g) - Group mean data

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No		Quarantine Day: 12	Dosing Day: 1	Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43
Control	(n)	15	15	15	15	15	15	15	15
	Mean	151.61	175.12	194.19	211.79	230.41	240.53	248.77	255.30
	SD	5.074	8.205	11.983	13.006	12.779	13.944	13.879	16.616
2	(n)	15	15	15	15	15	15	15	15
	Mean	151.71	172.88	191.11	208.51	228.21	237.96	246.75	253.62
	SD	4.815	9.725	12.634	14.602	15.598	16.271	20.911	18.125
3	(n)	15	15	15	15	15	15	15	15
	Mean	151.39	174.01	189.55	211.39	229.69	238.55	249.55	258.44
	SD	5.057	6.010	6.329	9.149	10.526	11.644	9.496	12.007
4	(n)	15	15	15	15	15	15	15	15
	Mean	151.85	173.71	193.13	209.56	229.20	236.78	245.67	255.76
	SD	4.641	7.669	7.316	9.521	12.367	11.477	13.062	11.201

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No		Dosing Day: 50	Day: 57	Day: 64	Day: 71	Day: 78	Day: 85	Day: 92
Control	(n)	15	15	15	15	15	15	15
	Mean	262.81	265.36	271.29	274.33	284.35	282.60	287.08
	SD	17.951	17.968	18.546	18.116	16.766	18.165	14.155
2	(n)	15	15	15	15	15	15	15
	Mean	258.73	262.02	267.44	272.48	278.70	275.17	282.96
	SD	18.123	17.759	20.395	19.512	17.265	16.612	18.037
3	(n)	15	15	15	15	15	15	15
	Mean	261.35	265.03	271.11	274.65	281.07	279.15	285.61
	SD	10.975	11.528	10.918	9.993	11.916	10.664	10.209
4	(n)	15	15	15	15	15	15	15
	Mean	260.43	264.16	267.19	275.39	281.41	276.57	285.42
	SD	12.405	12.318	8.670	11.901	13.282	18.566	12.562

REDACTED AS TO TRADE NAMES

Body weight (g) - Group mean data

Printed: 04 Mar 2016 09:14:04
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No		Recovery Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
Control	(n)	5	5	5	5	5	5	5	5
	Mean	443.06	445.42	450.04	456.80	461.30	467.92	471.90	460.84
	SD	20.092	19.733	17.239	19.800	20.116	20.995	19.077	19.148
2	(n)	5	5	5	5	5	5	5	5
	Mean	467.98	471.16	476.26	480.38	490.00	495.58	498.66	480.90
	SD	11.491	12.634	18.929	17.201	20.279	19.791	15.925	19.441
3	(n)	5	5	5	5	5	5	5	5
	Mean	456.40	460.96	467.22	468.30	477.20	477.44	484.48	466.20
	SD	26.758	27.983	29.046	26.480	29.122	27.211	31.585	27.618
4	(n)	5	5	5	5	5	5	5	5
	Mean	461.08	466.38	470.86	479.40	486.90	486.50	496.04	478.86
	SD	23.589	22.737	24.461	23.961	25.983	26.899	24.815	26.026

REDACTED AS TO TRADE NAMES

Body weight (g) - Group mean data

Printed: 04 Mar 2016 09:14:04
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No		Recovery Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
Control	(n)	5	5	5	5	5	5	5	5
	Mean	287.14	287.72	291.60	300.28	306.26	306.74	306.30	314.06
	SD	14.225	17.055	18.725	25.657	18.777	19.346	16.400	15.011
2	(n)	5	5	5	5	5	5	5	5
	Mean	287.38	286.82	290.68	287.68	294.16	294.82	296.66	298.88
	SD	18.606	19.341	23.523	18.311	19.433	22.457	22.123	24.369
3	(n)	5	5	5	5	5	5	5	5
	Mean	287.70	284.54	290.22	290.94	297.50	301.42	300.86	300.98
	SD	6.065	5.454	4.303	6.568	1.592	6.644	14.247	10.994
4	(n)	5	5	5	5	5	5	5	5
	Mean	282.08	282.24	286.90	291.66	294.40	293.94	298.66	299.30
	SD	5.631	6.326	5.026	5.885	5.161	7.469	9.880	9.130

REDACTED AS TO TRADE NAMES

Absolute body weight gain (g) - Group mean data

Printed: 04 Mar 2016 09:41:13
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No		Dosing Day: 1	Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
Control	(n)	15	15	15	15	15	15	15	15	15
	Mean	0.00	45.95	82.67	109.87	129.95	150.10	164.76	176.67	188.40
	SD	0.000	3.288	7.280	9.763	12.972	16.785	19.883	19.424	19.378
2	(n)	15	15	15	15	15	15	15	15	15
	Mean	0.00	44.47	80.89	112.69	133.53	153.11	167.35	181.20	192.33
	SD	0.000	4.053	7.410	6.641	9.933	9.307	10.891	10.417	13.625
3	(n)	15	15	15	15	15	15	15	15	15
	Mean	0.00	45.77	84.09	114.17	135.39	154.91	167.59	180.87	191.01
	SD	0.000	4.236	6.874	9.671	14.275	17.293	18.448	21.195	21.926
4	(n)	15	15	15	15	15	15	15	15	15
	Mean	0.00	47.79	84.29	112.19	132.94	153.61	168.55	181.81	191.21
	SD	0.000	3.132	7.389	10.518	9.521	10.956	11.937	12.672	13.551

REDACTED AS TO TRADE NAMES

Absolute body weight gain (g) - Group mean data

Printed: 04 Mar 2016 09:41:13
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No		Dosing Day: 64	Day: 71	Day: 78	Day: 85	Day: 92
Control	(n)	15	15	15	15	15
	Mean	198.60	208.34	222.29	222.48	218.79
	SD	20.432	21.353	22.993	23.321	22.050
2	(n)	15	15	15	15	15
	Mean	201.53	212.35	226.32	230.68	224.97
	SD	12.720	13.305	12.951	14.368	19.414
3	(n)	15	15	15	15	15
	Mean	201.91	211.25	224.31	226.02	219.99
	SD	23.406	22.783	20.991	22.773	21.986
4	(n)	15	15	15	15	15
	Mean	199.70	209.63	219.72	224.19	217.31
	SD	16.864	19.627	16.637	17.462	18.575

REDACTED AS TO TRADE NAMES

Absolute body weight gain (g) - Group mean data

Printed: 04 Mar 2016 09:42:31
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No		Dosing Day: 1	Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
Control	(n)	15	15	15	15	15	15	15	15	15
	Mean	0.00	19.07	36.67	55.29	65.41	73.65	80.18	87.69	90.24
	SD	0.000	8.039	6.028	6.580	8.180	7.056	10.440	11.734	10.727
2	(n)	15	15	15	15	15	15	15	15	15
	Mean	0.00	18.23	35.63	55.33	65.98	73.87	80.74	85.85	89.14
	SD	0.000	6.715	6.719	8.968	10.325	14.568	11.474	11.358	12.641
3	(n)	15	15	15	15	15	15	15	15	15
	Mean	0.00	15.55	37.39	55.68	64.54	75.55	84.43	87.34	91.03
	SD	0.000	4.401	6.753	8.588	10.216	8.005	10.488	10.430	8.916
4	(n)	15	15	15	15	15	15	15	15	15
	Mean	0.00	19.42	35.85	55.49	63.07	71.95	82.05	86.72	90.45
	SD	0.000	6.269	6.072	9.070	10.809	9.947	9.436	9.298	10.407

REDACTED AS TO TRADE NAMES

Absolute body weight gain (g) - Group mean data

Printed: 04 Mar 2016 09:42:31
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No		Dosing Day: 64	Day: 71	Day: 78	Day: 85	Day: 92
Control	(n)	15	15	15	15	15
	Mean	96.17	99.21	109.23	107.48	111.96
	SD	12.110	11.057	10.853	11.893	8.247
2	(n)	15	15	15	15	15
	Mean	94.56	99.60	105.82	102.29	110.98
	SD	14.888	14.788	12.696	11.524	13.572
3	(n)	15	15	15	15	15
	Mean	97.11	100.64	107.07	105.15	111.60
	SD	10.249	7.906	10.282	8.304	8.648
4	(n)	15	15	15	15	15
	Mean	93.47	101.67	107.70	102.86	111.71
	SD	8.527	9.724	12.044	18.310	10.887

REDACTED AS TO TRADE NAMES

Absolute body weight gain (g) - Group mean data

Printed: 04 Mar 2016 09:43:50
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No		Recovery Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
Control	(n)	5	5	5	5	5	5	5	5
	Mean	0.00	2.36	6.98	13.74	18.24	24.86	28.84	17.78
	SD	0.000	2.177	4.070	2.883	5.212	4.321	4.559	2.367
2	(n)	5	5	5	5	5	5	5	5
	Mean	0.00	3.18	8.28	12.40	22.02	27.60	30.68	12.92
	SD	0.000	3.669	9.338	7.391	10.876	11.354	8.460	10.029
3	(n)	5	5	5	5	5	5	5	5
	Mean	0.00	4.56	10.82	11.90	20.80	21.04	28.08	9.80
	SD	0.000	3.793	2.527	3.738	4.827	4.093	6.387	6.456
4	(n)	5	5	5	5	5	5	5	5
	Mean	0.00	5.30	9.78	18.32	25.82	25.42	34.96	17.78
	SD	0.000	2.469	3.744	4.394	5.434	5.237	3.499	4.872

REDACTED AS TO TRADE NAMES

Absolute body weight gain (g) - Group mean data

Printed: 04 Mar 2016 09:44:43
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No		Recovery Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
Control	(n)	5	5	5	5	5	5	5	5
	Mean	0.00	0.58	4.46	13.14	19.12	19.60	19.16	26.92
	SD	0.000	6.741	6.787	12.487	8.091	5.813	3.600	10.037
2	(n)	5	5	5	5	5	5	5	5
	Mean	0.00	-0.56	3.30	0.30	6.78*D	7.44	9.28	11.50
	SD	0.000	2.270	5.349	2.383	6.123	6.216	3.565	15.624
3	(n)	5	5	5	5	5	5	5	5
	Mean	0.00	-3.16	2.52	3.24	9.80	13.72	13.16	13.28
	SD	0.000	8.207	8.802	9.945	5.508	9.550	17.984	15.059
4	(n)	5	5	5	5	5	5	5	5
	Mean	0.00	0.16	4.82	9.58	12.32	11.86	16.58	17.22
	SD	0.000	5.314	2.367	3.981	3.823	6.607	5.747	6.452

REDACTED AS TO TRADE NAMES

Food consumption (g) - Group mean data

Printed: 04 Mar 2016 09:46:16
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No		Allocation Day: 8	Dosing Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50
Control	(n)	3	3	3	3	3	3	3	3
	Mean	19.57	22.85	25.21	24.94	24.06	24.42	23.27	22.60
	SD	1.903	0.782	0.664	1.129	1.060	1.264	1.481	1.094
2	(n)	3	3	3	3	3	3	3	3
	Mean	21.13	22.93	25.17	25.26	24.65	24.37	23.73	22.86
	SD	0.398	0.491	0.292	0.490	0.114	0.240	0.065	0.287
3	(n)	3	3	3	3	3	3	3	3
	Mean	21.17	23.19	25.52	25.09	24.23	24.90	23.70	23.31
	SD	0.277	0.312	0.134	0.655	0.384	0.430	0.290	0.576
4	(n)	3	3	3	3	3	3	3	3
	Mean	21.91	24.41*D	26.16	25.78	24.69	25.17	23.86	23.26
	SD	0.311	0.684	0.373	0.144	0.445	0.072	0.176	0.087

Non-GLP - Study Not Conducted Under GLP

TABLE 8 - Food consumption - Group data

REDACTED AS TO TRADE NAMES

Food consumption (g) - Group mean data

Printed: 04 Mar 2016 09:46:16
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No	Dosing	Day: 57	Day: 64	Day: 71	Day: 78	Day: 85	Day: 92
Control	(n)	3	3	3	3	3	3
	Mean	22.95	22.10	22.52	23.26	21.40	20.14
	SD	1.187	1.217	1.301	1.209	1.047	1.126
2	(n)	3	3	3	3	3	3
	Mean	23.38	21.71	22.68	23.54	22.18	20.60
	SD	0.191	0.142	0.103	0.229	0.024	1.435
3	(n)	3	3	3	3	3	3
	Mean	23.58	22.64	22.92	24.01	22.27	20.72
	SD	0.110	0.215	0.216	0.262	0.334	1.362
4	(n)	3	3	3	3	3	3
	Mean	23.65	22.60	22.41	24.26	22.83	20.89
	SD	0.282	0.624	1.464	0.514	0.377	1.831

Food consumption (g) - Group mean data

Printed: 04 Mar 2016 09:46:16
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No		Allocation Day: 8	Dosing Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50
Control	(n)	3	3	3	3	3	3	3	3
	Mean	16.53	16.86	17.68	18.95	18.01	18.37	17.68	17.66
	SD	0.701	0.208	0.395	0.596	0.710	0.897	0.664	0.861
2	(n)	3	3	3	3	3	3	3	3
	Mean	16.70	16.22	17.97	18.52	17.56	18.19	18.02	17.09
	SD	0.426	0.745	0.637	0.278	0.225	0.432	0.284	0.846
3	(n)	3	3	3	3	3	3	3	3
	Mean	17.01	16.91	18.49	18.68	17.80	18.38	18.29	17.27
	SD	0.333	0.869	0.332	0.152	0.692	0.374	0.513	0.336
4	(n)	3	3	3	3	3	3	3	3
	Mean	16.68	17.60	18.35	18.92	18.05	18.10	17.92	17.66
	SD	0.405	0.459	0.294	0.464	0.560	0.949	0.106	0.055

Study Director Initial Evaluation Only

TABLE 8 - Food consumption - Group data

REDACTED AS TO TRADE NAMES

Food consumption (g) - Group mean data

Printed: 04 Mar 2016 09:46:16
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No		Dosing Day: 57	Day: 64	Day: 71	Day: 78	Day: 85	Day: 92
Control	(n)	3	3	3	3	3	3
	Mean	17.89	16.70	17.44	18.13	16.50	16.74
	SD	0.839	0.101	0.371	0.364	0.314	0.466
2	(n)	3	3	3	3	3	3
	Mean	17.32	16.39	17.58	17.90	16.10	17.00
	SD	0.061	1.161	0.442	0.501	0.219	0.212
3	(n)	3	3	3	3	3	3
	Mean	17.23	17.04	17.30	17.48	16.21	16.69
	SD	1.113	0.922	0.260	0.156	0.553	0.456
4	(n)	3	3	3	3	3	3
	Mean	17.84	16.80	17.76	18.68	17.06	17.34
	SD	0.144	0.704	0.380	0.371	0.277	0.711

REDACTED AS TO TRADE NAMES

Food consumption (g) - Group mean data

Printed: 03 May 2016 09:21:06
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No		Recovery Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
Control	(n)	1	1	1	1	1	1	1	1
	Mean	21.94	21.34	21.38	21.88	21.46	21.41	21.22	18.67
	SD	-	-	-	-	-	-	-	-
2	(n)	1	1	1	1	1	1	1	1
	Mean	21.81	21.99	22.02	22.67	22.20	22.16	21.81	19.21
	SD	-	-	-	-	-	-	-	-
3	(n)	1	1	1	1	1	1	1	1
	Mean	22.00	22.39	22.40	22.24	22.12	21.96	21.67	19.21
	SD	-	-	-	-	-	-	-	-
4	(n)	1	1	1	1	1	1	1	1
	Mean	24.10	23.45	22.79	23.45	23.63	22.83	22.86	19.84
	SD	-	-	-	-	-	-	-	-

REDACTED AS TO TRADE NAMES

Food consumption (g) - Group mean data

Printed: 03 May 2016 09:21:06
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No		Recovery Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
Control	(n)	1	1	1	1	1	1	1	1
	Mean	16.77	17.81	17.20	19.51	18.55	17.76	16.53	17.20
	SD	-	-	-	-	-	-	-	-
2	(n)	1	1	1	1	1	1	1	1
	Mean	17.48	16.80	17.45	15.88	17.09	16.73	16.84	16.18
	SD	-	-	-	-	-	-	-	-
3	(n)	1	1	1	1	1	1	1	1
	Mean	18.40	17.21	17.71	17.21	17.31	17.49	17.33	16.25
	SD	-	-	-	-	-	-	-	-
4	(n)	1	1	1	1	1	1	1	1
	Mean	17.88	18.11	17.80	18.22	17.65	17.71	17.80	17.40
	SD	-	-	-	-	-	-	-	-

REDACTED AS TO TRADE NAMES

Ophthalmoscopy - Group incidence

Printed: 07 Mar 2016 14:29:12
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males
Quarantine, Day 15

Category, Observations	Dosage Group:	Control
	Number Examined:	1
	Number Normal:	1

Study Director - Not Determined

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males
Allocation, Day 4

Category, Observations	Dosage Group:	Control	2	3	4
	Number Examined:	14	15	15	15
	Number Normal:	14	15	15	15

REDACTED AS TO TRADE NAMES

Ophthalmoscopy - Group incidence

Printed: 07 Mar 2016 14:29:12
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females
Allocation, Day 4

Category, Observations	Dosage Group:	Control	2	3	4
	Number Examined:	15	15	15	15
	Number Normal:	15	15	15	15

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REDACTED AS TO TRADE NAMES

Ophthalmoscopy - Group incidence

Printed: 07 Mar 2016 14:31:15

Pristima® Version 6.3.2 Build 22

Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Dosing, Day 87

Category, Observations	Dosage Group:	Control	4
	Number Examined:	15	15
	Number Normal:	15	15

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REDACTED AS TO TRADE NAMES

Ophthalmoscopy - Group incidence

Printed: 07 Mar 2016 14:31:15
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females
Dosing, Day 87

Category, Observations	Dosage Group:	Control	4
	Number Examined:	15	15
	Number Normal:	15	15

TABLE 9 - Ophthalmoscopy - Group data

REDACTED AS TO TRADE NAMES

Printed: 26 Jan 2016 13:12:01
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Males

Group		RBC (x10^6/µL)	HGB (g/dL)	HCT (%)	MCV (fL)	MCH (pg)	MCHC (g/dL)	RET (x10^9/L)	RETR (%)	WBC (x10^3/µL)
Control	(n)	10	10	10	10	10	10	10	10	10
	Mean	8.904	15.01	47.09	52.89	16.87	31.92	153.41	1.726	7.443
	SD	0.3868	0.652	2.660	1.290	0.350	0.646	16.802	0.1999	2.3000
2	(n)	10	10	10	10	10	10	10	10	10
	Mean	8.485*D	14.41*D	43.83+D	51.66	16.97	32.86+D	138.69	1.636	5.876
	SD	0.2559	0.285	1.293	1.063	0.368	0.731	16.519	0.1928	1.2158
3	(n)	10	10	10	10	10	10	10	10	10
	Mean	8.743	14.78	45.79	52.40	16.91	32.28	144.76	1.660	7.780
	SD	0.3177	0.439	1.714	1.316	0.441	0.492	20.814	0.2519	2.8535
4	(n)	10	10	10	10	10	10	10	10	10
	Mean	8.111+D	14.30+D	43.55+D	53.74	17.65+D	32.87+D	142.73	1.760	8.111
	SD	0.3707	0.573	1.940	1.343	0.532	0.350	19.438	0.2310	1.8117

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Haematology Complete - Group mean data

Printed: 26 Jan 2016 13:12:01
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Males

Group		NEU (x10^3/µL)	LYM (x10^3/µL)	MON (x10^3/µL)	EOS (x10^3/µL)	BAS (x10^3/µL)	LUC (x10^3/µL)	NEUR (%)	LYMR (%)	MONR (%)
Control	(n)	10	10	10	10	10	10	10	10	10
	Mean	0.815	6.228	0.176	0.128	0.048	0.048	11.18	83.46	2.32
	SD	0.3671	2.0354	0.0825	0.0329	0.0249	0.0308	4.993	5.676	0.611
2	(n)	10	10	10	10	10	10	10	10	10
	Mean	0.806	4.713	0.175	0.115	0.028	0.037	14.00	79.78	3.07
	SD	0.2220	1.1724	0.0558	0.0196	0.0092	0.0177	4.202	4.441	0.964
3	(n)	10	10	10	10	10	10	10	10	10
	Mean	1.003	6.349	0.221	0.094*D	0.049	0.063	13.30	81.23	2.85
	SD	0.4237	2.5063	0.1050	0.0324	0.0390	0.0362	4.752	5.500	0.861
4	(n)	10	10	10	10	10	10	10	10	10
	Mean	0.715	7.006	0.186	0.085+D	0.046	0.071	8.77	86.43	2.27
	SD	0.1872	1.5519	0.0635	0.0232	0.0196	0.0260	0.917	1.152	0.523

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Males

Group		EOSR (%)	BASR (%)	LUCR (%)	PLT (x10^3/µL)
Control	(n)	10	10	10	10
	Mean	1.80	0.62	0.61	793.2
	SD	0.525	0.175	0.218	94.34
2	(n)	10	10	10	10
	Mean	2.07	0.46	0.62	822.3
	SD	0.525	0.126	0.193	29.53
3	(n)	10	10	10	10
	Mean	1.25*C	0.56	0.79	807.6
	SD	0.350	0.222	0.264	110.63
4	(n)	10	10	10	10
	Mean	1.06+C	0.57	0.91*D	695.2
	SD	0.178	0.125	0.363	216.52

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Haematology Complete - Group mean data

Printed: 26 Jan 2016 13:13:01
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Females

Group		RBC (x10^6/µL)	HGB (g/dL)	HCT (%)	MCV (fL)	MCH (pg)	MCHC (g/dL)	RET (x10^9/L)	RETR (%)	WBC (x10^3/µL)
Control	(n)	10	10	10	10	10	10	10	10	10
	Mean	7.538	13.73	41.63	55.22	18.21	33.00	141.79	1.883	4.969
	SD	0.2693	0.617	2.100	1.089	0.396	0.519	33.416	0.4609	1.0660
2	(n)	7	7	7	7	7	7	7	7	7
	Mean	7.673	14.09	41.66	54.30	18.36	33.81*D	178.23	2.323	4.870
	SD	0.2995	0.501	1.752	1.819	0.513	0.682	59.905	0.7607	1.0062
3	(n)	10	10	10	10	10	10	10	10	10
	Mean	7.951+D	14.30	42.96	54.04	18.00	33.29	144.82	1.821	6.143
	SD	0.3160	0.450	1.515	1.237	0.521	0.443	28.232	0.3407	1.7199
4	(n)	8	8	8	8	8	8	8	8	8
	Mean	7.611	14.01	41.50	54.53	18.43	33.80*D	124.29	1.631	5.468
	SD	0.2883	0.497	1.735	1.152	0.266	0.545	24.234	0.2971	1.0918

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Females

Group		NEU (x10^3/µL)	LYM (x10^3/µL)	MON (x10^3/µL)	EOS (x10^3/µL)	BAS (x10^3/µL)	LUC (x10^3/µL)	NEUR (%)	LYMR (%)	MONR (%)
Control	(n)	10	10	10	10	10	10	10	10	10
	Mean	0.363	4.320	0.123	0.099	0.019	0.042	7.42	86.92	2.45
	SD	0.0808	0.9445	0.0406	0.0191	0.0099	0.0210	1.314	1.440	0.595
2	(n)	7	7	7	7	7	7	7	7	7
	Mean	0.604*C	3.893	0.177	0.107	0.029	0.060	12.34*C	80.20+C	3.51
	SD	0.2501	0.7600	0.0869	0.0716	0.0135	0.0311	3.841	4.575	1.316
3	(n)	10	10	10	10	10	10	10	10	10
	Mean	0.623+C	5.148	0.187	0.078	0.028	0.077	10.46*C	83.37*C	3.19
	SD	0.2230	1.5736	0.0625	0.0290	0.0155	0.0350	3.695	4.621	1.251
4	(n)	8	8	8	8	8	7	8	8	8
	Mean	0.376	4.768	0.154	0.099	0.018	0.061	7.01	87.01	2.83
	SD	0.1707	1.0330	0.0496	0.0344	0.0104	0.0261	3.032	3.347	0.907

Abbreviations/symbols used are explained in Addendum

Haematology Complete - Group mean data

Printed: 26 Jan 2016 13:13:01
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Females

Group		EOSR (%)	BASR (%)	LUCR (%)	PLT (x10^3/µL)
Control	(n)	10	10	10	10
	Mean	1.99	0.42	0.80	874.2
	SD	0.311	0.132	0.254	42.18
2	(n)	7	7	7	7
	Mean	2.26	0.53	1.19	779.6
	SD	1.407	0.214	0.478	170.30
3	(n)	10	10	10	10
	Mean	1.27#C	0.47	1.25	893.8
	SD	0.356	0.095	0.412	59.56
4	(n)	8	8	7	8
	Mean	1.84	0.35	1.11	844.6
	SD	0.595	0.160	0.505	41.33

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Coagulation - Group mean data

Printed: 26 Jan 2016 13:07:58
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Males

Group		PT (sec)
Control	(n)	10
	Mean	24.38
	SD	0.883
2	(n)	9
	Mean	24.28
	SD	1.192
3	(n)	10
	Mean	23.22*C
	SD	0.787
4	(n)	9
	Mean	22.72
	SD	2.360

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Coagulation - Group mean data

Printed: 26 Jan 2016 13:08:34
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Females

Group		PT (sec)
Control	(n)	10
	Mean	24.15
	SD	0.695
2	(n)	8
	Mean	23.93
	SD	1.028
3	(n)	10
	Mean	24.03
	SD	0.710
4	(n)	10
	Mean	22.23+D
	SD	1.402

Draft - URGENT - 14th December 2016

Abbreviations/symbols used are explained in Addendum

Clinical Chemistry Complete - Group mean data

Printed: 26 Jan 2016 12:58:23
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Males

Group		ALP (U/L)	ALT (U/L)	AST (U/L)	GGT (U/L)	TBIL (mg/dL)	CHOL (mg/dL)	TRIG (mg/dL)	GLU (mg/dL)	UREA (mg/dL)
Control	(n)	10	10	10	1@	8@	10	10	10	10
	Mean	163.27	70.64	100.79	0.00	0.024	64.91	64.88	168.98	42.42
	SD	28.645	62.498	56.905	-	0.0074	8.815	32.437	48.846	5.034
2	(n)	10	10	10	0@	7@	10	10	10	10
	Mean	156.42	66.91	79.79	-	0.013	51.90+D	44.68	118.31*C	34.52+C
	SD	22.976	45.257	30.368	-	0.0075	3.567	11.464	19.677	2.630
3	(n)	10	10	10	2@	7@	10	10	10	10
	Mean	162.93	60.00	79.34	0.55	0.013	48.03+D	30.05+C	131.84	43.58
	SD	12.163	8.241	11.875	0.778	0.0214	5.434	8.440	37.618	7.775
4	(n)	10	10	10	4@	2@	10	10	10	10
	Mean	232.22*C	99.93	87.85	0.60	0.005	56.34*D	30.50*C	179.41	52.61+C
	SD	61.984	50.758	25.327	0.294	0.0071	8.267	10.666	53.943	7.507

Abbreviations/symbols used are explained in Addendum

@= Number examined reduced due to excluded data

Clinical Chemistry Complete - Group mean data

Printed: 26 Jan 2016 12:58:23
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Males

Group		CREA (mg/dL)	Cl (mmol/L)	Ca (mmol/L)	Na (mmol/L)	K (mmol/L)	IP (mg/dL)	PROT (g/dL)	ALB (g/dL)	GLO (g/dL)
Control	(n)	10	10	10	10	10	10	10	10	10
	Mean	0.387	106.30	2.455	142.39	4.392	6.208	6.23	3.69	2.54
	SD	0.0677	4.066	0.0931	2.071	1.7145	1.6560	0.362	0.228	0.165
2	(n)	10	10	10	10	10	10	10	10	10
	Mean	0.282+D	104.85	2.443	143.87	3.551	5.603	6.13	3.66	2.47
	SD	0.0282	6.472	0.0298	2.711	0.3159	0.6864	0.164	0.097	0.106
3	(n)	10	10	10	10	10	10	10	10	10
	Mean	0.328	104.53	2.483	143.69	3.827	6.179	6.08	3.57	2.51
	SD	0.0688	3.651	0.0403	0.880	0.2757	0.7788	0.220	0.164	0.088
4	(n)	10	10	10	10	10	10	10	10	10
	Mean	0.347	104.71	2.538*C	144.22	3.884	6.466	6.06	3.58	2.48
	SD	0.0600	5.501	0.0543	1.039	0.2495	0.5103	0.237	0.181	0.132

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Males

Group		A/G
Control	(n)	10
	Mean	1.45
	SD	0.085
2	(n)	10
	Mean	1.48
	SD	0.063
3	(n)	10
	Mean	1.43
	SD	0.082
4	(n)	10
	Mean	1.44
	SD	0.107

Abbreviations/symbols used are explained in Addendum

Clinical Chemistry Complete - Group mean data

Printed: 26 Jan 2016 12:59:20
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Females

Group		ALP (U/L)	ALT (U/L)	AST (U/L)	GGT (U/L)	TBIL (mg/dL)	CHOL (mg/dL)	TRIG (mg/dL)	GLU (mg/dL)	UREA (mg/dL)
Control	(n)	10	10	10	10	10	10	10	10	10
	Mean	112.05	40.66	72.58	0.88	0.082	81.64	42.74	113.34	41.29
	SD	23.131	6.657	9.067	0.541	0.0394	13.922	12.997	13.243	6.203
2	(n)	10	10	10	8@	10	10	10	10	10
	Mean	119.95	53.13	100.38	0.73	0.090	71.99	44.57	99.34	39.03
	SD	17.709	33.489	50.195	0.354	0.0670	11.998	9.944	12.364	3.729
3	(n)	10	10	10	8@	10	10	10	10	10
	Mean	97.79	40.89	68.88	0.51	0.065	72.64	37.86	105.96	41.63
	SD	10.689	7.020	8.884	0.360	0.0207	9.106	6.042	15.960	3.702
4	(n)	10	10	10	9@	10	10	10	10	10
	Mean	94.14	34.47	58.33+C	0.72	0.032+C	73.76	54.51*D	133.51*D	41.48
	SD	17.375	6.809	4.736	0.399	0.0114	9.341	12.141	18.117	7.156

Abbreviations/symbols used are explained in Addendum

@= Number examined reduced due to excluded data

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Females

Group		CREA (mg/dL)	Cl (mmol/L)	Ca (mmol/L)	Na (mmol/L)	K (mmol/L)	IP (mg/dL)	PROT (g/dL)	ALB (g/dL)	GLO (g/dL)
Control	(n)	10	10	10	10	10	10	10	10	10
	Mean	0.443	106.79	2.410	143.35	3.374	5.736	5.81	3.55	2.26
	SD	0.0374	4.469	0.0720	2.053	0.4928	1.2512	0.202	0.135	0.117
2	(n)	10	10	10	10	10	10	10	10	10
	Mean	0.379*D	107.91	2.437	141.58	4.695	6.021	5.96	3.66	2.30
	SD	0.0509	3.861	0.0497	2.245	2.1443	2.0008	0.212	0.117	0.149
3	(n)	10	10	10	10	10	10	10	10	10
	Mean	0.361+D	107.05	2.522+C	143.59	3.371	5.575	6.15+D	3.77+D	2.38
	SD	0.0433	5.364	0.0266	0.989	0.2420	0.6590	0.143	0.095	0.103
4	(n)	10	10	10	10	10	10	10	10	10
	Mean	0.347+D	106.45	2.486*C	143.25	3.461	5.780	6.07*D	3.73*D	2.34
	SD	0.0587	4.829	0.0695	1.976	0.2526	0.3907	0.254	0.195	0.126

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Clinical Chemistry Complete - Group mean data

Printed: 26 Jan 2016 12:59:20
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Females

Group		A/G
Control	(n)	10
	Mean	1.58
	SD	0.103
2	(n)	10
	Mean	1.59
	SD	0.088
3	(n)	10
	Mean	1.58
	SD	0.092
4	(n)	10
	Mean	1.60
	SD	0.125

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Clinical Chemistry Complete - Group mean data

Printed: 22 Mar 2016 15:02:44
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 57

Males

Group		ALP (U/L)	ALT (U/L)	AST (U/L)	GGT (U/L)	TBIL (mg/dL)	CHOL (mg/dL)	TRIG (mg/dL)	GLU (mg/dL)	UREA (mg/dL)
Control	(n)	5	5	5	1@	5	5	5	5	5
	Mean	190.56	41.46	64.00	0.50	0.022	80.28	82.16	158.88	43.38
	SD	50.391	8.916	7.902	-	0.0130	8.755	14.044	45.029	8.863
2	(n)	5	5	5	0@	5	5	5	5	5
	Mean	166.86	49.62	70.04	-	0.014	64.34	60.38*D	133.78	36.46
	SD	18.986	7.782	7.010	-	0.0167	11.850	11.321	23.675	3.420
3	(n)	5	5	5	5	5	5	5	5	5
	Mean	161.10	73.42	83.48	0.26	0.032	71.12	58.16*D	112.56	47.12
	SD	26.983	25.373	21.697	0.182	0.0130	10.800	8.364	33.179	5.038
4	(n)	5	5	5	4@	5	5	5	5	5
	Mean	187.64	107.30	81.20	0.35	0.012	72.14	33.78+D	148.80	43.82
	SD	38.433	113.829	28.304	0.238	0.0164	3.752	14.404	21.417	3.532

Abbreviations/symbols used are explained in Addendum

@= Number examined reduced due to excluded data

Clinical Chemistry Complete - Group mean data

Printed: 22 Mar 2016 15:02:44
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 57

Males

Group		CREA (mg/dL)	Cl (mmol/L)	Ca (mmol/L)	Na (mmol/L)	K (mmol/L)	IP (mg/dL)	PROT (g/dL)	ALB (g/dL)	GLO (g/dL)
Control	(n)	5	5	5	5	5	5	5	5	5
	Mean	0.474	101.80	2.394	141.66	4.110	4.478	6.30	3.72	2.58
	SD	0.0559	1.522	0.0498	0.934	0.3303	0.8742	0.212	0.110	0.130
2	(n)	5	5	5	5	5	5	5	5	5
	Mean	0.386*D	105.38	2.454	140.60	[illegible]	4.724	6.20	3.66	2.54
	SD	0.0167	4.676	0.0358	1.147	[illegible]	0.2349	0.187	0.114	0.152
3	(n)	5	5	5	5	5	5	5	5	5
	Mean	0.378+D	103.68	2.444	141.30	3.800	5.116	6.00*D	3.48+D	2.52
	SD	0.0597	1.348	0.0477	1.629	0.2158	0.2522	0.200	0.084	0.130
4	(n)	5	5	5	5	5	5	5	5	5
	Mean	0.386*D	103.80	2.528+D	141.44	3.744	5.456	6.34	3.74	2.60
	SD	0.0279	7.044	0.0507	2.578	0.1981	0.2365	0.089	0.089	0.100

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 57

Males

Group		A/G
Control	(n)	5
	Mean	1.44
	SD	0.055
2	(n)	5
	Mean	1.44
	SD	0.114
3	(n)	5
	Mean	1.38
	SD	0.045
4	(n)	5
	Mean	1.42
	SD	0.084

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Clinical Chemistry Complete - Group mean data

Printed: 22 Mar 2016 15:03:09
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 57

Females

Group		ALP (U/L)	ALT (U/L)	AST (U/L)	GGT (U/L)	TBIL (mg/dL)	CHOL (mg/dL)	TRIG (mg/dL)	GLU (mg/dL)	UREA (mg/dL)
Control	(n)	5	5	5	1@	5	5	5	5	5
	Mean	104.18	44.16	65.96	1.80	0.046	94.66	72.86	80.94	37.78
	SD	14.442	3.071	6.729	-	0.0230	14.452	29.781	12.706	2.130
2	(n)	5	5	5	2@	5	5	5	5	5
	Mean	95.72	38.66	64.84	0.15	0.020+D	83.36	49.94	99.54	34.56
	SD	22.837	5.891	5.632	0.212	0.0100	14.357	13.055	10.179	2.971
3	(n)	5	5	5	0@	5	5	5	5	5
	Mean	88.20	38.70	70.82	-	0.074	78.94	55.98	107.86*D	43.70
	SD	10.104	8.064	13.302	-	0.0230	15.223	14.802	19.043	3.585
4	(n)	5	5	5	2@	5	5	5	5	5
	Mean	98.66	36.58	64.02	0.25	0.030	90.68	56.76	120.80+D	41.02
	SD	39.228	9.313	6.366	0.212	0.0212	15.870	10.278	5.643	7.306

Abbreviations/symbols used are explained in Addendum

@= Number examined reduced due to excluded data

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 57

Females

Group		CREA (mg/dL)	Cl (mmol/L)	Ca (mmol/L)	Na (mmol/L)	K (mmol/L)	IP (mg/dL)	PROT (g/dL)	ALB (g/dL)	GLO (g/dL)
Control	(n)	5	5	5	5	5	5	5	5	5
	Mean	0.514	108.70	2.350	141.14	3.562	4.264	6.30	3.74	2.56
	SD	0.0351	1.840	0.0616	1.656	0.3426	0.8876	0.381	0.195	0.195
2	(n)	5	5	5	5	5	5	5	5	5
	Mean	0.450*D	100.88+D	2.418	139.30	3.350	4.022	6.28	3.84	2.44
	SD	0.0400	2.952	0.0782	2.493	0.1628	0.3964	0.217	0.089	0.167
3	(n)	5	5	5	5	5	5	5	5	5
	Mean	0.530	103.70	2.438	141.12	3.016+D	4.748	6.22	3.74	2.48
	SD	0.0464	4.294	0.0497	1.465	0.2881	0.7137	0.455	0.313	0.179
4	(n)	5	5	5	5	5	5	5	5	5
	Mean	0.458	105.58	2.412	140.40	3.166	4.644	6.16	3.72	2.44
	SD	0.0327	3.388	0.0545	0.897	0.0961	0.8513	0.152	0.084	0.114

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Clinical Chemistry Complete - Group mean data

Printed: 22 Mar 2016 15:03:09
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 57

Females

Group		A/G
Control	(n)	5
	Mean	1.44
	SD	0.089
2	(n)	5
	Mean	1.56
	SD	0.114
3	(n)	5
	Mean	1.52
	SD	0.110
4	(n)	5
	Mean	1.54
	SD	0.089

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Terminal body weight (g) - Group mean data

Printed: 06 Mar 2016 09:25:21
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

Males

Group	Control Group	2	3	4
(n)	10	10	10	10
Mean	440.96	435.12	436.73	442.57
SD	32.710	19.395	21.857	25.061

Analysis of variance: F ratio = 0.192 DF = 3/36 F probability = 0.901

Females

Group	Control Group	2	3	4
(n)	10	10	10	10
Mean	271.15	270.00	267.46	268.70
SD	15.165	11.927	13.037	12.518

Analysis of variance: F ratio = 0.146 DF = 3/36 F probability = 0.932

Terminal body weight (g) - Group mean data

Printed: 06 Mar 2016 09:26:45
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

Males

Group	Control Group	2	3	4
(n)	5	5	5	5
Mean	458.76	477.94	465.36	471.24
SD	19.039	17.169	28.299	24.887

Analysis of variance: F ratio = 0.646 DF = 3/16 F probability = 0.597

Females

Group	Control Group	2	3	4
(n)	5	5	5	5
Mean	295.40	282.44	283.04	278.22
SD	14.267	21.886	9.859	6.814

Analysis of variance: F ratio = 1.326 DF = 3/16 F probability = 0.301

REDACTED AS TO TRADE NAMES

Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

		Males					
Group No		TBW (g)	Adrenal glands (g)	Brain (g)	Epididymides (g)	Heart (g)	Kidneys (g)
Control	(n)	10	10	10	10	10	10
	Mean	440.96	0.0496	1.956	1.3856	1.458	2.608
	SD	32.710	0.00600	0.0659	0.17042	0.1405	0.2661
2	(n)	10	10	10	10	10	10
	Mean	435.12	0.0465	1.932	1.4455	1.408	2.496
	SD	19.395	0.00550	0.0567	0.18979	0.1026	0.1456
3	(n)	10	10	10	10	10	10
	Mean	436.73	0.0478	1.931	1.3957	1.441	2.597
	SD	21.857	0.00974	0.0869	0.22747	0.1250	0.2214
4	(n)	10	10	10	10	10	10
	Mean	442.57	0.0464	1.937	1.4210	1.416	2.732
	SD	25.061	0.00817	0.0587	0.09905	0.1267	0.1741

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

Males

Group No		TBW (g)	Liver (g)	Spleen (g)	Thymus (g)	Testes (g)
Control	(n)	10	10	10	10	10
	Mean	440.96	11.301	0.8166	0.3691	3.7366
	SD	32.710	1.2567	0.12846	0.07279	0.18093
2	(n)	10	10	10	10	10
	Mean	435.12	11.542	0.8032	0.3744	3.8490
	SD	19.395	0.7969	0.07679	0.06625	0.30102
3	(n)	10	10	10	10	10
	Mean	436.73	13.174+C	0.7558	0.3538	3.7657
	SD	21.857	0.8897	0.07184	0.07662	0.51810
4	(n)	10	10	10	10	10
	Mean	442.57	20.181#C	0.7890	0.3559	3.8497
	SD	25.061	2.3157	0.06036	0.05600	0.13689

TABLE 14 - Absolute organ weights (g) - Group mean data

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

Females

Group No		TBW (g)	Adrenal glands (g)	Brain (g)	Heart (g)	Kidneys (g)	Liver (g)
Control	(n)	10	10	10	10	10	10
	Mean	271.15	0.0608	1.761	0.979	1.548	6.529
	SD	15.165	0.00609	0.0692	0.1033	0.1036	0.4288
2	(n)	10	10	10	10	10	10
	Mean	270.00	0.0605	1.777	0.975	1.591	6.487
	SD	11.927	0.00698	0.1024	0.1067	0.1507	0.5552
3	(n)	10	10	10	10	10	10
	Mean	267.46	0.0553	1.757	0.946	1.546	6.533
	SD	13.037	0.00596	0.0807	0.1141	0.0778	0.3960
4	(n)	10	10	10	10	10	10
	Mean	268.70	0.0613	1.779	0.964	1.655	8.325+D
	SD	12.518	0.01102	0.0493	0.0690	0.1188	0.4385

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

Females

Group No		TBW (g)	Ovaries (g)	Spleen (g)	Thymus (g)	Uterus (g)
Control	(n)	10	10	10	10	10
	Mean	271.15	0.1138	0.6340	0.2552	0.6704
	SD	15.165	0.01050	0.04937	0.03349	0.26228
2	(n)	10	10	10	10	10
	Mean	270.00	0.1127	0.6457	0.2694	0.7452
	SD	11.927	0.02072	0.06440	0.04716	0.24001
3	(n)	10	10	10	10	10
	Mean	267.46	0.1179	0.6035	0.2712	0.7411
	SD	13.037	0.01367	0.06318	0.02814	0.33073
4	(n)	10	10	10	10	10
	Mean	268.70	0.1137	0.6151	0.2436	0.9419
	SD	12.518	0.01821	0.06303	0.04217	0.51267

REDACTED AS TO TRADE NAMES

Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

		Males					
Group No		TBW (g)	Adrenal glands (g)	Brain (g)	Epididymides (g)	Heart (g)	Kidneys (g)
Control	(n)	5	5	5	5	5	5
	Mean	458.76	0.0422	1.936	1.3338	1.506	2.876
	SD	19.039	0.00610	0.0410	0.09523	0.1222	0.2898
2	(n)	5	5	5	5	5	5
	Mean	477.94	0.0470	1.952	1.4804	1.462	2.688
	SD	17.169	0.00447	0.0638	0.17209	0.0444	0.1574
3	(n)	5	5	5	5	5	5
	Mean	465.36	0.0504	1.982	1.3370	1.548	2.876
	SD	28.299	0.00750	0.0653	0.12529	0.0614	0.2206
4	(n)	5	5	5	5	5	5
	Mean	471.24	0.0490	1.922	1.4224	1.506	2.946
	SD	24.887	0.00707	0.0597	0.08572	0.0879	0.2765

Absolute organ weight (g) - Group mean data

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

		Males				
Group No		TBW (g)	Liver (g)	Spleen (g)	Thymus (g)	Testes (g)
Control	(n)	5	5	5	5	5
	Mean	458.76	10.984	0.7846	0.2652	3.9898
	SD	19.039	1.2396	0.09574	0.04824	0.20091
2	(n)	5	5	5	5	5
	Mean	477.94	11.488	0.8382	0.2610	3.9990
	SD	17.169	0.6822	0.04816	0.03107	0.32843
3	(n)	5	5	5	5	5
	Mean	465.36	11.894	0.8036	0.2820	3.4516
	SD	28.299	1.0301	0.09588	0.02258	1.08011
4	(n)	5	5	5	5	5
	Mean	471.24	14.972+D	0.7850	0.2922	4.2800
	SD	24.887	1.3529	0.12128	0.02674	0.38366

TABLE 14 - Absolute organ weights (g) - Group mean data

REDACTED AS TO TRADE NAMES

Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

		Females					
Group No		TBW (g)	Adrenal glands (g)	Brain (g)	Heart (g)	Kidneys (g)	Liver (g)
Control	(n)	5	5	5	5	5	5
	Mean	295.40	0.0500	1.742	0.970	1.598	6.480
	SD	14.267	0.00794	0.0602	0.0784	0.2702	0.8107
2	(n)	5	5	5	5	5	5
	Mean	282.44	0.0588	1.814	0.950	1.654	6.132
	SD	21.886	0.00526	0.0313	0.0500	0.0760	0.3373
3	(n)	5	5	5	5	5	5
	Mean	283.04	0.0580	1.778	0.978	1.677	6.560
	SD	9.859	0.00324	0.0505	0.0823	0.0447	0.4705
4	(n)	5	5	5	5	5	5
	Mean	278.22	0.0546	1.817	0.953	1.572	7.854+D
	SD	6.814	0.00434	0.0372	0.0298	0.0882	0.3861

REDACTED AS TO TRADE NAMES

Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

Females

Group No		TBW (g)	Ovaries (g)	Spleen (g)	Thymus (g)	Uterus (g)
Control	(n)	5	5	5	5	5
	Mean	295.40	0.1056	0.6144	0.2332	0.5478
	SD	14.267	0.01481	0.06641	0.02681	0.09622
2	(n)	5	5	5	5	5
	Mean	282.44	0.1004	0.6196	0.1970	0.9250
	SD	21.886	0.01230	0.08211	0.03716	0.32025
3	(n)	5	5	5	5	5
	Mean	283.04	0.1194	0.6222	0.2164	0.7600*C
	SD	9.859	0.02726	0.07372	0.04300	0.06773
4	(n)	5	5	5	5	5
	Mean	278.22	0.1236	0.6236	0.1884	0.5914
	SD	6.814	0.01250	0.04495	0.03791	0.17232

TABLE 14 - Absolute organ weights (g) - Group mean data

REDACTED AS TO TRADE NAMES

Organ weight to terminal body weight (%) - Group mean data

Printed: 01 Feb 2016 11:41:49
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

TABLE 15 - Organ weight to terminal body weight - Group data

Death Status: Final sacrifice / Dosing

		Males					
Group No		TBW (g)	Adrenal glands	Brain	Epididymides	Heart	Kidneys
Control	(n)	10	10	10	10	10	10
	Mean	440.96	0.0113	0.4452	0.3146	0.3312	0.5911
	SD	32.710	0.00162	0.02688	0.03377	0.02879	0.03496
2	(n)	10	10	10	10	10	10
	Mean	435.12	0.0107	0.4452	0.3338	0.3246	0.5747
	SD	19.395	0.00147	0.03053	0.05360	0.03314	0.04285
3	(n)	10	10	10	10	10	10
	Mean	436.73	0.0109	0.4432	0.3194	0.3300	0.5944
	SD	21.857	0.00206	0.03048	0.04853	0.02323	0.03751
4	(n)	10	10	10	10	10	10
	Mean	442.57	0.0105	0.4386	0.3215	0.3202	0.6179
	SD	25.061	0.00200	0.02249	0.02204	0.02568	0.03327

REDACTED AS TO TRADE NAMES

Organ weight to terminal body weight (%) - Group mean data

Printed: 01 Feb 2016 11:41:49
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

		Males				
Group No		TBW (g)	Liver	Spleen	Thymus	Testes
Control	(n)	10	10	10	10	10
	Mean	440.96	2.5581	0.1849	0.0837	0.8501
	SD	32.710	0.14453	0.02278	0.01505	0.05179
2	(n)	10	10	10	10	10
	Mean	435.12	2.6592	0.1852	0.0864	0.8882
	SD	19.395	0.24788	0.02204	0.01714	0.10379
3	(n)	10	10	10	10	10
	Mean	436.73	3.0176#C	0.1729	0.0809	0.8617
	SD	21.857	0.16510	0.01204	0.01656	0.11059
4	(n)	10	10	10	10	10
	Mean	442.57	4.5567#C	0.1786	0.0806	0.8733
	SD	25.061	0.41626	0.01428	0.01323	0.07214

For DRAFT - Not to be used or quoted

Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

TABLE 15 - Organ weight to terminal body weight - Group data

Death Status: Final sacrifice / Dosing

			Females				
Group No		TBW (g)	Adrenal glands	Brain	Heart	Kidneys	Liver
Control	(n)	10	10	10	10	10	10
	Mean	271.15	0.0225	0.6518	0.3614	0.5711	2.4105
	SD	15.165	0.00248	0.05215	0.03632	0.02554	0.14366
2	(n)	10	10	10	10	10	10
	Mean	270.00	0.0224	0.6582	0.3614	0.5891	2.4041
	SD	11.927	0.00226	0.02503	0.03964	0.04776	0.19974
3	(n)	10	10	10	10	10	10
	Mean	267.46	0.0208	0.6585	0.3534	0.5793	2.4431
	SD	13.037	0.00294	0.04754	0.03453	0.04058	0.09994
4	(n)	10	10	10	10	10	10
	Mean	268.70	0.0228	0.6635	0.3594	0.6159	3.1082#C
	SD	12.518	0.00395	0.03766	0.02906	0.03211	0.27397

Organ weight to terminal body weight (%) - Group mean data

Printed: 01 Feb 2016 11:41:49
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

TABLE 15 - Organ weight to terminal body weight - Group data

Death Status: Final sacrifice / Dosing

			Females			
Group No		TBW (g)	Ovaries	Spleen	Thymus	Uterus
Control	(n)	10	10	10	10	10
	Mean	271.15	0.0421	0.2339	0.0939	0.2442
	SD	15.165	0.00414	0.01484	0.00840	0.08413
2	(n)	10	10	10	10	10
	Mean	270.00	0.0417	0.2395	0.0995	0.2777
	SD	11.927	0.00720	0.02619	0.01516	0.09440
3	(n)	10	10	10	10	10
	Mean	267.46	0.0440	0.2260	0.1016	0.2780
	SD	13.037	0.00412	0.02471	0.01110	0.12378
4	(n)	10	10	10	10	10
	Mean	268.70	0.0423	0.2288	0.0908	0.3469
	SD	12.518	0.00638	0.01835	0.01592	0.17498

Organ weight to terminal body weight (%) - Group mean data

Printed: 06 Mar 2016 09:34:34
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

TABLE 15 - Organ weight to terminal body weight - Group data

Death Status: Recovery sacrifice / Recovery

		Males					
Group No		TBW (g)	Adrenal glands	Brain	Epididymides	Heart	Kidneys
Control	(n)	5	5	5	5	5	5
	Mean	458.76	0.0092	0.4224	0.2916	0.3278	0.6266
	SD	19.039	0.00109	0.01156	0.02952	0.01362	0.05247
2	(n)	5	5	5	5	5	5
	Mean	477.94	0.0098	0.4090	0.3108	0.3062	0.5622
	SD	17.169	0.00099	0.02321	0.04556	0.01506	0.01970
3	(n)	5	5	5	5	5	5
	Mean	465.36	0.0109	0.4272	0.2886	0.3332	0.6180
	SD	28.299	0.00208	0.03064	0.03665	0.01460	0.02820
4	(n)	5	5	5	5	5	5
	Mean	471.24	0.0104	0.4086	0.3026	0.3203	0.6258
	SD	24.887	0.00131	0.02186	0.02564	0.02455	0.05747

REDACTED AS TO TRADE NAMES

Organ weight to terminal body weight (%) - Group mean data

Printed: 06 Mar 2016 09:34:34
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

		Males				
Group No		TBW (g)	Liver	Spleen	Thymus	Testes
Control	(n)	5	5	5	5	5
	Mean	458.76	2.3904	0.1711	0.0576	0.8705
	SD	19.039	0.20158	0.02046	0.00946	0.04753
2	(n)	5	5	5	5	5
	Mean	477.94	2.4036	0.1754	0.0547	0.8394
	SD	17.169	0.10948	0.00765	0.00770	0.09736
3	(n)	5	5	5	5	5
	Mean	465.36	2.5545	0.1724	0.0609	0.7496
	SD	28.299	0.12214	0.01479	0.00736	0.25166
4	(n)	5	5	5	5	5
	Mean	471.24	3.1835+D	0.1672	0.0623	0.9095
	SD	24.887	0.32534	0.02894	0.00851	0.08263

Organ weight to terminal body weight (%) - Group mean data

Printed: 06 Mar 2016 09:34:34
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

TABLE 15 - Organ weight to terminal body weight - Group data

Death Status: Recovery sacrifice / Recovery

Females

Group No		TBW (g)	Adrenal glands	Brain	Heart	Kidneys	Liver
Control	(n)	5	5	5	5	5	5
	Mean	295.40	0.0169	0.5901	0.3281	0.5388	2.1938
	SD	14.267	0.00275	0.01157	0.01549	0.06428	0.26285
2	(n)	5	5	5	5	5	5
	Mean	282.44	0.0210*D	0.6455	0.3381	0.5884	2.1778
	SD	21.886	0.00274	0.05405	0.03371	0.05294	0.15009
3	(n)	5	5	5	5	5	5
	Mean	283.04	0.0205*D	0.6289	0.3464	0.5926	2.3153
	SD	9.859	0.00094	0.03375	0.03799	0.00542	0.08929
4	(n)	5	5	5	5	5	5
	Mean	278.22	0.0196	0.6536+C	0.3425	0.5653	2.8219+D
	SD	6.814	0.00162	0.02203	0.00754	0.03267	0.07587

REDACTED AS TO TRADE NAMES

Organ weight to terminal body weight (%) - Group mean data

Printed: 06 Mar 2016 09:34:34
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

		Females				
Group No		TBW (g)	Ovaries	Spleen	Thymus	Uterus
Control	(n)	5	5	5	5	5
	Mean	295.40	0.0357	0.2076	0.0791	0.1857
	SD	14.267	0.00379	0.01369	0.01040	0.03388
2	(n)	5	5	5	5	5
	Mean	282.44	0.0355	0.2190	0.0697	0.3253*C
	SD	21.886	0.00298	0.01872	0.01144	0.10574
3	(n)	5	5	5	5	5
	Mean	283.04	0.0422	0.2198	0.0765	0.2686*C
	SD	9.859	0.00963	0.02463	0.01486	0.02359
4	(n)	5	5	5	5	5
	Mean	278.22	0.0445	0.2243	0.0679	0.2130
	SD	6.814	0.00545	0.01779	0.01479	0.06345

TABLE 15 - Organ weight to terminal body weight - Group data

REDACTED AS TO TRADE NAMES

Macroscopic observations - Group incidence

Printed: 01 Feb 2016 11:44:40
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

Males

Dosage Group:	Control	2	3	4
Number of Animals:	10	10	10	10
Number Examined:	10	10	10	10
Cervical nodes				
Abnormal colour	0	1	0	0
Liver				
Abnormal shape	0	0	2	9
Abnormal size	0	0	0	6
Spleen				
Abnormal shape	1	0	0	0
Stomach				
Abnormal area(s)	1	0	1	0

REDACTED AS TO TRADE NAMES

Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

Males

Dosage Group:	Control	2	3	4
Number of Animals:	10	10	10	10
Number Examined:	10	10	10	10
Thymus				
Abnormal colour	1	0	0	0
Whole animal				
No abnormalities detected	8	9	7	0

DO NOT COPY - Unpublished 2011

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

Females

Dosage Group:	Control	2	3	4
Number of Animals:	10	10	10	10
Number Examined:	10	10	10	10
Brain				
Abnormal shape	0	0	1	0
Liver				
Abnormal shape	0	0	0	1
Ovaries				
Abnormal size	2	2	3	3
Stomach				
Abnormal area(s)	2	0	0	0

REDACTED AS TO TRADE NAMES

Macroscopic observations - Group incidence

Printed: 01 Feb 2016 11:44:40
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

Females

Dosage Group:	Control	2	3	4
Number of Animals:	10	10	10	10
Number Examined:	10	10	10	10
Thymus				
Abnormal size	0	0	0	2
Uterus				
Abnormal contents	4	5	3	5
Abnormal size	4	5	3	5
Whole animal				
No abnormalities detected	4	4	5	2
Ear(s)				
Abnormal area(s)	0	0	0	2

19 January - 1400 December 2011

REDACTED AS TO TRADE NAMES

Macroscopic observations - Group incidence

Printed: 06 Mar 2016 09:37:11
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

Males

Dosage Group:	Control	2	3	4
Number of Animals:	5	5	5	5
Number Examined:	5	5	5	5
Kidneys				
Abnormal area(s)	0	1	0	0
Pelvic dilatation	1	0	0	0
Testes				
Abnormal consistency	0	0	1	0
Abnormal size	0	0	1	0
Thymus				
Abnormal size	1	0	0	0
Whole animal				
No abnormalities detected	3	4	4	5

REDACTED AS TO TRADE NAMES

Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

Females

Dosage Group:	Control	2	3	4
Number of Animals:	5	5	5	5
Number Examined:	5	5	5	5
Ovaries				
Abnormal size	1	0	1	2
Pancreas				
Abnormal colour	0	0	1	0
Skin				
Staining	0	2	0	1
Thymus				
Abnormal size	0	4	1	3

DRAFT - Not Used Subject 2016

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

Females

Dosage Group:	Control	2	3	4
Number of Animals:	5	5	5	5
Number Examined:	5	5	5	5
Uterus				
Abnormal contents	0	3	0	0
Abnormal size	0	3	1	0
Whole animal				
No abnormalities detected	4	0	4	1

REDACTED AS TO TRADE NAMES

Microscopic observations - Group incidence

Printed: 18 Apr 2016 14:54:03

Pristima® Version 6.3.2 Build 22

Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

Males

Dosage Group:	Control	2	3	4
Number of Animals:	10	10	10	10
Number Examined:	10	10	10	10
Adrenal glands				
CORTICAL VACUOLATION	0	0	0	1
Aorta				
INFLAMMATORY CELL FOCI	1	0	0	0
Heart				
INFLAMMATORY CELL FOCI	5	0	0	4

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

Males

Dosage Group:	Control	2	3	4
Number of Animals:	10	10	10	10
Number Examined:	10	10	10	10
Kidneys				
NEPHROPATHY	9	0	0	6
Liver				
CLEAR CELL FOCUS/I	0	0	0	1
Hepatocytic hypertrophy	0	0	10	10
HEPATOCYTIC NECROSIS	0	0	0	2
HEPATOCYTIC VACUOLATION	0	9	6	0
INFLAMMATORY CELL FOCI	10	10	10	9

REDACTED AS TO TRADE NAMES

Microscopic observations - Group incidence

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

Males

Dosage Group:	Control	2	3	4
Number of Animals:	10	10	10	10
Number Examined:	10	10	10	10
Lungs				
ALVEOLAR MACROPHAGE AGGREGATION	0	0	0	1
HAEMORRHAGE	0	0	0	2
INFLAMMATORY CELL FOCI	2	0	0	1
MINERALIZATION	5	0	0	3
Pituitary gland				
BASOPHILIC CELL HYPERTROPHY	0	0	0	10#
CYST/S	1	0	1	0
Prostate gland				
INFLAMMATORY CELL FOCI	3	0	0	3

= K-S 2 tailed test significant at the 0.001 level

REDACTED AS TO TRADE NAMES

Microscopic observations - Group incidence

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

Males

Dosage Group:	Control	2	3	4
Number of Animals:	10	10	10	10
Number Examined:	10	10	10	10
Seminal vesicles				
COLLOID DEPLETION	0	0	0	3
Thyroid gland				
FOLLICULAR HYPERTROPHY	0	0	8+	10#
GALT/PEYER'S PATCH				
LYMPHOID HYPERPLASIA	2	0	0	1

+ = K-S 2 tailed test significant at the 0.01 level # = K-S 2 tailed test significant at the 0.001 level

REDACTED AS TO TRADE NAMES

Microscopic observations - Group incidence

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

Females

Dosage Group:	Control	2	3	4
Number of Animals:	10	10	10	10
Number Examined:	10	10	10	10
Adrenal glands				
CYST/S	0	0	0	1
Brain				
CONGENITAL ABNORMALITY	0	0	1	0
Kidneys				
INFLAMMATORY CELL FOCI	0	0	0	1
MINERALIZATION	1	0	0	1
NEPHROPATHY	2	0	0	4

DRAFT - NOT FOR IMPLEMENTATION

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

Females

Dosage Group:	Control	2	3	4
Number of Animals:	10	10	10	10
Number Examined:	10	10	10	10
Liver				
Hepatocytic hypertrophy	0	0	0	10
HEPATOCYTIC NECROSIS	0	0	1	0
HEPATOCYTIC VACUOLATION	0	0	0	3
INFLAMMATORY CELL FOCI	9	9	10	10
Lungs				
ALVEOLAR MACROPHAGE AGGREGATION	1	0	0	0
MINERALIZATION	1	0	0	0
Oesophagus				
CHRONIC INFLAMMATION	1	0	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

DRAFT - 5th December 2016

Females

Dosage Group:	Control	2	3	4
Number of Animals:	10	10	10	10
Number Examined:	10	10	10	10
Pancreas				
ACINAR CELL DEGENERATION	0	0	0	1
Parathyroid glands				
FIBROSIS	1	0	0	0
Skeletal muscle				
INFLAMMATORY CELL FOCI	0	0	0	1

REDACTED AS TO TRADE NAMES

Microscopic observations - Group incidence

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

Females

Dosage Group:	Control	2	3	4
Number of Animals:	10	10	10	10
Number Examined:	10	10	10	10
Thymus				
ATROPHY	0	0	0	1
Thyroid gland				
ECTOPIC THYMUS	1	0	0	1
Uterus				
DILATION, LUMEN	3	5	3	6

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

Females

Dosage Group:	Control	2	3	4
Number of Animals:	10	10	10	10
Number Examined:	10	10	10	10
GALT/PEYER'S PATCH				
LYMPHOID HYPERPLASIA	1	0	0	1

DRAFT - Not for Distribution 2016

REDACTED AS TO TRADE NAMES

Microscopic observations - Group incidence

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

Males

Dosage Group:	Control	2	3	4
Number of Animals:	5	5	5	5
Number Examined:	5	5	5	5
Liver				
Hepatocytic hypertrophy	0	0	0	4
HEPATOCYTIC NECROSIS	0	0	0	2
HEPATOCYTIC VACUOLATION	0	4	3	3
INFLAMMATORY CELL FOCI	4	5	5	5
Pituitary gland				
BASOPHILIC CELL HYPERTROPHY	0	0	0	1
CYST/S	0	1	0	0
Thyroid gland				
FOLLICULAR HYPERTROPHY	0	0	0	1

REDACTED AS TO TRADE NAMES

Microscopic observations - Group incidence

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

Females

Dosage Group:	Control	2	3	4
Number of Animals:	5	5	5	5
Number Examined:	5	5	5	5
Liver				
INFLAMMATORY CELL FOCI	5	4	5	5

9 APPENDICES

REDACTED AS TO TRADE NAMES

Death status - Individual data

Printed: 04 Mar 2016 12:56:18

Pristima® Version 6.3.2 Build 22

Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Type of Death	Phase Name	Day of Phase
A1474002	M	1	Final sacrifice	Dosing	92
A1474004	M	1	Final sacrifice	Dosing	92
A1474006	M	1	Final sacrifice	Dosing	92
A1474008	M	1	Final sacrifice	Dosing	92
A1474010	M	1	Final sacrifice	Dosing	92
A1474012	M	1	Final sacrifice	Dosing	92
A1474014	M	1	Final sacrifice	Dosing	92
A1474016	M	1	Final sacrifice	Dosing	92
A1474018	M	1	Final sacrifice	Dosing	92
A1474020	M	1	Final sacrifice	Dosing	92
A1474022	M	1	Recovery sacrifice	Recovery	57
A1474024	M	1	Recovery sacrifice	Recovery	57
A1474026	M	1	Recovery sacrifice	Recovery	57
A1474028	M	1	Recovery sacrifice	Recovery	57
A1474030	M	1	Recovery sacrifice	Recovery	57
A1474032	M	2	Final sacrifice	Dosing	92
A1474034	M	2	Final sacrifice	Dosing	92
A1474036	M	2	Final sacrifice	Dosing	92
A1474038	M	2	Final sacrifice	Dosing	92
A1474040	M	2	Final sacrifice	Dosing	92
A1474042	M	2	Final sacrifice	Dosing	92
A1474044	M	2	Final sacrifice	Dosing	92
A1474046	M	2	Final sacrifice	Dosing	92
A1474048	M	2	Final sacrifice	Dosing	92

Death status - Individual data

Printed: 04 Mar 2016 12:56:18

Pristima® Version 6.3.2 Build 22

Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Type of Death	Phase Name	Day of Phase
A1474050	M	2	Final sacrifice	Dosing	92
A1474052	M	2	Recovery sacrifice	Recovery	57
A1474054	M	2	Recovery sacrifice	Recovery	57
A1474056	M	2	Recovery sacrifice	Recovery	57
A1474058	M	2	Recovery sacrifice	Recovery	57
A1474060	M	2	Recovery sacrifice	Recovery	57
A1474062	M	3	Final sacrifice	Dosing	92
A1474064	M	3	Final sacrifice	Dosing	92
A1474066	M	3	Final sacrifice	Dosing	92
A1474068	M	3	Final sacrifice	Dosing	92
A1474070	M	3	Final sacrifice	Dosing	92
A1474072	M	3	Final sacrifice	Dosing	92
A1474074	M	3	Final sacrifice	Dosing	92
A1474076	M	3	Final sacrifice	Dosing	92
A1474078	M	3	Final sacrifice	Dosing	92
A1474080	M	3	Final sacrifice	Dosing	92
A1474082	M	3	Recovery sacrifice	Recovery	57
A1474084	M	3	Recovery sacrifice	Recovery	57
A1474086	M	3	Recovery sacrifice	Recovery	57
A1474088	M	3	Recovery sacrifice	Recovery	57
A1474090	M	3	Recovery sacrifice	Recovery	57
A1474092	M	4	Final sacrifice	Dosing	92
A1474094	M	4	Final sacrifice	Dosing	92
A1474096	M	4	Final sacrifice	Dosing	92

REDACTED AS TO TRADE NAMES

Death status - Individual data

Printed: 04 Mar 2016 12:56:18

Pristima® Version 6.3.2 Build 22

Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Type of Death	Phase Name	Day of Phase
A1474098	M	4	Final sacrifice	Dosing	92
A1474100	M	4	Final sacrifice	Dosing	92
A1474102	M	4	Final sacrifice	Dosing	92
A1474104	M	4	Final sacrifice	Dosing	92
A1474106	M	4	Final sacrifice	Dosing	92
A1474108	M	4	Final sacrifice	Dosing	92
A1474110	M	4	Final sacrifice	Dosing	92
A1474112	M	4	Recovery sacrifice	Recovery	57
A1474114	M	4	Recovery sacrifice	Recovery	57
A1474116	M	4	Recovery sacrifice	Recovery	57
A1474118	M	4	Recovery sacrifice	Recovery	57
A1474120	M	4	Recovery sacrifice	Recovery	57
A1474001	F	1	Final sacrifice	Dosing	93
A1474003	F	1	Final sacrifice	Dosing	93
A1474005	F	1	Final sacrifice	Dosing	93
A1474007	F	1	Final sacrifice	Dosing	93
A1474009	F	1	Final sacrifice	Dosing	93
A1474011	F	1	Final sacrifice	Dosing	93
A1474013	F	1	Final sacrifice	Dosing	93
A1474015	F	1	Final sacrifice	Dosing	93
A1474017	F	1	Final sacrifice	Dosing	93
A1474019	F	1	Final sacrifice	Dosing	93
A1474021	F	1	Recovery sacrifice	Recovery	58
A1474023	F	1	Recovery sacrifice	Recovery	58

Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Type of Death	Phase Name	Day of Phase
A1474025	F	1	Recovery sacrifice	Recovery	58
A1474027	F	1	Recovery sacrifice	Recovery	58
A1474029	F	1	Recovery sacrifice	Recovery	58
A1474031	F	2	Final sacrifice	Dosing	93
A1474033	F	2	Final sacrifice	Dosing	93
A1474035	F	2	Final sacrifice	Dosing	93
A1474037	F	2	Final sacrifice	Dosing	93
A1474039	F	2	Final sacrifice	Dosing	93
A1474041	F	2	Final sacrifice	Dosing	93
A1474043	F	2	Final sacrifice	Dosing	93
A1474045	F	2	Final sacrifice	Dosing	93
A1474047	F	2	Final sacrifice	Dosing	93
A1474049	F	2	Final sacrifice	Dosing	93
A1474051	F	2	Recovery sacrifice	Recovery	58
A1474053	F	2	Recovery sacrifice	Recovery	58
A1474055	F	2	Recovery sacrifice	Recovery	58
A1474057	F	2	Recovery sacrifice	Recovery	58
A1474059	F	2	Recovery sacrifice	Recovery	58
A1474061	F	3	Final sacrifice	Dosing	93
A1474063	F	3	Final sacrifice	Dosing	93
A1474065	F	3	Final sacrifice	Dosing	93
A1474067	F	3	Final sacrifice	Dosing	93
A1474069	F	3	Final sacrifice	Dosing	93
A1474071	F	3	Final sacrifice	Dosing	93

REDACTED AS TO TRADE NAMES

Death status - Individual data

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Pristima® Version 6.3.2 Build 22

Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Type of Death	Phase Name	Day of Phase
A1474073	F	3	Final sacrifice	Dosing	93
A1474075	F	3	Final sacrifice	Dosing	93
A1474077	F	3	Final sacrifice	Dosing	93
A1474079	F	3	Final sacrifice	Dosing	93
A1474081	F	3	Recovery sacrifice	Recovery	58
A1474083	F	3	Recovery sacrifice	Recovery	58
A1474087	F	3	Recovery sacrifice	Recovery	58
A1474089	F	3	Recovery sacrifice	Recovery	58
A1474091	F	4	Final sacrifice	Dosing	93
A1474093	F	4	Final sacrifice	Dosing	93
A1474095	F	4	Final sacrifice	Dosing	93
A1474097	F	4	Final sacrifice	Dosing	93
A1474099	F	4	Final sacrifice	Dosing	93
A1474101	F	4	Final sacrifice	Dosing	93
A1474103	F	4	Final sacrifice	Dosing	93
A1474105	F	4	Final sacrifice	Dosing	93
A1474107	F	4	Final sacrifice	Dosing	93
A1474109	F	4	Final sacrifice	Dosing	93
A1474113	F	4	Recovery sacrifice	Recovery	58
A1474115	F	4	Recovery sacrifice	Recovery	58
A1474119	F	4	Recovery sacrifice	Recovery	58

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Observation	Days Seen
A1474002	M	1	No Significant signs	D1-86
			Tooth/teeth broken, Upper	D87-92
A1474004	M	1	No Significant signs	D1-92
A1474006	M	1	No Significant signs	D1-92
A1474008	M	1	No Significant signs	D1-92
A1474010	M	1	No Significant signs	D1-92
A1474012	M	1	No Significant signs	D1-92
A1474014	M	1	No Significant signs	D1-92
A1474016	M	1	No Significant signs	D1-92
A1474018	M	1	No Significant signs	D1-92
A1474020	M	1	No Significant signs	D1-92
A1474022	M	1	No Significant signs	D1-92
A1474024	M	1	No Significant signs	D1-92
A1474026	M	1	No Significant signs	D1-92
A1474028	M	1	No Significant signs	D1-92
A1474030	M	1	No Significant signs	D1-92

D = Dosing

REDACTED AS TO TRADE NAMES

Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Observation	Days Seen
A1474032	M	2	No Significant signs	D1-92
A1474034	M	2	No Significant signs	D1-92
A1474036	M	2	No Significant signs	D1-92
A1474038	M	2	No Significant signs	D1-92
A1474040	M	2	No Significant signs	D1-92
A1474042	M	2	No Significant signs	D1-92
A1474044	M	2	No Significant signs	D1-86 , 92
			Tooth/teeth broken, Upper	D87-91
A1474046	M	2	No Significant signs	D1-92
A1474048	M	2	No Significant signs	D1-92
A1474050	M	2	No Significant signs	D1-92
A1474052	M	2	No Significant signs	D1-92
A1474054	M	2	No Significant signs	D1-92
A1474056	M	2	No Significant signs	D1-92
A1474058	M	2	No Significant signs	D1-92
A1474060	M	2	No Significant signs	D1-92

D = Dosing

REDACTED AS TO TRADE NAMES

Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Observation	Days Seen
A1474062	M	3	No Significant signs	D1-92
A1474064	M	3	No Significant signs	D1-92
A1474066	M	3	No Significant signs	D1-92
A1474068	M	3	No Significant signs	D1-92
A1474070	M	3	No Significant signs	D1-92
A1474072	M	3	No Significant signs	D1-92
A1474074	M	3	No Significant signs	D1-92
A1474076	M	3	No Significant signs	D1-92
A1474078	M	3	No Significant signs	D1-92
A1474080	M	3	No Significant signs	D1-92
A1474082	M	3	No Significant signs	D1-92
A1474084	M	3	No Significant signs	D1-92
A1474086	M	3	No Significant signs	D1-92
A1474088	M	3	No Significant signs	D1-92
A1474090	M	3	No Significant signs	D1-92

D = Dosing

REDACTED AS TO TRADE NAMES

Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Observation	Days Seen
A1474092	M	4	No Significant signs	D1-92
A1474094	M	4	No Significant signs	D1-92
A1474096	M	4	No Significant signs	D1-92
A1474098	M	4	No Significant signs	D1-92
A1474100	M	4	No Significant signs	D1-92
A1474102	M	4	No Significant signs	D1-92
A1474104	M	4	No Significant signs	D1-92
A1474106	M	4	No Significant signs	D1-92
A1474108	M	4	No Significant signs	D1-92
A1474110	M	4	No Significant signs	D1-92
A1474112	M	4	No Significant signs	D1-92
A1474114	M	4	No Significant signs	D1-92
A1474116	M	4	No Significant signs	D1-92
A1474118	M	4	No Significant signs	D1-92
A1474120	M	4	No Significant signs	D1-92

D = Dosing

REDACTED AS TO TRADE NAMES

Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Observation	Days Seen
A1474001	F	1	No Significant signs	D1-93
A1474003	F	1	No Significant signs	D1-93
A1474005	F	1	No Significant signs	D1-93
A1474007	F	1	No Significant signs	D1-93
A1474009	F	1	No Significant signs	D1-93
A1474011	F	1	No Significant signs	D1-93
A1474013	F	1	No Significant signs	D1-93
A1474015	F	1	No Significant signs	D1-93
A1474017	F	1	No Significant signs	D1-93
A1474019	F	1	No Significant signs	D1-93
A1474021	F	1	No Significant signs	D1-92
A1474023	F	1	No Significant signs	D1-92
A1474025	F	1	No Significant signs	D1-92
A1474027	F	1	No Significant signs	D1-92
A1474029	F	1	No Significant signs	D1-92

D = Dosing

REDACTED AS TO TRADE NAMES

Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Observation	Days Seen
A1474031	F	2	No Significant signs	D1-93
A1474033	F	2	No Significant signs	D1-93
A1474035	F	2	No Significant signs	D1-93
A1474037	F	2	No Significant signs	D1-93
A1474039	F	2	No Significant signs	D1-93
A1474041	F	2	No Significant signs	D1-93
A1474043	F	2	No Significant signs	D1-93
A1474045	F	2	No Significant signs	D1-93
A1474047	F	2	No Significant signs	D1-93
A1474049	F	2	No Significant signs	D1-93
A1474051	F	2	No Significant signs	D1-92
A1474053	F	2	No Significant signs	D1-92
A1474055	F	2	No Significant signs	D1-92
A1474057	F	2	No Significant signs	D1-92
A1474059	F	2	No Significant signs	D1-92

D = Dosing

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Observation	Days Seen
A1474061	F	3	No Significant signs	D1-93
A1474063	F	3	No Significant signs	D1-93
A1474065	F	3	No Significant signs	D1-93
A1474067	F	3	No Significant signs	D1-93
A1474069	F	3	No Significant signs	D1-93
A1474071	F	3	No Significant signs	D1-93
A1474073	F	3	No Significant signs	D1-93
A1474075	F	3	No Significant signs	D1-93
A1474077	F	3	No Significant signs	D1-93
A1474079	F	3	No Significant signs	D1-93
A1474081	F	3	No Significant signs	D1-92
A1474083	F	3	No Significant signs	D1-92
A1474085	F	3	No Significant signs	D1-92
A1474087	F	3	No Significant signs	D1-92
A1474089	F	3	No Significant signs	D1-92

D = Dosing

REDACTED AS TO TRADE NAMES

Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Observation	Days Seen
A1474091	F	4	No Significant signs	D1-93
A1474093	F	4	No Significant signs	D1-21
			Damaged ear, Right	D22-93
A1474095	F	4	No Significant signs	D1-93
A1474097	F	4	No Significant signs	D1-93
A1474099	F	4	No Significant signs	D1-93
A1474101	F	4	No Significant signs	D1-93
A1474103	F	4	No Significant signs	D1-64
			Damaged ear, Right	D65-93
A1474105	F	4	No Significant signs	D1-93
A1474107	F	4	No Significant signs	D1-93
A1474109	F	4	No Significant signs	D1-93
A1474111	F	4	No Significant signs	D1-92
A1474113	F	4	No Significant signs	D1-92
A1474115	F	4	No Significant signs	D1-92
A1474117	F	4	No Significant signs	D1-92
A1474119	F	4	No Significant signs	D1-92

D = Dosing

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Observation	Days Seen
A1474022	M	1	No Significant signs	R2-57
A1474024	M	1	No Significant signs	R2-57
A1474026	M	1	No Significant signs	R2-57
A1474028	M	1	No Significant signs	R2-57
A1474030	M	1	No Significant signs	R2-57

R = Recovery

REDACTED AS TO TRADE NAMES

Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Observation	Days Seen
A1474052	M	2	No Significant signs	R2-57
A1474054	M	2	No Significant signs	R2-57
A1474056	M	2	No Significant signs	R2-57
A1474058	M	2	No Significant signs	R2-57
A1474060	M	2	No Significant signs	R2-57

R = Recovery

REDACTED AS TO TRADE NAMES

Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Observation	Days Seen
A1474082	M	3	No Significant signs	R2-57
A1474084	M	3	No Significant signs	R2-57
A1474086	M	3	No Significant signs	R2-57
A1474088	M	3	No Significant signs	R2-57
A1474090	M	3	No Significant signs	R2-57

R = Recovery

Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Observation	Days Seen
A1474112	M	4	No Significant signs	R2-57
A1474114	M	4	No Significant signs	R2-57
A1474116	M	4	No Significant signs	R2-57
A1474118	M	4	No Significant signs	R2-57
A1474120	M	4	No Significant signs	R2-57

R = Recovery

REDACTED AS TO TRADE NAMES

Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Observation	Days Seen
A1474021	F	1	No Significant signs	R2-58
A1474023	F	1	No Significant signs	R2-58
A1474025	F	1	No Significant signs	R2-58
A1474027	F	1	No Significant signs	R2-28
			Damaged eye, Right	R29-58
A1474029	F	1	No Significant signs	R2-58

R = Recovery

REDACTED AS TO TRADE NAMES

Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Observation	Days Seen
A1474051	F	2	No Significant signs	R2-57
			Staining, Neck, Moderate, Brown	R58
A1474053	F	2	No Significant signs	R2-57
			Staining, Neck, Slight, Brown	R58
A1474055	F	2	No Significant signs	R2-58
A1474057	F	2	No Significant signs	R2-58
A1474059	F	2	No Significant signs	R2-58

R = Recovery

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Observation	Days Seen
A1474081	F	3	No Significant signs	R2-58
A1474083	F	3	No Significant signs	R2-58
A1474085	F	3	No Significant signs	R2-58
A1474087	F	3	No Significant signs	R2-58
A1474089	F	3	No Significant signs	R2-58

R = Recovery

REDACTED AS TO TRADE NAMES

Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Observation	Days Seen
A1474111	F	4	No Significant signs	R2-58
A1474113	F	4	No Significant signs	R2-58
A1474115	F	4	No Significant signs	R2-58
A1474117	F	4	No Significant signs	R2-58
A1474119	F	4	No Significant signs	R2-57
			Staining, Neck, Slight, Brown	R58

R = Recovery

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Allocation Day 3

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474002	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474004	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474006	1	1	1	6	1	Absent	Absent	Absent	Absent
	A1474008	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474010	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474012	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474014	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474016	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474018	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474020	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474022	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474024	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474026	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474028	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474030	1	1	1	15	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Allocation Day 3

Males

Group	Animal No	BB	UN	UR	DE
Control	A1474002	Absent	Absent	0	0
	A1474004	Absent	Absent	0	3
	A1474006	Absent	Absent	0	0
	A1474008	Absent	Absent	0	0
	A1474010	Absent	Absent	0	0
	A1474012	Absent	Absent	0	0
	A1474014	Absent	Absent	0	0
	A1474016	Absent	Absent	0	0
	A1474018	Absent	Absent	0	0
	A1474020	Absent	Absent	0	0
	A1474022	Absent	Absent	0	0
	A1474024	Absent	Absent	0	0
	A1474026	Absent	Absent	0	0
	A1474028	Absent	Absent	0	0
	A1474030	Absent	Absent	0	0

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REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Allocation Day 3

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474032	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474034	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474036	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474038	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474040	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474042	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474044	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474046	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474048	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474050	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474052	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474054	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474056	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474058	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474060	1	1	1	16	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Allocation Day 3

Males

Group	Animal No	BB	UN	UR	DE
2	A1474032	Absent	Absent	0	0
	A1474034	Absent	Absent	0	0
	A1474036	Absent	Absent	2	0
	A1474038	Absent	Absent	0	0
	A1474040	Absent	Absent	0	0
	A1474042	Absent	Absent	0	0
	A1474044	Absent	Absent	0	0
	A1474046	Absent	Absent	0	0
	A1474048	Absent	Absent	0	0
	A1474050	Absent	Absent	0	0
	A1474052	Absent	Absent	0	0
	A1474054	Absent	Absent	0	0
	A1474056	Absent	Absent	0	0
	A1474058	Absent	Absent	0	0
	A1474060	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Allocation Day 3

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474062	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474064	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474066	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474068	1	1	1	8	1	Absent	Absent	Absent	Absent
	A1474070	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474072	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474074	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474076	1	1	1	22	1	Absent	Absent	Absent	Absent
	A1474078	1	1	1	9	1	Absent	Absent	Absent	Absent
	A1474080	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474082	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474084	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474086	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474088	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474090	1	1	1	20	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Allocation Day 3

Males

Group	Animal No	BB	UN	UR	DE
3	A1474062	Absent	Absent	0	0
	A1474064	Absent	Absent	0	0
	A1474066	Absent	Absent	0	0
	A1474068	Absent	Absent	0	0
	A1474070	Absent	Absent	0	0
	A1474072	Absent	Absent	0	0
	A1474074	Absent	Absent	0	0
	A1474076	Absent	Absent	0	0
	A1474078	Absent	Absent	0	0
	A1474080	Absent	Absent	0	0
	A1474082	Absent	Absent	0	0
	A1474084	Absent	Absent	0	0
	A1474086	Absent	Absent	0	0
	A1474088	Absent	Absent	0	0
	A1474090	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Allocation Day 3

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474092	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474094	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474096	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474098	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474100	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474102	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474104	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474106	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474108	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474110	1	1	1	8	1	Absent	Absent	Absent	Absent
	A1474112	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474114	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474116	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474118	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474120	1	1	1	15	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Allocation Day 3

Males

Group	Animal No	BB	UN	UR	DE
4	A1474092	Absent	Absent	0	0
	A1474094	Absent	Absent	3	0
	A1474096	Absent	Absent	0	0
	A1474098	Absent	Absent	0	0
	A1474100	Absent	Absent	0	0
	A1474102	Absent	Absent	0	0
	A1474104	Absent	Absent	0	0
	A1474106	Absent	Absent	0	0
	A1474108	Absent	Absent	0	0
	A1474110	Absent	Absent	0	0
	A1474112	Absent	Absent	0	0
	A1474114	Absent	Absent	0	0
	A1474116	Absent	Absent	0	0
	A1474118	Absent	Absent	0	0
	A1474120	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Allocation Day 4

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474001	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474003	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474005	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474007	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474009	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474011	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474013	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474015	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474017	1	1	1	22	1	Absent	Absent	Absent	Absent
	A1474019	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474021	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474023	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474025	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474027	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474029	1	1	1	17	1	Absent	Absent	Absent	Absent

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Allocation Day 4

Females

Group	Animal No	BB	UN	UR	DE
Control	A1474001	Absent	Absent	0	0
	A1474003	Absent	Absent	0	0
	A1474005	Absent	Absent	0	0
	A1474007	Absent	Absent	0	0
	A1474009	Absent	Absent	2	0
	A1474011	Absent	Absent	0	0
	A1474013	Absent	Absent	0	0
	A1474015	Absent	Absent	0	0
	A1474017	Absent	Absent	0	0
	A1474019	Absent	Absent	0	0
	A1474021	Absent	Absent	2	0
	A1474023	Absent	Absent	0	0
	A1474025	Absent	Absent	3	0
	A1474027	Absent	Absent	0	0
	A1474029	Absent	Absent	0	0

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REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Allocation Day 4

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474031	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474033	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474035	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474037	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474039	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474041	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474043	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474045	1	1	1	22	1	Absent	Absent	Absent	Absent
	A1474047	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474049	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474051	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474053	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474055	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474057	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474059	1	1	1	15	1	Absent	Absent	Absent	Absent

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Allocation Day 4

Females

Group	Animal No	BB	UN	UR	DE
2	A1474031	Absent	Absent	0	0
	A1474033	Absent	Absent	0	0
	A1474035	Absent	Absent	0	0
	A1474037	Absent	Absent	0	0
	A1474039	Absent	Absent	0	0
	A1474041	Absent	Absent	0	0
	A1474043	Absent	Absent	2	0
	A1474045	Absent	Absent	0	0
	A1474047	Absent	Absent	0	0
	A1474049	Absent	Absent	0	0
	A1474051	Absent	Absent	0	0
	A1474053	Absent	Absent	0	0
	A1474055	Absent	Absent	0	0
	A1474057	Absent	Absent	0	0
	A1474059	Absent	Absent	1	0

DRAFT - NOT FOR DISTRIBUTION

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Allocation Day 4

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474061	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474063	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474065	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474067	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474069	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474071	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474073	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474075	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474077	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474079	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474081	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474083	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474085	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474087	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474089	1	1	1	17	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Allocation Day 4

Females

Group	Animal No	BB	UN	UR	DE
3	A1474061	Absent	Absent	0	0
	A1474063	Absent	Absent	0	0
	A1474065	Absent	Absent	0	0
	A1474067	Absent	Absent	2	0
	A1474069	Absent	Absent	0	0
	A1474071	Absent	Absent	0	0
	A1474073	Absent	Absent	0	0
	A1474075	Absent	Absent	0	0
	A1474077	Absent	Absent	0	0
	A1474079	Absent	Absent	0	0
	A1474081	Absent	Absent	0	0
	A1474083	Absent	Absent	0	0
	A1474085	Absent	Absent	0	0
	A1474087	Absent	Absent	0	0
	A1474089	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Allocation Day 4

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474091	1	1	1	22	1	Absent	Absent	Absent	Absent
	A1474093	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474095	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474097	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474099	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474101	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474103	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474105	1	1	1	23	1	Absent	Absent	Absent	Absent
	A1474107	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474109	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474111	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474113	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474115	1	1	1	23	1	Absent	Absent	Absent	Absent
	A1474117	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474119	1	1	1	17	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Allocation Day 4

Females

Group	Animal No	BB	UN	UR	DE
4	A1474091	Absent	Absent	0	0
	A1474093	Absent	Absent	0	0
	A1474095	Absent	Absent	0	0
	A1474097	Absent	Absent	0	0
	A1474099	Absent	Absent	0	0
	A1474101	Absent	Absent	0	0
	A1474103	Absent	Absent	0	0
	A1474105	Absent	Absent	0	0
	A1474107	Absent	Absent	0	0
	A1474109	Absent	Absent	0	0
	A1474111	Absent	Absent	0	0
	A1474113	Absent	Absent	0	0
	A1474115	Absent	Absent	0	0
	A1474117	Absent	Absent	0	0
	A1474119	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 2

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474002	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474004	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474006	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474008	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474010	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474012	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474014	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474016	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474018	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474020	1	1	1	23	1	Absent	Absent	Absent	Absent
	A1474022	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474024	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474026	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474028	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474030	1	1	1	20	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 2

Males

Group	Animal No	BB	UN	UR	DE
Control	A1474002	Absent	Absent	0	0
	A1474004	Absent	Absent	0	0
	A1474006	Absent	Absent	0	0
	A1474008	Absent	Absent	0	0
	A1474010	Absent	Absent	0	0
	A1474012	Absent	Absent	0	0
	A1474014	Absent	Absent	0	0
	A1474016	Absent	Absent	0	0
	A1474018	Absent	Absent	0	0
	A1474020	Absent	Absent	0	0
	A1474022	Absent	Absent	0	0
	A1474024	Absent	Absent	0	0
	A1474026	Absent	Absent	0	0
	A1474028	Absent	Absent	0	0
	A1474030	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 2

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474032	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474034	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474036	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474038	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474040	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474042	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474044	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474046	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474048	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474050	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474052	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474054	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474056	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474058	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474060	1	1	1	14	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 2

Males

Group	Animal No	BB	UN	UR	DE
2	A1474032	Absent	Absent	0	0
	A1474034	Absent	Absent	3	4
	A1474036	Absent	Absent	0	0
	A1474038	Absent	Absent	0	0
	A1474040	Absent	Absent	0	0
	A1474042	Absent	Absent	0	0
	A1474044	Absent	Absent	2	0
	A1474046	Absent	Absent	0	0
	A1474048	Absent	Absent	1	0
	A1474050	Absent	Absent	0	0
	A1474052	Absent	Absent	1	0
	A1474054	Absent	Absent	0	0
	A1474056	Absent	Absent	0	0
	A1474058	Absent	Absent	0	0
	A1474060	Absent	Absent	1	0

NOT OFFICIAL UNTIL SIGNED BY QAU

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 2

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474062	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474064	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474066	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474068	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474070	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474072	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474074	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474076	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474078	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474080	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474082	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474084	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474086	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474088	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474090	1	1	1	13	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 2

Males

Group	Animal No	BB	UN	UR	DE
3	A1474062	Absent	Absent	0	0
	A1474064	Absent	Absent	0	0
	A1474066	Absent	Absent	0	0
	A1474068	Absent	Absent	2	0
	A1474070	Absent	Absent	0	0
	A1474072	Absent	Absent	0	0
	A1474074	Absent	Absent	0	0
	A1474076	Absent	Absent	0	0
	A1474078	Absent	Absent	0	0
	A1474080	Absent	Absent	0	0
	A1474082	Absent	Absent	0	0
	A1474084	Absent	Absent	3	2
	A1474086	Absent	Absent	0	0
	A1474088	Absent	Absent	0	0
	A1474090	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 2
Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474092	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474094	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474096	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474098	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474100	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474102	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474104	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474106	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474108	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474110	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474112	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474114	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474116	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474118	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474120	1	1	1	18	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 2

Males

Group	Animal No	BB	UN	UR	DE
4	A1474092	Absent	Absent	0	0
	A1474094	Absent	Absent	0	0
	A1474096	Absent	Absent	0	0
	A1474098	Absent	Absent	0	0
	A1474100	Absent	Absent	0	0
	A1474102	Absent	Absent	0	0
	A1474104	Absent	Absent	0	0
	A1474106	Absent	Absent	0	0
	A1474108	Absent	Absent	0	0
	A1474110	Absent	Absent	0	0
	A1474112	Absent	Absent	0	0
	A1474114	Absent	Absent	0	0
	A1474116	Absent	Absent	0	0
	A1474118	Absent	Absent	0	0
	A1474120	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 9

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474002	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474004	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474006	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474008	1	1	1	9	1	Absent	Absent	Absent	Absent
	A1474010	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474012	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474014	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474016	1	1	1	8	1	Absent	Absent	Absent	Absent
	A1474018	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474020	1	1	1	7	1	Absent	Absent	Absent	Absent
	A1474022	1	1	1	6	1	Absent	Absent	Absent	Absent
	A1474024	1	1	1	7	1	Absent	Absent	Absent	Absent
	A1474026	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474028	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474030	1	1	1	11	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 9

Males

Group	Animal No	BB	UN	UR	DE
Control	A1474002	Absent	Absent	0	0
	A1474004	Absent	Absent	0	0
	A1474006	Absent	Absent	0	0
	A1474008	Absent	Absent	1	0
	A1474010	Absent	Absent	4	0
	A1474012	Absent	Absent	0	0
	A1474014	Absent	Absent	0	0
	A1474016	Absent	Absent	0	0
	A1474018	Absent	Absent	0	0
	A1474020	Absent	Absent	0	0
	A1474022	Absent	Absent	0	0
	A1474024	Absent	Absent	0	0
	A1474026	Absent	Absent	0	0
	A1474028	Absent	Absent	0	0
	A1474030	Absent	Absent	0	0

DRAFT - NOT UNDER GLP

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 9

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474032	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474034	1	1	1	8	1	Absent	Absent	Absent	Absent
	A1474036	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474038	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474040	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474042	1	1	1	9	1	Absent	Absent	Absent	Absent
	A1474044	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474046	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474048	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474050	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474052	1	1	1	6	1	Absent	Absent	Absent	Absent
	A1474054	1	1	1	8	1	Absent	Absent	Absent	Absent
	A1474056	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474058	1	1	1	9	1	Absent	Absent	Absent	Absent
	A1474060	1	1	1	15	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 9

Males

Group	Animal No	BB	UN	UR	DE
2	A1474032	Absent	Absent	0	0
	A1474034	Absent	Absent	0	0
	A1474036	Absent	Absent	0	0
	A1474038	Absent	Absent	0	0
	A1474040	Absent	Absent	0	0
	A1474042	Absent	Absent	0	0
	A1474044	Absent	Absent	0	0
	A1474046	Absent	Absent	0	0
	A1474048	Absent	Absent	0	0
	A1474050	Absent	Absent	0	0
	A1474052	Absent	Absent	0	0
	A1474054	Absent	Absent	0	0
	A1474056	Absent	Absent	0	0
	A1474058	Absent	Absent	0	0
	A1474060	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 9

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474062	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474064	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474066	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474068	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474070	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474072	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474074	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474076	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474078	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474080	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474082	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474084	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474086	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474088	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474090	1	1	1	17	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 9

Males

Group	Animal No	BB	UN	UR	DE
3	A1474062	Absent	Absent	0	0
	A1474064	Absent	Absent	0	0
	A1474066	Absent	Absent	0	0
	A1474068	Absent	Absent	1	0
	A1474070	Absent	Absent	0	0
	A1474072	Absent	Absent	0	0
	A1474074	Absent	Absent	0	0
	A1474076	Absent	Absent	0	0
	A1474078	Absent	Absent	0	0
	A1474080	Absent	Absent	1	0
	A1474082	Absent	Absent	1	0
	A1474084	Absent	Absent	1	0
	A1474086	Absent	Absent	0	0
	A1474088	Absent	Absent	0	0
	A1474090	Absent	Absent	0	0

DRAFT - NOT FOR CIRCULATION

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 9

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474092	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474094	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474096	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474098	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474100	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474102	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474104	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474106	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474108	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474110	1	1	1	9	1	Absent	Absent	Absent	Absent
	A1474112	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474114	1	1	1	7	1	Absent	Absent	Absent	Absent
	A1474116	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474118	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474120	1	1	1	12	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 9

Males

Group	Animal No	BB	UN	UR	DE
4	A1474092	Absent	Absent	0	0
	A1474094	Absent	Absent	0	0
	A1474096	Absent	Absent	0	0
	A1474098	Absent	Absent	0	0
	A1474100	Absent	Absent	0	0
	A1474102	Absent	Absent	0	0
	A1474104	Absent	Absent	0	0
	A1474106	Absent	Absent	0	0
	A1474108	Absent	Absent	0	0
	A1474110	Absent	Absent	0	0
	A1474112	Absent	Absent	0	0
	A1474114	Absent	Absent	0	0
	A1474116	Absent	Absent	0	0
	A1474118	Absent	Absent	0	0
	A1474120	Absent	Absent	0	0

GLP - ORIGINAL - NOT UNDER AUDIT - 2010

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 16

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474002	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474004	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474006	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474008	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474010	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474012	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474014	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474016	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474018	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474020	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474022	1	1	1	8	1	Absent	Absent	Absent	Absent
	A1474024	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474026	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474028	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474030	1	1	1	14	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 16

Males

Group	Animal No	BB	UN	UR	DE
Control	A1474002	Absent	Absent	0	0
	A1474004	Absent	Absent	0	0
	A1474006	Absent	Absent	0	0
	A1474008	Absent	Absent	2	0
	A1474010	Absent	Absent	0	0
	A1474012	Absent	Absent	0	0
	A1474014	Absent	Absent	1	0
	A1474016	Absent	Absent	0	0
	A1474018	Absent	Absent	1	0
	A1474020	Absent	Absent	0	0
	A1474022	Absent	Absent	0	0
	A1474024	Absent	Absent	1	0
	A1474026	Absent	Absent	0	0
	A1474028	Absent	Absent	0	0
	A1474030	Absent	Absent	0	0

Not Drug Related (Non-treatment Related)

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 16

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474032	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474034	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474036	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474038	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474040	1	1	1	9	1	Absent	Absent	Absent	Absent
	A1474042	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474044	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474046	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474048	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474050	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474052	1	1	1	8	1	Absent	Absent	Absent	Absent
	A1474054	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474056	1	1	1	9	1	Absent	Absent	Absent	Absent
	A1474058	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474060	1	1	1	13	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 16

Males

Group	Animal No	BB	UN	UR	DE
2	A1474032	Absent	Absent	0	0
	A1474034	Absent	Absent	0	0
	A1474036	Absent	Absent	0	0
	A1474038	Absent	Absent	0	0
	A1474040	Absent	Absent	2	0
	A1474042	Absent	Absent	0	0
	A1474044	Absent	Absent	0	0
	A1474046	Absent	Absent	0	0
	A1474048	Absent	Absent	0	0
	A1474050	Absent	Absent	2	0
	A1474052	Absent	Absent	0	0
	A1474054	Absent	Absent	0	0
	A1474056	Absent	Absent	1	0
	A1474058	Absent	Absent	0	0
	A1474060	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 16

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474062	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474064	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474066	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474068	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474070	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474072	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474074	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474076	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474078	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474080	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474082	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474084	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474086	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474088	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474090	1	1	1	16	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 16

Males

Group	Animal No	BB	UN	UR	DE
3	A1474062	Absent	Absent	0	0
	A1474064	Absent	Absent	1	0
	A1474066	Absent	Absent	0	0
	A1474068	Absent	Absent	0	0
	A1474070	Absent	Absent	0	0
	A1474072	Absent	Absent	0	0
	A1474074	Absent	Absent	0	0
	A1474076	Absent	Absent	0	0
	A1474078	Absent	Absent	0	0
	A1474080	Absent	Absent	0	0
	A1474082	Absent	Absent	0	0
	A1474084	Absent	Absent	0	0
	A1474086	Absent	Absent	0	0
	A1474088	Absent	Absent	0	0
	A1474090	Absent	Absent	0	0

For Inspection Purposes Only

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 16

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474092	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474094	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474096	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474098	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474100	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474102	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474104	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474106	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474108	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474110	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474112	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474114	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474116	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474118	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474120	1	1	1	16	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 16

Males

Group	Animal No	BB	UN	UR	DE
4	A1474092	Absent	Absent	0	0
	A1474094	Absent	Absent	0	0
	A1474096	Absent	Absent	0	0
	A1474098	Absent	Absent	0	0
	A1474100	Absent	Absent	0	0
	A1474102	Absent	Absent	0	0
	A1474104	Absent	Absent	0	0
	A1474106	Absent	Absent	0	0
	A1474108	Absent	Absent	0	0
	A1474110	Absent	Absent	0	0
	A1474112	Absent	Absent	0	0
	A1474114	Absent	Absent	0	0
	A1474116	Absent	Absent	0	0
	A1474118	Absent	Absent	0	0
	A1474120	Absent	Absent	0	0

DRAFT - Not Dosed (December 2010)

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 23

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474002	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474004	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474006	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474008	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474010	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474012	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474014	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474016	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474018	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474020	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474022	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474024	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474026	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474028	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474030	1	1	1	14	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 23

Males

Group	Animal No	BB	UN	UR	DE
Control	A1474002	Absent	Absent	0	0
	A1474004	Absent	Absent	0	0
	A1474006	Absent	Absent	2	0
	A1474008	Absent	Absent	0	0
	A1474010	Absent	Absent	0	0
	A1474012	Absent	Absent	1	0
	A1474014	Absent	Absent	0	0
	A1474016	Absent	Absent	1	0
	A1474018	Absent	Absent	0	0
	A1474020	Absent	Absent	0	0
	A1474022	Absent	Absent	0	0
	A1474024	Absent	Absent	0	0
	A1474026	Absent	Absent	0	0
	A1474028	Absent	Absent	0	0
	A1474030	Absent	Absent	0	0

DRAFT - FOR DISCUSSION 2016

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 23

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474032	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474034	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474036	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474038	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474040	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474042	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474044	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474046	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474048	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474050	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474052	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474054	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474056	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474058	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474060	1	1	1	12	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 23

Males

Group	Animal No	BB	UN	UR	DE
2	A1474032	Absent	Absent	0	0
	A1474034	Absent	Absent	0	0
	A1474036	Absent	Absent	0	0
	A1474038	Absent	Absent	0	0
	A1474040	Absent	Absent	0	0
	A1474042	Absent	Absent	1	0
	A1474044	Absent	Absent	0	0
	A1474046	Absent	Absent	0	0
	A1474048	Absent	Absent	0	0
	A1474050	Absent	Absent	0	0
	A1474052	Absent	Absent	1	0
	A1474054	Absent	Absent	0	0
	A1474056	Absent	Absent	0	0
	A1474058	Absent	Absent	0	0
	A1474060	Absent	Absent	0	0

19 - URAF - Final December 2016

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 23

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474062	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474064	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474066	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474068	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474070	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474072	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474074	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474076	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474078	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474080	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474082	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474084	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474086	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474088	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474090	1	1	1	9	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 23

Males

Group	Animal No	BB	UN	UR	DE
3	A1474062	Absent	Absent	0	0
	A1474064	Absent	Absent	0	0
	A1474066	Absent	Absent	0	0
	A1474068	Absent	Absent	1	0
	A1474070	Absent	Absent	0	0
	A1474072	Absent	Absent	0	0
	A1474074	Absent	Absent	0	0
	A1474076	Absent	Absent	0	0
	A1474078	Absent	Absent	0	0
	A1474080	Absent	Absent	0	0
	A1474082	Absent	Absent	0	0
	A1474084	Absent	Absent	0	0
	A1474086	Absent	Absent	0	0
	A1474088	Absent	Absent	0	0
	A1474090	Absent	Absent	1	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 23

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474092	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474094	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474096	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474098	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474100	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474102	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474104	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474106	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474108	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474110	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474112	1	1	1	9	1	Absent	Absent	Absent	Absent
	A1474114	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474116	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474118	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474120	1	1	1	14	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 3 WEEK RECOVERY PERIOD

Dosing Day 23

Males

Group	Animal No	BB	UN	UR	DE
4	A1474092	Absent	Absent	0	0
	A1474094	Absent	Absent	1	0
	A1474096	Absent	Absent	0	0
	A1474098	Absent	Absent	0	0
	A1474100	Absent	Absent	0	0
	A1474102	Absent	Absent	0	0
	A1474104	Absent	Absent	0	0
	A1474106	Absent	Absent	0	0
	A1474108	Absent	Absent	0	0
	A1474110	Absent	Absent	0	0
	A1474112	Absent	Absent	0	0
	A1474114	Absent	Absent	0	0
	A1474116	Absent	Absent	0	0
	A1474118	Absent	Absent	0	0
	A1474120	Absent	Absent	0	0

Study Director - Data Management

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 30

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474002	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474004	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474006	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474008	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474010	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474012	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474014	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474016	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474018	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474020	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474022	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474024	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474026	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474028	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474030	1	1	1	13	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 30

Males

Group	Animal No	BB	UN	UR	DE
Control	A1474002	Absent	Absent	0	0
	A1474004	Absent	Absent	1	0
	A1474006	Absent	Absent	0	0
	A1474008	Absent	Absent	0	0
	A1474010	Absent	Absent	0	0
	A1474012	Absent	Absent	0	0
	A1474014	Absent	Absent	0	0
	A1474016	Absent	Absent	0	0
	A1474018	Absent	Absent	0	0
	A1474020	Absent	Absent	0	0
	A1474022	Absent	Absent	0	0
	A1474024	Absent	Absent	0	0
	A1474026	Absent	Absent	1	0
	A1474028	Absent	Absent	0	0
	A1474030	Absent	Absent	0	0

DRAFT - Jan December 2019

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 30

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474032	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474034	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474036	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474038	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474040	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474042	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474044	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474046	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474048	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474050	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474052	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474054	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474056	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474058	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474060	1	1	1	13	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 30

Males

Group	Animal No	BB	UN	UR	DE
2	A1474032	Absent	Absent	0	0
	A1474034	Absent	Absent	0	0
	A1474036	Absent	Absent	1	0
	A1474038	Absent	Absent	0	0
	A1474040	Absent	Absent	0	0
	A1474042	Absent	Absent	0	0
	A1474044	Absent	Absent	1	0
	A1474046	Absent	Absent	0	0
	A1474048	Absent	Absent	0	0
	A1474050	Absent	Absent	0	0
	A1474052	Absent	Absent	0	0
	A1474054	Absent	Absent	0	0
	A1474056	Absent	Absent	0	0
	A1474058	Absent	Absent	0	0
	A1474060	Absent	Absent	0	0

GLP - QUALITY ASSURANCE 2016

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 30

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474062	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474064	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474066	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474068	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474070	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474072	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474074	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474076	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474078	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474080	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474082	1	1	1	9	1	Absent	Absent	Absent	Absent
	A1474084	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474086	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474088	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474090	1	1	1	10	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 3 WEEK RECOVERY PERIOD

Dosing Day 30

Males

Group	Animal No	BB	UN	UR	DE
3	A1474062	Absent	Absent	0	0
	A1474064	Absent	Absent	0	0
	A1474066	Absent	Absent	0	0
	A1474068	Absent	Absent	0	0
	A1474070	Absent	Absent	0	0
	A1474072	Absent	Absent	0	0
	A1474074	Absent	Absent	0	0
	A1474076	Absent	Absent	0	0
	A1474078	Absent	Absent	0	0
	A1474080	Absent	Absent	0	0
	A1474082	Absent	Absent	0	0
	A1474084	Absent	Absent	0	0
	A1474086	Absent	Absent	0	0
	A1474088	Absent	Absent	0	0
	A1474090	Absent	Absent	0	0

GLP DRAFT - NOT Document 2016

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 30

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474092	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474094	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474096	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474098	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474100	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474102	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474104	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474106	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474108	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474110	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474112	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474114	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474116	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474118	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474120	1	1	1	12	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 30

Males

Group	Animal No	BB	UN	UR	DE
4	A1474092	Absent	Absent	0	0
	A1474094	Absent	Absent	0	0
	A1474096	Absent	Absent	0	0
	A1474098	Absent	Absent	0	0
	A1474100	Absent	Absent	0	0
	A1474102	Absent	Absent	0	0
	A1474104	Absent	Absent	0	0
	A1474106	Absent	Absent	0	0
	A1474108	Absent	Absent	1	0
	A1474110	Absent	Absent	0	0
	A1474112	Absent	Absent	2	0
	A1474114	Absent	Absent	0	0
	A1474116	Absent	Absent	0	0
	A1474118	Absent	Absent	0	0
	A1474120	Absent	Absent	1	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 37

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474002	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474004	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474006	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474008	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474010	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474012	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474014	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474016	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474018	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474020	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474022	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474024	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474026	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474028	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474030	1	1	1	15	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 37

Males

Group	Animal No	BB	UN	UR	DE
Control	A1474002	Absent	Absent	0	0
	A1474004	Absent	Absent	1	0
	A1474006	Absent	Absent	0	0
	A1474008	Absent	Absent	0	0
	A1474010	Absent	Absent	0	0
	A1474012	Absent	Absent	0	0
	A1474014	Absent	Absent	0	0
	A1474016	Absent	Absent	2	0
	A1474018	Absent	Absent	0	0
	A1474020	Absent	Absent	1	0
	A1474022	Absent	Absent	1	0
	A1474024	Absent	Absent	0	0
	A1474026	Absent	Absent	3	0
	A1474028	Absent	Absent	0	0
	A1474030	Absent	Absent	1	0

Study - A1474 - 13 Week Oral Toxicity Rat

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 37
Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474032	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474034	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474036	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474038	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474040	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474042	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474044	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474046	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474048	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474050	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474052	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474054	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474056	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474058	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474060	1	1	1	15	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 37

Males

Group	Animal No	BB	UN	UR	DE
2	A1474032	Absent	Absent	0	0
	A1474034	Absent	Absent	0	0
	A1474036	Absent	Absent	0	0
	A1474038	Absent	Absent	1	0
	A1474040	Absent	Absent	1	0
	A1474042	Absent	Absent	0	0
	A1474044	Absent	Absent	0	0
	A1474046	Absent	Absent	0	0
	A1474048	Absent	Absent	0	0
	A1474050	Absent	Absent	0	0
	A1474052	Absent	Absent	0	0
	A1474054	Absent	Absent	0	0
	A1474056	Absent	Absent	0	0
	A1474058	Absent	Absent	0	0
	A1474060	Absent	Absent	0	0

SPONSOR - NON CONFIDENTIAL

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 37

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474062	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474064	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474066	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474068	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474070	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474072	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474074	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474076	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474078	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474080	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474082	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474084	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474086	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474088	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474090	1	1	1	12	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 37

Males

Group	Animal No	BB	UN	UR	DE
3	A1474062	Absent	Absent	0	0
	A1474064	Absent	Absent	0	0
	A1474066	Absent	Absent	1	0
	A1474068	Absent	Absent	0	0
	A1474070	Absent	Absent	0	0
	A1474072	Absent	Absent	0	0
	A1474074	Absent	Absent	0	0
	A1474076	Absent	Absent	2	0
	A1474078	Absent	Absent	0	0
	A1474080	Absent	Absent	1	0
	A1474082	Absent	Absent	0	0
	A1474084	Absent	Absent	0	0
	A1474086	Absent	Absent	0	0
	A1474088	Absent	Absent	0	0
	A1474090	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 37

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474092	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474094	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474096	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474098	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474100	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474102	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474104	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474106	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474108	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474110	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474112	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474114	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474116	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474118	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474120	1	1	1	14	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 37

Males

Group	Animal No	BB	UN	UR	DE
4	A1474092	Absent	Absent	0	0
	A1474094	Absent	Absent	0	0
	A1474096	Absent	Absent	0	0
	A1474098	Absent	Absent	1	0
	A1474100	Absent	Absent	0	0
	A1474102	Absent	Absent	0	0
	A1474104	Absent	Absent	0	0
	A1474106	Absent	Absent	0	0
	A1474108	Absent	Absent	0	0
	A1474110	Absent	Absent	0	0
	A1474112	Absent	Absent	0	0
	A1474114	Absent	Absent	0	0
	A1474116	Absent	Absent	0	0
	A1474118	Absent	Absent	0	0
	A1474120	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 44

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474002	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474004	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474006	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474008	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474010	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474012	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474014	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474016	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474018	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474020	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474022	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474024	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474026	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474028	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474030	1	1	1	14	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 44

Males

Group	Animal No	BB	UN	UR	DE
Control	A1474002	Absent	Absent	0	0
	A1474004	Absent	Absent	0	0
	A1474006	Absent	Absent	0	0
	A1474008	Absent	Absent	1	0
	A1474010	Absent	Absent	0	0
	A1474012	Absent	Absent	0	0
	A1474014	Absent	Absent	1	0
	A1474016	Absent	Absent	0	0
	A1474018	Absent	Absent	0	0
	A1474020	Absent	Absent	1	0
	A1474022	Absent	Absent	2	0
	A1474024	Absent	Absent	0	0
	A1474026	Absent	Absent	0	0
	A1474028	Absent	Absent	0	0
	A1474030	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 44

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474032	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474034	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474036	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474038	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474040	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474042	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474044	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474046	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474048	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474050	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474052	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474054	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474056	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474058	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474060	1	1	1	17	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 44

Males

Group	Animal No	BB	UN	UR	DE
2	A1474032	Absent	Absent	0	0
	A1474034	Absent	Absent	0	0
	A1474036	Absent	Absent	1	0
	A1474038	Absent	Absent	0	0
	A1474040	Absent	Absent	2	0
	A1474042	Absent	Absent	0	0
	A1474044	Absent	Absent	0	0
	A1474046	Absent	Absent	0	0
	A1474048	Absent	Absent	0	0
	A1474050	Absent	Absent	0	0
	A1474052	Absent	Absent	0	0
	A1474054	Absent	Absent	0	0
	A1474056	Absent	Absent	0	0
	A1474058	Absent	Absent	0	0
	A1474060	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 44

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474062	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474064	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474066	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474068	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474070	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474072	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474074	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474076	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474078	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474080	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474082	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474084	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474086	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474088	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474090	1	1	1	14	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 44

Males

Group	Animal No	BB	UN	UR	DE
3	A1474062	Absent	Absent	0	0
	A1474064	Absent	Absent	0	0
	A1474066	Absent	Absent	0	0
	A1474068	Absent	Absent	0	0
	A1474070	Absent	Absent	0	0
	A1474072	Absent	Absent	0	0
	A1474074	Absent	Absent	0	0
	A1474076	Absent	Absent	0	0
	A1474078	Absent	Absent	0	0
	A1474080	Absent	Absent	0	0
	A1474082	Absent	Absent	0	0
	A1474084	Absent	Absent	0	0
	A1474086	Absent	Absent	0	0
	A1474088	Absent	Absent	0	0
	A1474090	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 44

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474092	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474094	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474096	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474098	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474100	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474102	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474104	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474106	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474108	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474110	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474112	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474114	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474116	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474118	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474120	1	1	1	11	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 44

Males

Group	Animal No	BB	UN	UR	DE
4	A1474092	Absent	Absent	0	0
	A1474094	Absent	Absent	0	0
	A1474096	Absent	Absent	0	0
	A1474098	Absent	Absent	0	0
	A1474100	Absent	Absent	0	0
	A1474102	Absent	Absent	3	0
	A1474104	Absent	Absent	0	0
	A1474106	Absent	Absent	2	1
	A1474108	Absent	Absent	0	0
	A1474110	Absent	Absent	0	0
	A1474112	Absent	Absent	0	0
	A1474114	Absent	Absent	0	0
	A1474116	Absent	Absent	0	0
	A1474118	Absent	Absent	0	0
	A1474120	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 51

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474002	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474004	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474006	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474008	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474010	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474012	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474014	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474016	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474018	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474020	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474022	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474024	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474026	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474028	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474030	1	1	1	13	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 51

Males

Group	Animal No	BB	UN	UR	DE
Control	A1474002	Absent	Absent	0	0
	A1474004	Absent	Absent	0	0
	A1474006	Absent	Absent	2	0
	A1474008	Absent	Absent	0	0
	A1474010	Absent	Absent	1	0
	A1474012	Absent	Absent	0	0
	A1474014	Absent	Absent	1	0
	A1474016	Absent	Absent	0	0
	A1474018	Absent	Absent	0	0
	A1474020	Absent	Absent	0	0
	A1474022	Absent	Absent	0	0
	A1474024	Absent	Absent	0	0
	A1474026	Absent	Absent	1	0
	A1474028	Absent	Absent	0	0
	A1474030	Absent	Absent	1	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 51

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474032	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474034	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474036	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474038	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474040	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474042	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474044	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474046	1	1	1	8	1	Absent	Absent	Absent	Absent
	A1474048	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474050	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474052	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474054	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474056	1	1	1	22	1	Absent	Absent	Absent	Absent
	A1474058	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474060	1	1	1	17	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 51

Males

Group	Animal No	BB	UN	UR	DE
2	A1474032	Absent	Absent	0	0
	A1474034	Absent	Absent	2	0
	A1474036	Absent	Absent	0	0
	A1474038	Absent	Absent	0	0
	A1474040	Absent	Absent	0	0
	A1474042	Absent	Absent	0	0
	A1474044	Absent	Absent	1	0
	A1474046	Absent	Absent	2	0
	A1474048	Absent	Absent	0	0
	A1474050	Absent	Absent	0	0
	A1474052	Absent	Absent	6	2
	A1474054	Absent	Absent	0	0
	A1474056	Absent	Absent	2	0
	A1474058	Absent	Absent	0	0
	A1474060	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 51

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474062	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474064	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474066	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474068	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474070	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474072	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474074	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474076	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474078	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474080	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474082	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474084	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474086	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474088	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474090	1	1	1	21	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 51

Males

Group	Animal No	BB	UN	UR	DE
3	A1474062	Absent	Absent	0	0
	A1474064	Absent	Absent	0	0
	A1474066	Absent	Absent	2	0
	A1474068	Absent	Absent	0	0
	A1474070	Absent	Absent	0	0
	A1474072	Absent	Absent	0	0
	A1474074	Absent	Absent	1	0
	A1474076	Absent	Absent	0	0
	A1474078	Absent	Absent	0	0
	A1474080	Absent	Absent	0	0
	A1474082	Absent	Absent	2	0
	A1474084	Absent	Absent	0	0
	A1474086	Absent	Absent	0	0
	A1474088	Absent	Absent	0	0
	A1474090	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 51

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474092	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474094	1	1	1	9	1	Absent	Absent	Absent	Absent
	A1474096	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474098	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474100	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474102	1	1	1	9	1	Absent	Absent	Absent	Absent
	A1474104	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474106	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474108	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474110	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474112	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474114	1	1	1	8	1	Absent	Absent	Absent	Absent
	A1474116	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474118	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474120	1	1	1	11	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 51

Males

Group	Animal No	BB	UN	UR	DE
4	A1474092	Absent	Absent	0	0
	A1474094	Absent	Absent	0	0
	A1474096	Absent	Absent	0	0
	A1474098	Absent	Absent	0	0
	A1474100	Absent	Absent	0	0
	A1474102	Absent	Absent	0	0
	A1474104	Absent	Absent	0	0
	A1474106	Absent	Absent	0	0
	A1474108	Absent	Absent	0	0
	A1474110	Absent	Absent	0	0
	A1474112	Absent	Absent	3	0
	A1474114	Absent	Absent	0	0
	A1474116	Absent	Absent	0	0
	A1474118	Absent	Absent	0	4
	A1474120	Absent	Absent	3	0

Not Original - Not Guaranteed - GLP

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 58

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474002	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474004	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474006	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474008	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474010	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474012	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474014	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474016	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474018	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474020	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474022	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474024	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474026	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474028	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474030	1	1	1	16	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 58

Males

Group	Animal No	BB	UN	UR	DE
Control	A1474002	Absent	Absent	0	0
	A1474004	Absent	Absent	1	0
	A1474006	Absent	Absent	0	0
	A1474008	Absent	Absent	0	0
	A1474010	Absent	Absent	2	0
	A1474012	Absent	Absent	0	0
	A1474014	Absent	Absent	1	0
	A1474016	Absent	Absent	0	0
	A1474018	Absent	Absent	0	0
	A1474020	Absent	Absent	1	0
	A1474022	Absent	Absent	0	0
	A1474024	Absent	Absent	1	0
	A1474026	Absent	Absent	0	0
	A1474028	Absent	Absent	0	0
	A1474030	Absent	Absent	1	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 58

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474032	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474034	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474036	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474038	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474040	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474042	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474044	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474046	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474048	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474050	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474052	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474054	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474056	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474058	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474060	1	1	1	17	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 58

Males

Group	Animal No	BB	UN	UR	DE
2	A1474032	Absent	Absent	0	0
	A1474034	Absent	Absent	0	0
	A1474036	Absent	Absent	0	0
	A1474038	Absent	Absent	0	0
	A1474040	Absent	Absent	1	0
	A1474042	Absent	Absent	0	0
	A1474044	Absent	Absent	1	0
	A1474046	Absent	Absent	0	0
	A1474048	Absent	Absent	0	0
	A1474050	Absent	Absent	0	0
	A1474052	Absent	Absent	0	0
	A1474054	Absent	Absent	0	0
	A1474056	Absent	Absent	0	0
	A1474058	Absent	Absent	0	0
	A1474060	Absent	Absent	0	0

Study - Unaudited - Data Quality Verification - 2010

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 58

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474062	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474064	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474066	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474068	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474070	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474072	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474074	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474076	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474078	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474080	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474082	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474084	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474086	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474088	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474090	1	1	1	19	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 58

Males

Group	Animal No	BB	UN	UR	DE
3	A1474062	Absent	Absent	0	0
	A1474064	Absent	Absent	0	0
	A1474066	Absent	Absent	0	0
	A1474068	Absent	Absent	1	0
	A1474070	Absent	Absent	0	0
	A1474072	Absent	Absent	1	0
	A1474074	Absent	Absent	0	0
	A1474076	Absent	Absent	0	0
	A1474078	Absent	Absent	0	0
	A1474080	Absent	Absent	0	0
	A1474082	Absent	Absent	0	0
	A1474084	Absent	Absent	0	0
	A1474086	Absent	Absent	0	0
	A1474088	Absent	Absent	0	0
	A1474090	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 58

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474092	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474094	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474096	1	1	1	9	1	Absent	Absent	Absent	Absent
	A1474098	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474100	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474102	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474104	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474106	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474108	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474110	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474112	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474114	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474116	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474118	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474120	1	1	1	16	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 58

Males

Group	Animal No	BB	UN	UR	DE
4	A1474092	Absent	Absent	0	0
	A1474094	Absent	Absent	0	0
	A1474096	Absent	Absent	0	0
	A1474098	Absent	Absent	0	0
	A1474100	Absent	Absent	0	0
	A1474102	Absent	Absent	0	0
	A1474104	Absent	Absent	0	0
	A1474106	Absent	Absent	0	0
	A1474108	Absent	Absent	0	0
	A1474110	Absent	Absent	0	0
	A1474112	Absent	Absent	0	0
	A1474114	Absent	Absent	0	0
	A1474116	Absent	Absent	0	0
	A1474118	Absent	Absent	0	0
	A1474120	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 66
Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474002	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474004	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474006	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474008	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474010	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474012	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474014	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474016	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474018	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474020	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474022	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474024	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474026	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474028	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474030	1	1	1	14	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 66

Males

Group	Animal No	BB	UN	UR	DE
Control	A1474002	Absent	Absent	0	0
	A1474004	Absent	Absent	0	0
	A1474006	Absent	Absent	0	0
	A1474008	Absent	Absent	0	0
	A1474010	Absent	Absent	0	0
	A1474012	Absent	Absent	1	0
	A1474014	Absent	Absent	0	0
	A1474016	Absent	Absent	0	0
	A1474018	Absent	Absent	0	0
	A1474020	Absent	Absent	1	0
	A1474022	Absent	Absent	0	0
	A1474024	Absent	Absent	2	0
	A1474026	Absent	Absent	0	0
	A1474028	Absent	Absent	0	0
	A1474030	Absent	Absent	0	0

Signature - Date: 1 May Quarantine 2016

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 66

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474032	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474034	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474036	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474038	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474040	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474042	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474044	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474046	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474048	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474050	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474052	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474054	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474056	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474058	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474060	1	1	1	15	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 66

Males

Group	Animal No	BB	UN	UR	DE
2	A1474032	Absent	Absent	0	0
	A1474034	Absent	Absent	0	0
	A1474036	Absent	Absent	0	0
	A1474038	Absent	Absent	0	0
	A1474040	Absent	Absent	0	0
	A1474042	Absent	Absent	0	0
	A1474044	Absent	Absent	0	0
	A1474046	Absent	Absent	0	0
	A1474048	Absent	Absent	0	0
	A1474050	Absent	Absent	0	0
	A1474052	Absent	Absent	0	0
	A1474054	Absent	Absent	0	0
	A1474056	Absent	Absent	0	0
	A1474058	Absent	Absent	0	0
	A1474060	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 66

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474062	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474064	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474066	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474068	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474070	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474072	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474074	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474076	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474078	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474080	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474082	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474084	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474086	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474088	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474090	1	1	1	16	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 66

Males

Group	Animal No	BB	UN	UR	DE
3	A1474062	Absent	Absent	0	0
	A1474064	Absent	Absent	0	0
	A1474066	Absent	Absent	0	0
	A1474068	Absent	Absent	0	0
	A1474070	Absent	Absent	0	0
	A1474072	Absent	Absent	0	0
	A1474074	Absent	Absent	0	0
	A1474076	Absent	Absent	0	0
	A1474078	Absent	Absent	0	0
	A1474080	Absent	Absent	0	0
	A1474082	Absent	Absent	0	0
	A1474084	Absent	Absent	0	0
	A1474086	Absent	Absent	0	0
	A1474088	Absent	Absent	0	0
	A1474090	Absent	Absent	0	0

GLP - ORIGINAL - NOT FOR DISTRIBUTION

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 66

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474092	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474094	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474096	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474098	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474100	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474102	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474104	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474106	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474108	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474110	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474112	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474114	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474116	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474118	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474120	1	1	1	14	1	Absent	Absent	Absent	Absent

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REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 66

Males

Group	Animal No	BB	UN	UR	DE
4	A1474092	Absent	Absent	0	0
	A1474094	Absent	Absent	0	0
	A1474096	Absent	Absent	0	0
	A1474098	Absent	Absent	0	0
	A1474100	Absent	Absent	0	0
	A1474102	Absent	Absent	0	0
	A1474104	Absent	Absent	0	0
	A1474106	Absent	Absent	0	0
	A1474108	Absent	Absent	0	0
	A1474110	Absent	Absent	0	0
	A1474112	Absent	Absent	0	0
	A1474114	Absent	Absent	0	0
	A1474116	Absent	Absent	0	0
	A1474118	Absent	Absent	0	0
	A1474120	Absent	Absent	0	0

UNAFF - NOT DAKOTA'S

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 72

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474002	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474004	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474006	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474008	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474010	1	1	1	22	1	Absent	Absent	Absent	Absent
	A1474012	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474014	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474016	1	1	1	4	1	Absent	Absent	Absent	Absent
	A1474018	1	1	1	7	1	Absent	Absent	Absent	Absent
	A1474020	1	1	1	8	1	Absent	Absent	Absent	Absent
	A1474022	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474024	1	1	1	7	1	Absent	Absent	Absent	Absent
	A1474026	1	1	1	6	1	Absent	Absent	Absent	Absent
	A1474028	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474030	1	1	1	4	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 72

Males

Group	Animal No	BB	UN	UR	DE
Control	A1474002	Absent	Absent	1	0
	A1474004	Absent	Absent	0	0
	A1474006	Absent	Absent	2	0
	A1474008	Absent	Absent	10	0
	A1474010	Absent	Absent	0	0
	A1474012	Absent	Absent	0	0
	A1474014	Absent	Absent	0	0
	A1474016	Absent	Absent	0	0
	A1474018	Absent	Absent	0	0
	A1474020	Absent	Absent	0	0
	A1474022	Absent	Absent	0	0
	A1474024	Absent	Absent	0	0
	A1474026	Absent	Absent	0	0
	A1474028	Absent	Absent	0	0
	A1474030	Absent	Absent	0	0

DRAFT - NOT FOR DISTRIBUTION

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 72

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474032	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474034	1	1	1	22	1	Absent	Absent	Absent	Absent
	A1474036	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474038	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474040	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474042	1	1	1	3	1	Absent	Absent	Absent	Absent
	A1474044	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474046	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474048	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474050	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474052	1	1	1	8	1	Absent	Absent	Absent	Absent
	A1474054	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474056	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474058	1	1	1	25	1	Absent	Absent	Absent	Absent
	A1474060	1	1	1	8	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 72

Males

Group	Animal No	BB	UN	UR	DE
2	A1474032	Absent	Absent	0	0
	A1474034	Absent	Absent	0	0
	A1474036	Absent	Absent	0	0
	A1474038	Absent	Absent	5	0
	A1474040	Absent	Absent	0	0
	A1474042	Absent	Absent	0	0
	A1474044	Absent	Absent	0	0
	A1474046	Absent	Absent	0	0
	A1474048	Absent	Absent	0	0
	A1474050	Absent	Absent	0	0
	A1474052	Absent	Absent	1	0
	A1474054	Absent	Absent	0	0
	A1474056	Absent	Absent	0	0
	A1474058	Absent	Absent	0	0
	A1474060	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 72

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474062	1	1	1	8	1	Absent	Absent	Absent	Absent
	A1474064	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474066	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474068	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474070	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474072	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474074	1	1	1	7	1	Absent	Absent	Absent	Absent
	A1474076	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474078	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474080	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474082	1	1	1	6	1	Absent	Absent	Absent	Absent
	A1474084	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474086	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474088	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474090	1	1	1	9	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 72

Males

Group	Animal No	BB	UN	UR	DE
3	A1474062	Absent	Absent	0	0
	A1474064	Absent	Absent	0	0
	A1474066	Absent	Absent	0	0
	A1474068	Absent	Absent	0	0
	A1474070	Absent	Absent	0	0
	A1474072	Absent	Absent	0	0
	A1474074	Absent	Absent	0	0
	A1474076	Absent	Absent	0	0
	A1474078	Absent	Absent	0	0
	A1474080	Absent	Absent	8	0
	A1474082	Absent	Absent	0	0
	A1474084	Absent	Absent	0	0
	A1474086	Absent	Absent	0	0
	A1474088	Absent	Absent	0	0
	A1474090	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 72

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474092	1	1	1	8	1	Absent	Absent	Absent	Absent
	A1474094	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474096	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474098	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474100	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474102	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474104	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474106	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474108	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474110	1	1	1	9	1	Absent	Absent	Absent	Absent
	A1474112	1	1	1	7	1	Absent	Absent	Absent	Absent
	A1474114	1	1	1	9	1	Absent	Absent	Absent	Absent
	A1474116	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474118	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474120	1	1	1	12	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 72

Males

Group	Animal No	BB	UN	UR	DE
4	A1474092	Absent	Absent	0	0
	A1474094	Absent	Absent	0	0
	A1474096	Absent	Absent	0	0
	A1474098	Absent	Absent	0	0
	A1474100	Absent	Absent	0	0
	A1474102	Absent	Absent	0	0
	A1474104	Absent	Absent	0	0
	A1474106	Absent	Absent	0	0
	A1474108	Absent	Absent	0	0
	A1474110	Absent	Absent	0	0
	A1474112	Absent	Absent	0	0
	A1474114	Absent	Absent	0	0
	A1474116	Absent	Absent	0	0
	A1474118	Absent	Absent	0	0
	A1474120	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 79

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474002	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474004	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474006	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474008	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474010	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474012	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474014	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474016	1	1	1	9	1	Absent	Absent	Absent	Absent
	A1474018	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474020	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474022	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474024	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474026	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474028	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474030	1	1	1	8	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 79

Males

Group	Animal No	BB	UN	UR	DE
Control	A1474002	Absent	Absent	0	0
	A1474004	Absent	Absent	0	0
	A1474006	Absent	Absent	0	0
	A1474008	Absent	Absent	0	0
	A1474010	Absent	Absent	0	0
	A1474012	Absent	Absent	0	0
	A1474014	Absent	Absent	0	0
	A1474016	Absent	Absent	0	0
	A1474018	Absent	Absent	0	0
	A1474020	Absent	Absent	0	0
	A1474022	Absent	Absent	0	0
	A1474024	Absent	Absent	0	0
	A1474026	Absent	Absent	1	0
	A1474028	Absent	Absent	0	0
	A1474030	Absent	Absent	0	0

Draft Report - Not Quality Control

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 79

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474032	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474034	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474036	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474038	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474040	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474042	1	1	1	8	1	Absent	Absent	Absent	Absent
	A1474044	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474046	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474048	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474050	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474052	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474054	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474056	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474058	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474060	1	1	1	10	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 79

Males

Group	Animal No	BB	UN	UR	DE
2	A1474032	Absent	Absent	0	0
	A1474034	Absent	Absent	0	0
	A1474036	Absent	Absent	0	0
	A1474038	Absent	Absent	0	0
	A1474040	Absent	Absent	0	0
	A1474042	Absent	Absent	0	0
	A1474044	Absent	Absent	0	0
	A1474046	Absent	Absent	0	0
	A1474048	Absent	Absent	0	0
	A1474050	Absent	Absent	0	0
	A1474052	Absent	Absent	0	0
	A1474054	Absent	Absent	0	0
	A1474056	Absent	Absent	0	0
	A1474058	Absent	Absent	0	0
	A1474060	Absent	Absent	0	0

DRAFT - FOR DISCUSSION ONLY

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 79

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474062	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474064	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474066	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474068	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474070	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474072	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474074	1	1	1	9	1	Absent	Absent	Absent	Absent
	A1474076	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474078	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474080	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474082	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474084	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474086	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474088	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474090	1	1	1	12	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 79

Males

Group	Animal No	BB	UN	UR	DE
3	A1474062	Absent	Absent	0	0
	A1474064	Absent	Absent	0	0
	A1474066	Absent	Absent	0	0
	A1474068	Absent	Absent	0	0
	A1474070	Absent	Absent	0	0
	A1474072	Absent	Absent	0	0
	A1474074	Absent	Absent	0	0
	A1474076	Absent	Absent	0	0
	A1474078	Absent	Absent	0	0
	A1474080	Absent	Absent	0	0
	A1474082	Absent	Absent	0	0
	A1474084	Absent	Absent	0	0
	A1474086	Absent	Absent	0	0
	A1474088	Absent	Absent	0	0
	A1474090	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 79

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474092	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474094	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474096	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474098	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474100	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474102	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474104	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474106	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474108	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474110	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474112	1	1	1	9	1	Absent	Absent	Absent	Absent
	A1474114	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474116	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474118	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474120	1	1	1	13	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 79

Males

Group	Animal No	BB	UN	UR	DE
4	A1474092	Absent	Absent	0	0
	A1474094	Absent	Absent	0	0
	A1474096	Absent	Absent	0	0
	A1474098	Absent	Absent	0	0
	A1474100	Absent	Absent	0	0
	A1474102	Absent	Absent	0	0
	A1474104	Absent	Absent	0	0
	A1474106	Absent	Absent	0	0
	A1474108	Absent	Absent	0	0
	A1474110	Absent	Absent	0	0
	A1474112	Absent	Absent	0	0
	A1474114	Absent	Absent	0	0
	A1474116	Absent	Absent	0	0
	A1474118	Absent	Absent	0	0
	A1474120	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 86

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474002	1	1	1	7	1	Absent	Absent	Absent	Absent
	A1474004	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474006	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474008	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474010	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474012	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474014	1	1	1	6	1	Absent	Absent	Absent	Absent
	A1474016	1	1	1	9	1	Absent	Absent	Absent	Absent
	A1474018	1	1	1	7	1	Absent	Absent	Absent	Absent
	A1474020	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474022	1	1	1	8	1	Absent	Absent	Absent	Absent
	A1474024	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474026	1	1	1	7	1	Absent	Absent	Absent	Absent
	A1474028	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474030	1	1	1	12	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 86

Males

Group	Animal No	BB	UN	UR	DE
Control	A1474002	Absent	Absent	0	0
	A1474004	Absent	Absent	0	0
	A1474006	Absent	Absent	0	0
	A1474008	Absent	Absent	1	0
	A1474010	Absent	Absent	0	0
	A1474012	Absent	Absent	0	0
	A1474014	Absent	Absent	0	0
	A1474016	Absent	Absent	0	0
	A1474018	Absent	Absent	0	0
	A1474020	Absent	Absent	0	0
	A1474022	Absent	Absent	0	0
	A1474024	Absent	Absent	0	0
	A1474026	Absent	Absent	0	0
	A1474028	Absent	Absent	0	0
	A1474030	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 86

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474032	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474034	1	1	1	8	1	Absent	Absent	Absent	Absent
	A1474036	1	1	1	5	1	Absent	Absent	Absent	Absent
	A1474038	1	1	1	9	1	Absent	Absent	Absent	Absent
	A1474040	1	1	1	7	1	Absent	Absent	Absent	Absent
	A1474042	1	1	1	8	1	Absent	Absent	Absent	Absent
	A1474044	1	1	1	9	1	Absent	Absent	Absent	Absent
	A1474046	1	1	1	5	1	Absent	Absent	Absent	Absent
	A1474048	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474050	1	1	1	7	1	Absent	Absent	Absent	Absent
	A1474052	1	1	1	8	1	Absent	Absent	Absent	Absent
	A1474054	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474056	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474058	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474060	1	1	1	6	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 86

Males

Group	Animal No	BB	UN	UR	DE
2	A1474032	Absent	Absent	0	0
	A1474034	Absent	Absent	0	0
	A1474036	Absent	Absent	0	0
	A1474038	Absent	Absent	1	0
	A1474040	Absent	Absent	0	0
	A1474042	Absent	Absent	0	0
	A1474044	Absent	Absent	0	0
	A1474046	Absent	Absent	0	0
	A1474048	Absent	Absent	0	0
	A1474050	Absent	Absent	0	0
	A1474052	Absent	Absent	1	0
	A1474054	Absent	Absent	0	0
	A1474056	Absent	Absent	0	0
	A1474058	Absent	Absent	0	0
	A1474060	Absent	Absent	0	0

Not Dosed - Not Dissected

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 86

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474062	1	1	1	7	1	Absent	Absent	Absent	Absent
	A1474064	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474066	1	1	1	9	1	Absent	Absent	Absent	Absent
	A1474068	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474070	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474072	1	1	1	9	1	Absent	Absent	Absent	Absent
	A1474074	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474076	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474078	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474080	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474082	1	1	1	7	1	Absent	Absent	Absent	Absent
	A1474084	1	1	1	9	1	Absent	Absent	Absent	Absent
	A1474086	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474088	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474090	1	1	1	10	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 86

Males

Group	Animal No	BB	UN	UR	DE
3	A1474062	Absent	Absent	0	0
	A1474064	Absent	Absent	0	0
	A1474066	Absent	Absent	0	0
	A1474068	Absent	Absent	0	0
	A1474070	Absent	Absent	0	0
	A1474072	Absent	Absent	0	0
	A1474074	Absent	Absent	0	0
	A1474076	Absent	Absent	0	0
	A1474078	Absent	Absent	0	0
	A1474080	Absent	Absent	0	0
	A1474082	Absent	Absent	0	0
	A1474084	Absent	Absent	1	0
	A1474086	Absent	Absent	0	0
	A1474088	Absent	Absent	0	0
	A1474090	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 86

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474092	1	1	1	8	1	Absent	Absent	Absent	Absent
	A1474094	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474096	1	1	1	6	1	Absent	Absent	Absent	Absent
	A1474098	1	1	1	8	1	Absent	Absent	Absent	Absent
	A1474100	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474102	1	1	1	6	1	Absent	Absent	Absent	Absent
	A1474104	1	1	1	5	1	Absent	Absent	Absent	Absent
	A1474106	1	1	1	9	1	Absent	Absent	Absent	Absent
	A1474108	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474110	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474112	1	1	1	5	1	Absent	Absent	Absent	Absent
	A1474114	1	1	1	8	1	Absent	Absent	Absent	Absent
	A1474116	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474118	1	1	1	7	1	Absent	Absent	Absent	Absent
	A1474120	1	1	1	9	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 86

Males

Group	Animal No	BB	UN	UR	DE
4	A1474092	Absent	Absent	0	0
	A1474094	Absent	Absent	0	0
	A1474096	Absent	Absent	0	0
	A1474098	Absent	Absent	0	0
	A1474100	Absent	Absent	0	0
	A1474102	Absent	Absent	0	0
	A1474104	Absent	Absent	0	0
	A1474106	Absent	Absent	0	0
	A1474108	Absent	Absent	0	0
	A1474110	Absent	Absent	0	0
	A1474112	Absent	Absent	0	0
	A1474114	Absent	Absent	0	0
	A1474116	Absent	Absent	0	0
	A1474118	Absent	Absent	0	0
	A1474120	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 3

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474001	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474003	1	1	1	23	1	Absent	Absent	Absent	Absent
	A1474005	1	1	1	28	1	Absent	Absent	Absent	Absent
	A1474007	1	1	1	23	1	Absent	Absent	Absent	Absent
	A1474009	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474011	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474013	1	1	1	24	1	Absent	Absent	Absent	Absent
	A1474015	1	1	1	23	1	Absent	Absent	Absent	Absent
	A1474017	1	1	1	25	1	Absent	Absent	Absent	Absent
	A1474019	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474021	1	1	1	23	1	Absent	Absent	Absent	Absent
	A1474023	1	1	1	25	1	Absent	Absent	Absent	Absent
	A1474025	1	1	1	26	1	Absent	Absent	Absent	Absent
	A1474027	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474029	1	1	1	23	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 3

Females

Group	Animal No	BB	UN	UR	DE
Control	A1474001	Absent	Absent	0	0
	A1474003	Absent	Absent	0	0
	A1474005	Absent	Absent	0	0
	A1474007	Absent	Absent	0	0
	A1474009	Absent	Absent	0	0
	A1474011	Absent	Absent	0	3
	A1474013	Absent	Absent	0	0
	A1474015	Absent	Absent	0	0
	A1474017	Absent	Absent	0	0
	A1474019	Absent	Absent	0	0
	A1474021	Absent	Absent	0	0
	A1474023	Absent	Absent	0	0
	A1474025	Absent	Absent	0	0
	A1474027	Absent	Absent	0	0
	A1474029	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 3

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474031	1	1	1	23	1	Absent	Absent	Absent	Absent
	A1474033	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474035	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474037	1	1	1	24	1	Absent	Absent	Absent	Absent
	A1474039	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474041	1	1	1	23	1	Absent	Absent	Absent	Absent
	A1474043	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474045	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474047	1	1	1	23	1	Absent	Absent	Absent	Absent
	A1474049	1	1	1	24	1	Absent	Absent	Absent	Absent
	A1474051	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474053	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474055	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474057	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474059	1	1	1	31	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 3

Females

Group	Animal No	BB	UN	UR	DE
2	A1474031	Absent	Absent	0	0
	A1474033	Absent	Absent	0	0
	A1474035	Absent	Absent	0	0
	A1474037	Absent	Absent	0	0
	A1474039	Absent	Absent	0	0
	A1474041	Absent	Absent	0	0
	A1474043	Absent	Absent	0	0
	A1474045	Absent	Absent	3	1
	A1474047	Absent	Absent	0	0
	A1474049	Absent	Absent	0	0
	A1474051	Absent	Absent	0	0
	A1474053	Absent	Absent	0	0
	A1474055	Absent	Absent	0	0
	A1474057	Absent	Absent	0	0
	A1474059	Absent	Absent	3	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 3

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474061	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474063	1	1	1	22	1	Absent	Absent	Absent	Absent
	A1474065	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474067	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474069	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474071	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474073	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474075	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474077	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474079	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474081	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474083	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474085	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474087	1	1	1	23	1	Absent	Absent	Absent	Absent
	A1474089	1	1	1	20	1	Absent	Absent	Absent	Absent

FOR DRAFT - NOT FOR DISTRIBUTION

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 3

Females

Group	Animal No	BB	UN	UR	DE
3	A1474061	Absent	Absent	0	0
	A1474063	Absent	Absent	0	0
	A1474065	Absent	Absent	0	0
	A1474067	Absent	Absent	0	0
	A1474069	Absent	Absent	0	0
	A1474071	Absent	Absent	0	0
	A1474073	Absent	Absent	0	0
	A1474075	Absent	Absent	0	0
	A1474077	Absent	Absent	0	0
	A1474079	Absent	Absent	0	0
	A1474081	Absent	Absent	0	0
	A1474083	Absent	Absent	0	0
	A1474085	Absent	Absent	0	0
	A1474087	Absent	Absent	0	0
	A1474089	Absent	Absent	0	0

Re - DRAFT - Not Released 2010

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 3

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474091	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474093	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474095	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474097	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474099	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474101	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474103	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474105	1	1	1	23	1	Absent	Absent	Absent	Absent
	A1474107	1	1	1	24	1	Absent	Absent	Absent	Absent
	A1474109	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474111	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474113	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474115	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474117	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474119	1	1	1	16	1	Absent	Absent	Absent	Absent

GLP - DRAFT - Not Under GLP Control

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 3

Females

Group	Animal No	BB	UN	UR	DE
4	A1474091	Absent	Absent	0	0
	A1474093	Absent	Absent	0	0
	A1474095	Absent	Absent	0	0
	A1474097	Absent	Absent	0	0
	A1474099	Absent	Absent	0	0
	A1474101	Absent	Absent	0	0
	A1474103	Absent	Absent	0	0
	A1474105	Absent	Absent	0	0
	A1474107	Absent	Absent	0	0
	A1474109	Absent	Absent	0	0
	A1474111	Absent	Absent	0	0
	A1474113	Absent	Absent	0	0
	A1474115	Absent	Absent	0	0
	A1474117	Absent	Absent	0	0
	A1474119	Absent	Absent	0	0

EX. DRAFT - Data Unaudited 2015

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 10

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474001	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474003	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474005	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474007	1	1	1	23	1	Absent	Absent	Absent	Absent
	A1474009	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474011	1	1	1	24	1	Absent	Absent	Absent	Absent
	A1474013	1	1	1	22	1	Absent	Absent	Absent	Absent
	A1474015	1	1	1	23	1	Absent	Absent	Absent	Absent
	A1474017	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474019	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474021	1	1	1	23	1	Absent	Absent	Absent	Absent
	A1474023	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474025	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474027	1	1	1	23	1	Absent	Absent	Absent	Absent
	A1474029	1	1	1	20	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 10

Females

Group	Animal No	BB	UN	UR	DE
Control	A1474001	Absent	Absent	0	0
	A1474003	Absent	Absent	0	0
	A1474005	Absent	Absent	0	0
	A1474007	Absent	Absent	0	0
	A1474009	Absent	Absent	0	0
	A1474011	Absent	Absent	0	0
	A1474013	Absent	Absent	0	0
	A1474015	Absent	Absent	0	0
	A1474017	Absent	Absent	0	0
	A1474019	Absent	Absent	0	0
	A1474021	Absent	Absent	0	0
	A1474023	Absent	Absent	0	0
	A1474025	Absent	Absent	0	0
	A1474027	Absent	Absent	0	0
	A1474029	Absent	Absent	0	0

DRAFT - Not for Distribution 2010

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 10

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474031	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474033	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474035	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474037	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474039	1	1	1	23	1	Absent	Absent	Absent	Absent
	A1474041	1	1	1	24	1	Absent	Absent	Absent	Absent
	A1474043	1	1	1	23	1	Absent	Absent	Absent	Absent
	A1474045	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474047	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474049	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474051	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474053	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474055	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474057	1	1	1	23	1	Absent	Absent	Absent	Absent
	A1474059	1	1	1	25	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 10

Females

Group	Animal No	BB	UN	UR	DE
2	A1474031	Absent	Absent	0	0
	A1474033	Absent	Absent	0	0
	A1474035	Absent	Absent	0	0
	A1474037	Absent	Absent	0	0
	A1474039	Absent	Absent	0	0
	A1474041	Absent	Absent	0	0
	A1474043	Absent	Absent	0	0
	A1474045	Absent	Absent	0	0
	A1474047	Absent	Absent	0	0
	A1474049	Absent	Absent	0	0
	A1474051	Absent	Absent	0	0
	A1474053	Absent	Absent	0	0
	A1474055	Absent	Absent	0	0
	A1474057	Absent	Absent	0	0
	A1474059	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 10
Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474061	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474063	1	1	1	23	1	Absent	Absent	Absent	Absent
	A1474065	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474067	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474069	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474071	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474073	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474075	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474077	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474079	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474081	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474083	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474085	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474087	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474089	1	1	1	18	1	Absent	Absent	Absent	Absent

DRAFT - Not for Distribution

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 10

Females

Group	Animal No	BB	UN	UR	DE
3	A1474061	Absent	Absent	0	0
	A1474063	Absent	Absent	2	3
	A1474065	Absent	Absent	0	0
	A1474067	Absent	Absent	0	0
	A1474069	Absent	Absent	1	0
	A1474071	Absent	Absent	0	0
	A1474073	Absent	Absent	0	0
	A1474075	Absent	Absent	0	0
	A1474077	Absent	Absent	0	0
	A1474079	Absent	Absent	0	0
	A1474081	Absent	Absent	0	0
	A1474083	Absent	Absent	0	0
	A1474085	Absent	Absent	0	0
	A1474087	Absent	Absent	0	0
	A1474089	Absent	Absent	0	0

GLP - Data - Not Guaranteed 2016

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 10

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474091	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474093	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474095	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474097	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474099	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474101	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474103	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474105	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474107	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474109	1	1	1	23	1	Absent	Absent	Absent	Absent
	A1474111	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474113	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474115	1	1	1	23	1	Absent	Absent	Absent	Absent
	A1474117	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474119	1	1	1	18	1	Absent	Absent	Absent	Absent

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 10

Females

Group	Animal No	BB	UN	UR	DE
4	A1474091	Absent	Absent	0	0
	A1474093	Absent	Absent	0	0
	A1474095	Absent	Absent	0	0
	A1474097	Absent	Absent	0	0
	A1474099	Absent	Absent	0	0
	A1474101	Absent	Absent	0	0
	A1474103	Absent	Absent	0	0
	A1474105	Absent	Absent	0	0
	A1474107	Absent	Absent	0	0
	A1474109	Absent	Absent	0	0
	A1474111	Absent	Absent	0	0
	A1474113	Absent	Absent	10	0
	A1474115	Absent	Absent	0	0
	A1474117	Absent	Absent	0	0
	A1474119	Absent	Absent	0	0

DRAFT - Not for Distribution - 2015

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 17

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474001	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474003	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474005	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474007	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474009	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474011	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474013	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474015	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474017	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474019	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474021	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474023	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474025	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474027	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474029	1	1	1	17	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 17

Females

Group	Animal No	BB	UN	UR	DE
Control	A1474001	Absent	Absent	1	0
	A1474003	Absent	Absent	0	0
	A1474005	Absent	Absent	0	0
	A1474007	Absent	Absent	0	0
	A1474009	Absent	Absent	0	0
	A1474011	Absent	Absent	0	0
	A1474013	Absent	Absent	1	0
	A1474015	Absent	Absent	0	0
	A1474017	Absent	Absent	0	0
	A1474019	Absent	Absent	0	0
	A1474021	Absent	Absent	3	0
	A1474023	Absent	Absent	0	0
	A1474025	Absent	Absent	0	0
	A1474027	Absent	Absent	0	0
	A1474029	Absent	Absent	0	0

DRAFT - Not Approved 2016

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 17

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474031	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474033	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474035	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474037	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474039	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474041	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474043	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474045	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474047	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474049	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474051	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474053	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474055	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474057	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474059	1	1	1	15	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 17

Females

Group	Animal No	BB	UN	UR	DE
2	A1474031	Absent	Absent	0	0
	A1474033	Absent	Absent	0	0
	A1474035	Absent	Absent	1	0
	A1474037	Absent	Absent	0	0
	A1474039	Absent	Absent	2	0
	A1474041	Absent	Absent	0	0
	A1474043	Absent	Absent	0	0
	A1474045	Absent	Absent	2	0
	A1474047	Absent	Absent	0	0
	A1474049	Absent	Absent	0	0
	A1474051	Absent	Absent	0	0
	A1474053	Absent	Absent	0	0
	A1474055	Absent	Absent	0	0
	A1474057	Absent	Absent	0	0
	A1474059	Absent	Absent	0	0

[illegible] - DRAFT - [illegible] December 2016

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 17

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474061	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474063	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474065	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474067	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474069	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474071	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474073	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474075	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474077	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474079	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474081	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474083	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474085	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474087	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474089	1	1	1	16	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 17

Females

Group	Animal No	BB	UN	UR	DE
3	A1474061	Absent	Absent	2	0
	A1474063	Absent	Absent	0	0
	A1474065	Absent	Absent	0	0
	A1474067	Absent	Absent	0	0
	A1474069	Absent	Absent	0	0
	A1474071	Absent	Absent	1	0
	A1474073	Absent	Absent	0	0
	A1474075	Absent	Absent	0	0
	A1474077	Absent	Absent	0	0
	A1474079	Absent	Absent	0	0
	A1474081	Absent	Absent	0	0
	A1474083	Absent	Absent	1	0
	A1474085	Absent	Absent	0	0
	A1474087	Absent	Absent	0	0
	A1474089	Absent	Absent	0	0

Study History Data Document 2011

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 17

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474091	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474093	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474095	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474097	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474099	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474101	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474103	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474105	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474107	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474109	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474111	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474113	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474115	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474117	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474119	1	1	1	16	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 17

Females

Group	Animal No	BB	UN	UR	DE
4	A1474091	Absent	Absent	0	0
	A1474093	Absent	Absent	0	0
	A1474095	Absent	Absent	0	0
	A1474097	Absent	Absent	0	0
	A1474099	Absent	Absent	0	0
	A1474101	Absent	Absent	0	0
	A1474103	Absent	Absent	0	0
	A1474105	Absent	Absent	0	0
	A1474107	Absent	Absent	0	0
	A1474109	Absent	Absent	0	0
	A1474111	Absent	Absent	0	0
	A1474113	Absent	Absent	0	0
	A1474115	Absent	Absent	0	0
	A1474117	Absent	Absent	0	0
	A1474119	Absent	Absent	0	0

Study - A1474 - Day 1 (1) December 2010

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 24

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474001	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474003	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474005	1	1	1	22	1	Absent	Absent	Absent	Absent
	A1474007	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474009	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474011	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474013	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474015	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474017	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474019	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474021	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474023	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474025	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474027	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474029	1	1	1	15	1	Absent	Absent	Absent	Absent

DRAFT - NOT FOR DISTRIBUTION

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 24

Females

Group	Animal No	BB	UN	UR	DE
Control	A1474001	Absent	Absent	0	0
	A1474003	Absent	Absent	2	0
	A1474005	Absent	Absent	0	0
	A1474007	Absent	Absent	1	0
	A1474009	Absent	Absent	0	0
	A1474011	Absent	Absent	0	0
	A1474013	Absent	Absent	0	0
	A1474015	Absent	Absent	0	0
	A1474017	Absent	Absent	0	0
	A1474019	Absent	Absent	0	0
	A1474021	Absent	Absent	0	0
	A1474023	Absent	Absent	0	0
	A1474025	Absent	Absent	1	0
	A1474027	Absent	Absent	0	0
	A1474029	Absent	Absent	0	0

DRAFT - Not Dissemination

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 24

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474031	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474033	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474035	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474037	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474039	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474041	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474043	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474045	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474047	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474049	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474051	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474053	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474055	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474057	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474059	1	1	1	19	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 24

Females

Group	Animal No	BB	UN	UR	DE
2	A1474031	Absent	Absent	0	0
	A1474033	Absent	Absent	0	0
	A1474035	Absent	Absent	0	0
	A1474037	Absent	Absent	0	0
	A1474039	Absent	Absent	0	0
	A1474041	Absent	Absent	0	0
	A1474043	Absent	Absent	0	0
	A1474045	Absent	Absent	0	0
	A1474047	Absent	Absent	0	0
	A1474049	Absent	Absent	0	0
	A1474051	Absent	Absent	0	0
	A1474053	Absent	Absent	0	0
	A1474055	Absent	Absent	0	0
	A1474057	Absent	Absent	0	0
	A1474059	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 24

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474061	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474063	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474065	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474067	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474069	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474071	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474073	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474075	1	1	1	22	1	Absent	Absent	Absent	Absent
	A1474077	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474079	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474081	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474083	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474085	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474087	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474089	1	1	1	15	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 24

Females

Group	Animal No	BB	UN	UR	DE
3	A1474061	Absent	Absent	0	0
	A1474063	Absent	Absent	0	0
	A1474065	Absent	Absent	0	0
	A1474067	Absent	Absent	0	0
	A1474069	Absent	Absent	0	0
	A1474071	Absent	Absent	0	0
	A1474073	Absent	Absent	0	0
	A1474075	Absent	Absent	0	0
	A1474077	Absent	Absent	0	0
	A1474079	Absent	Absent	0	0
	A1474081	Absent	Absent	0	0
	A1474083	Absent	Absent	1	0
	A1474085	Absent	Absent	0	0
	A1474087	Absent	Absent	0	0
	A1474089	Absent	Absent	0	0

IS - DRAFT - Vol.1 December 2015

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 24

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474091	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474093	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474095	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474097	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474099	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474101	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474103	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474105	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474107	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474109	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474111	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474113	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474115	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474117	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474119	1	1	1	14	1	Absent	Absent	Absent	Absent

Not Under Oath 2016

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 24

Females

Group	Animal No	BB	UN	UR	DE
4	A1474091	Absent	Absent	0	0
	A1474093	Absent	Absent	1	0
	A1474095	Absent	Absent	0	0
	A1474097	Absent	Absent	0	0
	A1474099	Absent	Absent	0	0
	A1474101	Absent	Absent	0	0
	A1474103	Absent	Absent	0	0
	A1474105	Absent	Absent	0	0
	A1474107	Absent	Absent	0	0
	A1474109	Absent	Absent	0	0
	A1474111	Absent	Absent	0	0
	A1474113	Absent	Absent	0	0
	A1474115	Absent	Absent	0	0
	A1474117	Absent	Absent	0	0
	A1474119	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 31

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474001	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474003	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474005	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474007	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474009	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474011	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474013	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474015	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474017	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474019	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474021	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474023	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474025	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474027	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474029	1	1	1	18	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 31

Females

Group	Animal No	BB	UN	UR	DE
Control	A1474001	Absent	Absent	0	0
	A1474003	Absent	Absent	0	0
	A1474005	Absent	Absent	0	0
	A1474007	Absent	Absent	0	0
	A1474009	Absent	Absent	0	0
	A1474011	Absent	Absent	0	0
	A1474013	Absent	Absent	1	0
	A1474015	Absent	Absent	0	0
	A1474017	Absent	Absent	1	0
	A1474019	Absent	Absent	0	0
	A1474021	Absent	Absent	0	0
	A1474023	Absent	Absent	0	0
	A1474025	Absent	Absent	0	0
	A1474027	Absent	Absent	0	0
	A1474029	Absent	Absent	0	0

Sponsor's Draft - Not Disclosable 2016

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 31

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474031	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474033	1	1	1	16	0	Absent	Absent	Absent	Absent
	A1474035	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474037	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474039	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474041	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474043	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474045	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474047	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474049	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474051	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474053	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474055	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474057	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474059	1	1	1	20	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 31

Females

Group	Animal No	BB	UN	UR	DE
2	A1474031	Absent	Absent	0	0
	A1474033	Absent	Absent	0	0
	A1474035	Absent	Absent	0	0
	A1474037	Absent	Absent	0	0
	A1474039	Absent	Absent	1	0
	A1474041	Absent	Absent	0	0
	A1474043	Absent	Absent	0	0
	A1474045	Absent	Absent	0	0
	A1474047	Absent	Absent	0	0
	A1474049	Absent	Absent	0	0
	A1474051	Absent	Absent	0	0
	A1474053	Absent	Absent	0	0
	A1474055	Absent	Absent	0	0
	A1474057	Absent	Absent	0	0
	A1474059	Absent	Absent	0	0

19 - 0[illegible] - [illegible] December 2019

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 31

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474061	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474063	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474065	1	1	1	22	1	Absent	Absent	Absent	Absent
	A1474067	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474069	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474071	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474073	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474075	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474077	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474079	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474081	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474083	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474085	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474087	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474089	1	1	1	18	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 31

Females

Group	Animal No	BB	UN	UR	DE
3	A1474061	Absent	Absent	0	0
	A1474063	Absent	Absent	0	0
	A1474065	Absent	Absent	0	0
	A1474067	Absent	Absent	0	0
	A1474069	Absent	Absent	0	0
	A1474071	Absent	Absent	0	0
	A1474073	Absent	Absent	0	0
	A1474075	Absent	Absent	0	0
	A1474077	Absent	Absent	0	0
	A1474079	Absent	Absent	0	0
	A1474081	Absent	Absent	0	0
	A1474083	Absent	Absent	0	0
	A1474085	Absent	Absent	0	0
	A1474087	Absent	Absent	0	0
	A1474089	Absent	Absent	0	0

US - Draft - Not Dated December 2016

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 31

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474091	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474093	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474095	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474097	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474099	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474101	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474103	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474105	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474107	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474109	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474111	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474113	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474115	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474117	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474119	1	1	1	11	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 31

Females

Group	Animal No	BB	UN	UR	DE
4	A1474091	Absent	Absent	0	0
	A1474093	Absent	Absent	0	0
	A1474095	Absent	Absent	0	0
	A1474097	Absent	Absent	0	0
	A1474099	Absent	Absent	0	0
	A1474101	Absent	Absent	0	0
	A1474103	Absent	Absent	0	0
	A1474105	Absent	Absent	0	0
	A1474107	Absent	Absent	0	0
	A1474109	Absent	Absent	0	0
	A1474111	Absent	Absent	0	0
	A1474113	Absent	Absent	0	0
	A1474115	Absent	Absent	0	0
	A1474117	Absent	Absent	0	0
	A1474119	Absent	Absent	0	0

GLP - DRAFT - Not Guaranteed - 2010

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 38

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474001	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474003	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474005	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474007	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474009	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474011	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474013	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474015	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474017	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474019	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474021	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474023	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474025	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474027	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474029	1	1	1	20	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 38

Females

Group	Animal No	BB	UN	UR	DE
Control	A1474001	Absent	Absent	0	0
	A1474003	Absent	Absent	1	0
	A1474005	Absent	Absent	0	0
	A1474007	Absent	Absent	0	0
	A1474009	Absent	Absent	0	0
	A1474011	Absent	Absent	1	0
	A1474013	Absent	Absent	0	0
	A1474015	Absent	Absent	0	0
	A1474017	Absent	Absent	1	0
	A1474019	Absent	Absent	0	0
	A1474021	Absent	Absent	0	0
	A1474023	Absent	Absent	2	0
	A1474025	Absent	Absent	0	0
	A1474027	Absent	Absent	0	0
	A1474029	Absent	Absent	0	0

29 - DRAFT - Wed, December 2010

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 38

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474031	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474033	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474035	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474037	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474039	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474041	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474043	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474045	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474047	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474049	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474051	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474053	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474055	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474057	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474059	1	1	1	21	1	Absent	Absent	Absent	Absent

For Inspection Purposes Only

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 38

Females

Group	Animal No	BB	UN	UR	DE
2	A1474031	Absent	Absent	0	0
	A1474033	Absent	Absent	1	0
	A1474035	Absent	Absent	0	0
	A1474037	Absent	Absent	0	0
	A1474039	Absent	Absent	0	0
	A1474041	Absent	Absent	0	0
	A1474043	Absent	Absent	1	0
	A1474045	Absent	Absent	0	0
	A1474047	Absent	Absent	0	0
	A1474049	Absent	Absent	0	0
	A1474051	Absent	Absent	1	0
	A1474053	Absent	Absent	0	0
	A1474055	Absent	Absent	1	0
	A1474057	Absent	Absent	1	0
	A1474059	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 38

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474061	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474063	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474065	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474067	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474069	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474071	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474073	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474075	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474077	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474079	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474081	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474083	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474085	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474087	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474089	1	1	1	21	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 38

Females

Group	Animal No	BB	UN	UR	DE
3	A1474061	Absent	Absent	0	0
	A1474063	Absent	Absent	0	0
	A1474065	Absent	Absent	1	0
	A1474067	Absent	Absent	1	0
	A1474069	Absent	Absent	1	0
	A1474071	Absent	Absent	0	0
	A1474073	Absent	Absent	0	0
	A1474075	Absent	Absent	0	0
	A1474077	Absent	Absent	0	0
	A1474079	Absent	Absent	2	0
	A1474081	Absent	Absent	0	0
	A1474083	Absent	Absent	0	0
	A1474085	Absent	Absent	0	0
	A1474087	Absent	Absent	0	0
	A1474089	Absent	Absent	0	0

DRAFT - 15th December 2016

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 38

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474091	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474093	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474095	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474097	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474099	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474101	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474103	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474105	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474107	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474109	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474111	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474113	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474115	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474117	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474119	1	1	1	13	1	Absent	Absent	Absent	Absent

For Study Investigator Use Only

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 38

Females

Group	Animal No	BB	UN	UR	DE
4	A1474091	Absent	Absent	1	0
	A1474093	Absent	Absent	0	0
	A1474095	Absent	Absent	0	0
	A1474097	Absent	Absent	0	0
	A1474099	Absent	Absent	1	0
	A1474101	Absent	Absent	0	0
	A1474103	Absent	Absent	0	0
	A1474105	Absent	Absent	0	0
	A1474107	Absent	Absent	1	0
	A1474109	Absent	Absent	0	0
	A1474111	Absent	Absent	0	0
	A1474113	Absent	Absent	0	0
	A1474115	Absent	Absent	0	0
	A1474117	Absent	Absent	0	0
	A1474119	Absent	Absent	0	0

Study Director - Non-Disclosure Only

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 45

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474001	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474003	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474005	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474007	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474009	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474011	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474013	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474015	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474017	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474019	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474021	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474023	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474025	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474027	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474029	1	1	1	17	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 45

Females

Group	Animal No	BB	UN	UR	DE
Control	A1474001	Absent	Absent	0	0
	A1474003	Absent	Absent	0	0
	A1474005	Absent	Absent	0	0
	A1474007	Absent	Absent	0	0
	A1474009	Absent	Absent	0	0
	A1474011	Absent	Absent	0	0
	A1474013	Absent	Absent	0	0
	A1474015	Absent	Absent	1	0
	A1474017	Absent	Absent	1	0
	A1474019	Absent	Absent	0	0
	A1474021	Absent	Absent	0	0
	A1474023	Absent	Absent	1	0
	A1474025	Absent	Absent	0	0
	A1474027	Absent	Absent	0	0
	A1474029	Absent	Absent	0	0

RTC UNOFFICIAL - FOR Dosing Day 2016

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 45

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474031	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474033	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474035	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474037	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474039	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474041	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474043	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474045	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474047	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474049	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474051	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474053	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474055	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474057	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474059	1	1	1	19	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 45

Females

Group	Animal No	BB	UN	UR	DE
2	A1474031	Absent	Absent	0	0
	A1474033	Absent	Absent	0	0
	A1474035	Absent	Absent	0	0
	A1474037	Absent	Absent	0	0
	A1474039	Absent	Absent	0	0
	A1474041	Absent	Absent	0	0
	A1474043	Absent	Absent	0	0
	A1474045	Absent	Absent	0	0
	A1474047	Absent	Absent	0	0
	A1474049	Absent	Absent	0	0
	A1474051	Absent	Absent	0	0
	A1474053	Absent	Absent	0	0
	A1474055	Absent	Absent	0	0
	A1474057	Absent	Absent	0	0
	A1474059	Absent	Absent	0	0

DRAFT - Not Document

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 45

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474061	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474063	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474065	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474067	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474069	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474071	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474073	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474075	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474077	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474079	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474081	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474083	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474085	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474087	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474089	1	1	1	19	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 45

Females

Group	Animal No	BB	UN	UR	DE
3	A1474061	Absent	Absent	0	0
	A1474063	Absent	Absent	0	0
	A1474065	Absent	Absent	0	0
	A1474067	Absent	Absent	0	0
	A1474069	Absent	Absent	0	0
	A1474071	Absent	Absent	0	0
	A1474073	Absent	Absent	0	0
	A1474075	Absent	Absent	0	0
	A1474077	Absent	Absent	0	0
	A1474079	Absent	Absent	0	0
	A1474081	Absent	Absent	0	0
	A1474083	Absent	Absent	1	0
	A1474085	Absent	Absent	1	0
	A1474087	Absent	Absent	0	0
	A1474089	Absent	Absent	2	0

RX - DRAFT - For Discussion Only

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 45

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474091	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474093	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474095	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474097	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474099	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474101	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474103	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474105	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474107	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474109	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474111	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474113	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474115	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474117	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474119	1	1	1	15	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 45

Females

Group	Animal No	BB	UN	UR	DE
4	A1474091	Absent	Absent	0	0
	A1474093	Absent	Absent	0	0
	A1474095	Absent	Absent	1	0
	A1474097	Absent	Absent	0	0
	A1474099	Absent	Absent	0	0
	A1474101	Absent	Absent	0	0
	A1474103	Absent	Absent	0	0
	A1474105	Absent	Absent	0	0
	A1474107	Absent	Absent	0	0
	A1474109	Absent	Absent	0	0
	A1474111	Absent	Absent	0	0
	A1474113	Absent	Absent	0	0
	A1474115	Absent	Absent	0	0
	A1474117	Absent	Absent	0	0
	A1474119	Absent	Absent	0	0

SS - [illegible] - [illegible] University - 2010

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 52

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474001	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474003	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474005	1	1	1	22	1	Absent	Absent	Absent	Absent
	A1474007	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474009	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474011	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474013	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474015	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474017	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474019	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474021	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474023	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474025	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474027	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474029	1	1	1	20	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 52

Females

Group	Animal No	BB	UN	UR	DE
Control	A1474001	Absent	Absent	0	0
	A1474003	Absent	Absent	0	0
	A1474005	Absent	Absent	0	0
	A1474007	Absent	Absent	1	0
	A1474009	Absent	Absent	0	0
	A1474011	Absent	Absent	0	0
	A1474013	Absent	Absent	0	0
	A1474015	Absent	Absent	1	0
	A1474017	Absent	Absent	0	0
	A1474019	Absent	Absent	1	0
	A1474021	Absent	Absent	0	0
	A1474023	Absent	Absent	0	0
	A1474025	Absent	Absent	0	0
	A1474027	Absent	Absent	1	0
	A1474029	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 52

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474031	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474033	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474035	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474037	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474039	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474041	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474043	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474045	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474047	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474049	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474051	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474053	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474055	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474057	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474059	1	1	1	21	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 52

Females

Group	Animal No	BB	UN	UR	DE
2	A1474031	Absent	Absent	0	0
	A1474033	Absent	Absent	1	0
	A1474035	Absent	Absent	0	0
	A1474037	Absent	Absent	0	0
	A1474039	Absent	Absent	0	0
	A1474041	Absent	Absent	0	0
	A1474043	Absent	Absent	1	0
	A1474045	Absent	Absent	0	0
	A1474047	Absent	Absent	0	0
	A1474049	Absent	Absent	1	0
	A1474051	Absent	Absent	0	0
	A1474053	Absent	Absent	0	0
	A1474055	Absent	Absent	0	0
	A1474057	Absent	Absent	0	0
	A1474059	Absent	Absent	0	0

GLP - DRAFT - Not Proofread or QC'd

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 52

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474061	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474063	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474065	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474067	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474069	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474071	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474073	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474075	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474077	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474079	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474081	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474083	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474085	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474087	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474089	1	1	1	17	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 52

Females

Group	Animal No	BB	UN	UR	DE
3	A1474061	Absent	Absent	0	0
	A1474063	Absent	Absent	0	0
	A1474065	Absent	Absent	0	0
	A1474067	Absent	Absent	1	0
	A1474069	Absent	Absent	0	0
	A1474071	Absent	Absent	0	0
	A1474073	Absent	Absent	0	0
	A1474075	Absent	Absent	1	0
	A1474077	Absent	Absent	0	0
	A1474079	Absent	Absent	0	0
	A1474081	Absent	Absent	0	0
	A1474083	Absent	Absent	1	0
	A1474085	Absent	Absent	2	0
	A1474087	Absent	Absent	0	0
	A1474089	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 52

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474091	1	1	1	24	1	Absent	Absent	Absent	Absent
	A1474093	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474095	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474097	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474099	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474101	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474103	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474105	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474107	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474109	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474111	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474113	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474115	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474117	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474119	1	1	1	17	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 52

Females

Group	Animal No	BB	UN	UR	DE
4	A1474091	Absent	Absent	0	0
	A1474093	Absent	Absent	1	0
	A1474095	Absent	Absent	0	0
	A1474097	Absent	Absent	0	0
	A1474099	Absent	Absent	0	0
	A1474101	Absent	Absent	0	0
	A1474103	Absent	Absent	1	0
	A1474105	Absent	Absent	0	0
	A1474107	Absent	Absent	0	0
	A1474109	Absent	Absent	0	0
	A1474111	Absent	Absent	0	0
	A1474113	Absent	Absent	0	0
	A1474115	Absent	Absent	0	0
	A1474117	Absent	Absent	0	0
	A1474119	Absent	Absent	0	0

Study - Draft - Not Dec 2016

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 59

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474001	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474003	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474005	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474007	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474009	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474011	1	1	1	9	1	Absent	Absent	Absent	Absent
	A1474013	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474015	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474017	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474019	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474021	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474023	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474025	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474027	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474029	1	1	1	11	1	Absent	Absent	Absent	Absent

DRAFT - NOT FOR DISTRIBUTION

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 59

Females

Group	Animal No	BB	UN	UR	DE
Control	A1474001	Absent	Absent	0	0
	A1474003	Absent	Absent	0	0
	A1474005	Absent	Absent	0	0
	A1474007	Absent	Absent	0	0
	A1474009	Absent	Absent	0	0
	A1474011	Absent	Absent	0	0
	A1474013	Absent	Absent	0	0
	A1474015	Absent	Absent	0	0
	A1474017	Absent	Absent	0	0
	A1474019	Absent	Absent	0	0
	A1474021	Absent	Absent	0	0
	A1474023	Absent	Absent	0	0
	A1474025	Absent	Absent	0	0
	A1474027	Absent	Absent	0	0
	A1474029	Absent	Absent	0	0

GLP - DRAFT - Not Yet Archived

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 59

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474031	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474033	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474035	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474037	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474039	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474041	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474043	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474045	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474047	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474049	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474051	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474053	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474055	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474057	1	1	1	9	1	Absent	Absent	Absent	Absent
	A1474059	1	1	1	16	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 59

Females

Group	Animal No	BB	UN	UR	DE
2	A1474031	Absent	Absent	0	0
	A1474033	Absent	Absent	0	0
	A1474035	Absent	Absent	0	0
	A1474037	Absent	Absent	0	0
	A1474039	Absent	Absent	0	0
	A1474041	Absent	Absent	0	0
	A1474043	Absent	Absent	0	0
	A1474045	Absent	Absent	0	0
	A1474047	Absent	Absent	0	0
	A1474049	Absent	Absent	0	0
	A1474051	Absent	Absent	0	0
	A1474053	Absent	Absent	0	0
	A1474055	Absent	Absent	0	0
	A1474057	Absent	Absent	0	0
	A1474059	Absent	Absent	0	0

DRAFT - NOT FOR SIGNATURE

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 59

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474061	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474063	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474065	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474067	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474069	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474071	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474073	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474075	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474077	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474079	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474081	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474083	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474085	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474087	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474089	1	1	1	18	1	Absent	Absent	Absent	Absent

DRAFT - NOT FOR DISTRIBUTION

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 59

Females

Group	Animal No	BB	UN	UR	DE
3	A1474061	Absent	Absent	0	0
	A1474063	Absent	Absent	0	0
	A1474065	Absent	Absent	0	0
	A1474067	Absent	Absent	0	0
	A1474069	Absent	Absent	0	0
	A1474071	Absent	Absent	0	0
	A1474073	Absent	Absent	0	0
	A1474075	Absent	Absent	0	0
	A1474077	Absent	Absent	0	0
	A1474079	Absent	Absent	0	0
	A1474081	Absent	Absent	0	0
	A1474083	Absent	Absent	0	0
	A1474085	Absent	Absent	0	0
	A1474087	Absent	Absent	0	0
	A1474089	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 59

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474091	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474093	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474095	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474097	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474099	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474101	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474103	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474105	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474107	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474109	1	1	1	9	1	Absent	Absent	Absent	Absent
	A1474111	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474113	1	1	1	9	1	Absent	Absent	Absent	Absent
	A1474115	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474117	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474119	1	1	1	13	1	Absent	Absent	Absent	Absent

DRAFT - Not Dosimetry Verified

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 59

Females

Group	Animal No	BB	UN	UR	DE
4	A1474091	Absent	Absent	0	0
	A1474093	Absent	Absent	0	0
	A1474095	Absent	Absent	0	0
	A1474097	Absent	Absent	0	0
	A1474099	Absent	Absent	0	0
	A1474101	Absent	Absent	0	0
	A1474103	Absent	Absent	0	0
	A1474105	Absent	Absent	0	0
	A1474107	Absent	Absent	0	0
	A1474109	Absent	Absent	0	0
	A1474111	Absent	Absent	0	0
	A1474113	Absent	Absent	0	0
	A1474115	Absent	Absent	0	0
	A1474117	Absent	Absent	0	0
	A1474119	Absent	Absent	0	0

DRAFT - Not Disclosable 2016

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 67

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474001	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474003	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474005	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474007	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474009	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474011	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474013	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474015	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474017	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474019	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474021	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474023	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474025	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474027	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474029	1	1	1	17	1	Absent	Absent	Absent	Absent

SS - DRAFT - Not Reviewed - 00.0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 67

Females

Group	Animal No	BB	UN	UR	DE
Control	A1474001	Absent	Absent	0	0
	A1474003	Absent	Absent	1	0
	A1474005	Absent	Absent	0	0
	A1474007	Absent	Absent	1	0
	A1474009	Absent	Absent	0	0
	A1474011	Absent	Absent	0	0
	A1474013	Absent	Absent	0	0
	A1474015	Absent	Absent	1	0
	A1474017	Absent	Absent	0	0
	A1474019	Absent	Absent	2	0
	A1474021	Absent	Absent	0	0
	A1474023	Absent	Absent	0	0
	A1474025	Absent	Absent	0	0
	A1474027	Absent	Absent	0	0
	A1474029	Absent	Absent	0	0

GLP - DRAFT - Not Dated/Signed 2015

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 67

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474031	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474033	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474035	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474037	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474039	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474041	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474043	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474045	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474047	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474049	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474051	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474053	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474055	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474057	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474059	1	1	1	14	1	Absent	Absent	Absent	Absent

DRAFT - NOT FOR DISTRIBUTION

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 67

Females

Group	Animal No	BB	UN	UR	DE
2	A1474031	Absent	Absent	0	0
	A1474033	Absent	Absent	0	0
	A1474035	Absent	Absent	0	0
	A1474037	Absent	Absent	0	0
	A1474039	Absent	Absent	1	0
	A1474041	Absent	Absent	0	0
	A1474043	Absent	Absent	0	0
	A1474045	Absent	Absent	0	0
	A1474047	Absent	Absent	0	0
	A1474049	Absent	Absent	1	0
	A1474051	Absent	Absent	0	0
	A1474053	Absent	Absent	0	0
	A1474055	Absent	Absent	0	0
	A1474057	Absent	Absent	0	0
	A1474059	Absent	Absent	0	0

DRAFT - NOT FOR DISTRIBUTION

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 67

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474061	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474063	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474065	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474067	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474069	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474071	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474073	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474075	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474077	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474079	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474081	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474083	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474085	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474087	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474089	1	1	1	16	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 67

Females

Group	Animal No	BB	UN	UR	DE
3	A1474061	Absent	Absent	0	0
	A1474063	Absent	Absent	0	0
	A1474065	Absent	Absent	0	0
	A1474067	Absent	Absent	0	0
	A1474069	Absent	Absent	0	0
	A1474071	Absent	Absent	0	0
	A1474073	Absent	Absent	0	0
	A1474075	Absent	Absent	0	0
	A1474077	Absent	Absent	0	0
	A1474079	Absent	Absent	0	0
	A1474081	Absent	Absent	0	0
	A1474083	Absent	Absent	0	0
	A1474085	Absent	Absent	0	0
	A1474087	Absent	Absent	0	0
	A1474089	Absent	Absent	0	0

DRAFT - Not Dated 2016

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 67

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474091	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474093	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474095	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474097	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474099	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474101	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474103	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474105	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474107	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474109	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474111	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474113	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474115	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474117	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474119	1	1	1	10	1	Absent	Absent	Absent	Absent

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 67

Females

Group	Animal No	BB	UN	UR	DE
4	A1474091	Absent	Absent	0	0
	A1474093	Absent	Absent	0	0
	A1474095	Absent	Absent	0	0
	A1474097	Absent	Absent	0	0
	A1474099	Absent	Absent	0	0
	A1474101	Absent	Absent	0	0
	A1474103	Absent	Absent	0	0
	A1474105	Absent	Absent	0	0
	A1474107	Absent	Absent	0	0
	A1474109	Absent	Absent	0	0
	A1474111	Absent	Absent	0	0
	A1474113	Absent	Absent	0	0
	A1474115	Absent	Absent	0	0
	A1474117	Absent	Absent	0	0
	A1474119	Absent	Absent	0	0

For URINARY USE Unscanned 2016

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 73

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474001	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474003	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474005	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474007	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474009	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474011	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474013	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474015	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474017	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474019	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474021	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474023	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474025	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474027	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474029	1	1	1	16	1	Absent	Absent	Absent	Absent

DRAFT - NOT FOR CITATION

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 73

Females

Group	Animal No	BB	UN	UR	DE
Control	A1474001	Absent	Absent	0	0
	A1474003	Absent	Absent	1	0
	A1474005	Absent	Absent	0	0
	A1474007	Absent	Absent	0	0
	A1474009	Absent	Absent	1	0
	A1474011	Absent	Absent	0	0
	A1474013	Absent	Absent	0	0
	A1474015	Absent	Absent	0	0
	A1474017	Absent	Absent	1	0
	A1474019	Absent	Absent	0	0
	A1474021	Absent	Absent	0	0
	A1474023	Absent	Absent	0	0
	A1474025	Absent	Absent	0	0
	A1474027	Absent	Absent	0	0
	A1474029	Absent	Absent	0	0

DRAFT - Not Released - 2010

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 73

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474031	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474033	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474035	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474037	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474039	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474041	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474043	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474045	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474047	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474049	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474051	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474053	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474055	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474057	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474059	1	1	1	15	1	Absent	Absent	Absent	Absent

RTC - ORIGINAL - DO NOT REMOVE

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 73

Females

Group	Animal No	BB	UN	UR	DE
2	A1474031	Absent	Absent	0	0
	A1474033	Absent	Absent	0	0
	A1474035	Absent	Absent	0	0
	A1474037	Absent	Absent	0	0
	A1474039	Absent	Absent	0	0
	A1474041	Absent	Absent	0	0
	A1474043	Absent	Absent	1	0
	A1474045	Absent	Absent	0	0
	A1474047	Absent	Absent	0	0
	A1474049	Absent	Absent	0	0
	A1474051	Absent	Absent	0	0
	A1474053	Absent	Absent	0	0
	A1474055	Absent	Absent	0	0
	A1474057	Absent	Absent	0	0
	A1474059	Absent	Absent	0	0

Study Initiation Draft Document 2010

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 73

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474061	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474063	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474065	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474067	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474069	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474071	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474073	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474075	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474077	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474079	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474081	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474083	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474085	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474087	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474089	1	1	1	18	1	Absent	Absent	Absent	Absent

FDA - CDER/OTS - Mail Document - 2018

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 73

Females

Group	Animal No	BB	UN	UR	DE
3	A1474061	Absent	Absent	0	0
	A1474063	Absent	Absent	0	0
	A1474065	Absent	Absent	0	0
	A1474067	Absent	Absent	0	0
	A1474069	Absent	Absent	0	0
	A1474071	Absent	Absent	0	0
	A1474073	Absent	Absent	0	0
	A1474075	Absent	Absent	0	0
	A1474077	Absent	Absent	0	0
	A1474079	Absent	Absent	0	0
	A1474081	Absent	Absent	0	0
	A1474083	Absent	Absent	0	0
	A1474085	Absent	Absent	0	0
	A1474087	Absent	Absent	0	0
	A1474089	Absent	Absent	0	0

GLP - DRAFT - Data Dependent 2016

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 73

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474091	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474093	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474095	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474097	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474099	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474101	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474103	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474105	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474107	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474109	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474111	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474113	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474115	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474117	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474119	1	1	1	14	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 73

Females

Group	Animal No	BB	UN	UR	DE
4	A1474091	Absent	Absent	0	0
	A1474093	Absent	Absent	0	0
	A1474095	Absent	Absent	0	0
	A1474097	Absent	Absent	0	0
	A1474099	Absent	Absent	0	0
	A1474101	Absent	Absent	0	0
	A1474103	Absent	Absent	0	0
	A1474105	Absent	Absent	0	0
	A1474107	Absent	Absent	0	0
	A1474109	Absent	Absent	0	0
	A1474111	Absent	Absent	0	0
	A1474113	Absent	Absent	0	0
	A1474115	Absent	Absent	0	0
	A1474117	Absent	Absent	0	0
	A1474119	Absent	Absent	0	0

Study Director Final Report Version 2015

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 80

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474001	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474003	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474005	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474007	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474009	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474011	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474013	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474015	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474017	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474019	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474021	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474023	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474025	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474027	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474029	1	1	1	15	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 80

Females

Group	Animal No	BB	UN	UR	DE
Control	A1474001	Absent	Absent	0	0
	A1474003	Absent	Absent	0	0
	A1474005	Absent	Absent	0	0
	A1474007	Absent	Absent	0	0
	A1474009	Absent	Absent	0	0
	A1474011	Absent	Absent	0	0
	A1474013	Absent	Absent	0	0
	A1474015	Absent	Absent	0	0
	A1474017	Absent	Absent	0	0
	A1474019	Absent	Absent	0	0
	A1474021	Absent	Absent	0	0
	A1474023	Absent	Absent	0	0
	A1474025	Absent	Absent	0	0
	A1474027	Absent	Absent	0	0
	A1474029	Absent	Absent	0	0

SR - DRAFT - NOT Updated 2010

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 80

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474031	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474033	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474035	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474037	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474039	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474041	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474043	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474045	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474047	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474049	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474051	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474053	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474055	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474057	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474059	1	1	1	17	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 80

Females

Group	Animal No	BB	UN	UR	DE
2	A1474031	Absent	Absent	0	0
	A1474033	Absent	Absent	0	0
	A1474035	Absent	Absent	0	0
	A1474037	Absent	Absent	0	0
	A1474039	Absent	Absent	0	0
	A1474041	Absent	Absent	0	0
	A1474043	Absent	Absent	0	0
	A1474045	Absent	Absent	0	0
	A1474047	Absent	Absent	0	0
	A1474049	Absent	Absent	0	0
	A1474051	Absent	Absent	0	0
	A1474053	Absent	Absent	0	0
	A1474055	Absent	Absent	0	0
	A1474057	Absent	Absent	0	0
	A1474059	Absent	Absent	0	0

GLP - DRAFT - Not for Distribution 2016

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 80

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474061	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474063	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474065	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474067	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474069	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474071	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474073	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474075	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474077	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474079	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474081	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474083	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474085	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474087	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474089	1	1	1	16	1	Absent	Absent	Absent	Absent

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REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 80

Females

Group	Animal No	BB	UN	UR	DE
3	A1474061	Absent	Absent	0	0
	A1474063	Absent	Absent	0	0
	A1474065	Absent	Absent	0	0
	A1474067	Absent	Absent	0	0
	A1474069	Absent	Absent	0	0
	A1474071	Absent	Absent	0	0
	A1474073	Absent	Absent	0	0
	A1474075	Absent	Absent	0	0
	A1474077	Absent	Absent	0	0
	A1474079	Absent	Absent	0	0
	A1474081	Absent	Absent	0	0
	A1474083	Absent	Absent	0	0
	A1474085	Absent	Absent	0	0
	A1474087	Absent	Absent	0	0
	A1474089	Absent	Absent	0	0

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 80

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474091	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474093	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474095	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474097	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474099	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474101	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474103	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474105	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474107	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474109	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474111	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474113	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474115	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474117	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474119	1	1	1	16	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 80

Females

Group	Animal No	BB	UN	UR	DE
4	A1474091	Absent	Absent	0	0
	A1474093	Absent	Absent	0	0
	A1474095	Absent	Absent	0	0
	A1474097	Absent	Absent	0	0
	A1474099	Absent	Absent	0	0
	A1474101	Absent	Absent	0	0
	A1474103	Absent	Absent	0	0
	A1474105	Absent	Absent	0	0
	A1474107	Absent	Absent	0	0
	A1474109	Absent	Absent	0	0
	A1474111	Absent	Absent	0	0
	A1474113	Absent	Absent	0	0
	A1474115	Absent	Absent	0	0
	A1474117	Absent	Absent	0	0
	A1474119	Absent	Absent	0	0

GLP - ORIGINAL - Not Dated - 2016

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 87

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474001	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474003	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474005	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474007	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474009	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474011	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474013	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474015	1	1	1	23	1	Absent	Absent	Absent	Absent
	A1474017	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474019	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474021	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474023	1	1	1	8	1	Absent	Absent	Absent	Absent
	A1474025	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474027	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474029	1	1	1	10	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 87

Females

Group	Animal No	BB	UN	UR	DE
Control	A1474001	Absent	Absent	0	0
	A1474003	Absent	Absent	0	0
	A1474005	Absent	Absent	0	0
	A1474007	Absent	Absent	0	0
	A1474009	Absent	Absent	0	0
	A1474011	Absent	Absent	0	0
	A1474013	Absent	Absent	1	0
	A1474015	Absent	Absent	0	0
	A1474017	Absent	Absent	0	0
	A1474019	Absent	Absent	0	0
	A1474021	Absent	Absent	0	0
	A1474023	Absent	Absent	0	0
	A1474025	Absent	Absent	3	0
	A1474027	Absent	Absent	0	0
	A1474029	Absent	Absent	0	0

FOR OFFICIAL USE ONLY

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 87

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474031	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474033	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474035	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474037	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474039	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474041	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474043	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474045	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474047	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474049	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474051	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474053	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474055	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474057	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474059	1	1	1	10	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 87

Females

Group	Animal No	BB	UN	UR	DE
2	A1474031	Absent	Absent	0	0
	A1474033	Absent	Absent	0	0
	A1474035	Absent	Absent	0	0
	A1474037	Absent	Absent	0	0
	A1474039	Absent	Absent	0	0
	A1474041	Absent	Absent	0	0
	A1474043	Absent	Absent	0	0
	A1474045	Absent	Absent	2	0
	A1474047	Absent	Absent	0	0
	A1474049	Absent	Absent	0	0
	A1474051	Absent	Absent	0	0
	A1474053	Absent	Absent	0	0
	A1474055	Absent	Absent	0	0
	A1474057	Absent	Absent	2	0
	A1474059	Absent	Absent	1	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 87

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474061	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474063	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474065	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474067	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474069	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474071	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474073	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474075	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474077	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474079	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474081	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474083	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474085	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474087	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474089	1	1	1	17	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 87

Females

Group	Animal No	BB	UN	UR	DE
3	A1474061	Absent	Absent	0	0
	A1474063	Absent	Absent	0	0
	A1474065	Absent	Absent	0	0
	A1474067	Absent	Absent	0	0
	A1474069	Absent	Absent	0	0
	A1474071	Absent	Absent	0	0
	A1474073	Absent	Absent	1	0
	A1474075	Absent	Absent	0	0
	A1474077	Absent	Absent	0	0
	A1474079	Absent	Absent	0	0
	A1474081	Absent	Absent	0	0
	A1474083	Absent	Absent	0	0
	A1474085	Absent	Absent	0	0
	A1474087	Absent	Absent	0	0
	A1474089	Absent	Absent	0	0

FOR DRAFT - Last Dec-ember 2016

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 87

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474091	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474093	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474095	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474097	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474099	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474101	1	1	1	9	1	Absent	Absent	Absent	Absent
	A1474103	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474105	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474107	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474109	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474111	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474113	1	1	1	9	1	Absent	Absent	Absent	Absent
	A1474115	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474117	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474119	1	1	1	12	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 87

Females

Group	Animal No	BB	UN	UR	DE
4	A1474091	Absent	Absent	0	0
	A1474093	Absent	Absent	0	0
	A1474095	Absent	Absent	0	0
	A1474097	Absent	Absent	0	0
	A1474099	Absent	Absent	0	0
	A1474101	Absent	Absent	0	0
	A1474103	Absent	Absent	0	0
	A1474105	Absent	Absent	0	0
	A1474107	Absent	Absent	0	0
	A1474109	Absent	Absent	0	0
	A1474111	Absent	Absent	0	0
	A1474113	Absent	Absent	1	0
	A1474115	Absent	Absent	1	0
	A1474117	Absent	Absent	0	0
	A1474119	Absent	Absent	0	0

DRAFT - Not Disclosed

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 2

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474022	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474024	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474026	1	1	1	9	1	Absent	Absent	Absent	Absent
	A1474028	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474030	1	1	1	13	1	Absent	Absent	Absent	Absent

FOR LIBRARY PURPOSES ONLY

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 2

Males

Group	Animal No	BB	UN	UR	DE
Control	A1474022	Absent	Absent	0	0
	A1474024	Absent	Absent	0	0
	A1474026	Absent	Absent	0	0
	A1474028	Absent	Absent	0	0
	A1474030	Absent	Absent	0	0

GLP - DRAFT - Not Determined 2010

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 2

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474052	1	1	1	8	1	Absent	Absent	Absent	Absent
	A1474054	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474056	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474058	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474060	1	1	1	11	1	Absent	Absent	Absent	Absent

DRAFT - NOT APPROVED 2016

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 2

Males

Group	Animal No	BB	UN	UR	DE
2	A1474052	Absent	Absent	0	0
	A1474054	Absent	Absent	0	0
	A1474056	Absent	Absent	0	0
	A1474058	Absent	Absent	0	0
	A1474060	Absent	Absent	0	0

GLP - DRAFT - Non-confidential 2010

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 2

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474082	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474084	1	1	1	8	1	Absent	Absent	Absent	Absent
	A1474086	1	1	1	6	1	Absent	Absent	Absent	Absent
	A1474088	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474090	1	1	1	14	1	Absent	Absent	Absent	Absent

FDA - DRAFT - Not Document (2010)

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 2

Males

Group	Animal No	BB	UN	UR	DE
3	A1474082	Absent	Absent	0	0
	A1474084	Absent	Absent	0	0
	A1474086	Absent	Absent	0	0
	A1474088	Absent	Absent	0	0
	A1474090	Absent	Absent	0	0

DRAFT - Not Operational 2016

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 2

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474112	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474114	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474116	1	1	1	7	1	Absent	Absent	Absent	Absent
	A1474118	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474120	1	1	1	9	1	Absent	Absent	Absent	Absent

DRAFT - NOT FOR DISTRIBUTION

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 2

Males

Group	Animal No	BB	UN	UR	DE
4	A1474112	Absent	Absent	0	0
	A1474114	Absent	Absent	0	0
	A1474116	Absent	Absent	0	0
	A1474118	Absent	Absent	0	0
	A1474120	Absent	Absent	0	0

For DRAFT - Not Dissemination

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 9

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474022	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474024	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474026	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474028	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474030	1	1	1	16	1	Absent	Absent	Absent	Absent

DRAFT - NOT FOR DISTRIBUTION

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 9

Males

Group	Animal No	BB	UN	UR	DE
Control	A1474022	Absent	Absent	0	0
	A1474024	Absent	Absent	0	0
	A1474026	Absent	Absent	0	0
	A1474028	Absent	Absent	0	0
	A1474030	Absent	Absent	0	0

Test - Not for Distribution 2015

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 9

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474052	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474054	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474056	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474058	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474060	1	1	1	9	1	Absent	Absent	Absent	Absent

Not Quality Assurance Audited

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 9

Males

Group	Animal No	BB	UN	UR	DE
2	A1474052	Absent	Absent	0	0
	A1474054	Absent	Absent	0	0
	A1474056	Absent	Absent	0	0
	A1474058	Absent	Absent	0	0
	A1474060	Absent	Absent	0	0

GLP - URAC1 - Study Document 2010

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 9

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474082	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474084	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474086	1	1	1	8	1	Absent	Absent	Absent	Absent
	A1474088	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474090	1	1	1	16	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 9

Males

Group	Animal No	BB	UN	UR	DE
3	A1474082	Absent	Absent	0	0
	A1474084	Absent	Absent	0	0
	A1474086	Absent	Absent	0	0
	A1474088	Absent	Absent	0	0
	A1474090	Absent	Absent	0	0

GLP - QAU Ref. - Draft Quarantine 2019

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 9

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474112	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474114	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474116	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474118	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474120	1	1	1	13	1	Absent	Absent	Absent	Absent

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REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 9

Males

Group	Animal No	BB	UN	UR	DE
4	A1474112	Absent	Absent	0	0
	A1474114	Absent	Absent	0	0
	A1474116	Absent	Absent	0	0
	A1474118	Absent	Absent	0	0
	A1474120	Absent	Absent	0	0

GLP - DRAFT - Wyeth Document 2010

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 16

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474022	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474024	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474026	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474028	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474030	1	1	1	14	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 16

Males

Group	Animal No	BB	UN	UR	DE
Control	A1474022	Absent	Absent	0	0
	A1474024	Absent	Absent	0	0
	A1474026	Absent	Absent	0	0
	A1474028	Absent	Absent	0	0
	A1474030	Absent	Absent	0	0

GLP - DRAFT - Not for Distribution

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 16

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474052	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474054	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474056	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474058	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474060	1	1	1	11	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 16

Males

Group	Animal No	BB	UN	UR	DE
2	A1474052	Absent	Absent	0	0
	A1474054	Absent	Absent	0	0
	A1474056	Absent	Absent	0	0
	A1474058	Absent	Absent	0	0
	A1474060	Absent	Absent	0	0

For Official Use Only

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 16

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474082	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474084	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474086	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474088	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474090	1	1	1	14	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 16

Males

Group	Animal No	BB	UN	UR	DE
3	A1474082	Absent	Absent	0	0
	A1474084	Absent	Absent	0	0
	A1474086	Absent	Absent	0	0
	A1474088	Absent	Absent	0	0
	A1474090	Absent	Absent	0	0

FOR INTERNAL USE ONLY

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 16

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474112	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474114	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474116	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474118	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474120	1	1	1	11	1	Absent	Absent	Absent	Absent

Draft - Not for Distribution

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 16

Males

Group	Animal No	BB	UN	UR	DE
4	A1474112	Absent	Absent	0	0
	A1474114	Absent	Absent	0	0
	A1474116	Absent	Absent	0	0
	A1474118	Absent	Absent	0	0
	A1474120	Absent	Absent	0	0

GLP - CONFIDENTIAL - Property of Charles River - 2016

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 23

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474022	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474024	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474026	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474028	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474030	1	1	1	17	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 23

Males

Group	Animal No	BB	UN	UR	DE
Control	A1474022	Absent	Absent	0	0
	A1474024	Absent	Absent	0	0
	A1474026	Absent	Absent	0	0
	A1474028	Absent	Absent	0	0
	A1474030	Absent	Absent	0	0

Sai - DMPT - Post Treatment 2010

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 23

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474052	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474054	1	1	1	8	1	Absent	Absent	Absent	Absent
	A1474056	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474058	1	1	1	9	1	Absent	Absent	Absent	Absent
	A1474060	1	1	1	11	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 23

Males

Group	Animal No	BB	UN	UR	DE
2	A1474052	Absent	Absent	0	0
	A1474054	Absent	Absent	0	0
	A1474056	Absent	Absent	0	0
	A1474058	Absent	Absent	0	0
	A1474060	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 23

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474082	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474084	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474086	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474088	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474090	1	1	1	16	1	Absent	Absent	Absent	Absent

DRAFT - Final Operation Only

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 23

Males

Group	Animal No	BB	UN	UR	DE
3	A1474082	Absent	Absent	0	0
	A1474084	Absent	Absent	0	0
	A1474086	Absent	Absent	0	0
	A1474088	Absent	Absent	0	0
	A1474090	Absent	Absent	0	0

GLP - QUALITY ASSURANCE - Original Document 2010

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 23

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474112	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474114	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474116	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474118	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474120	1	1	1	18	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 23

Males

Group	Animal No	BB	UN	UR	DE
4	A1474112	Absent	Absent	0	0
	A1474114	Absent	Absent	0	0
	A1474116	Absent	Absent	0	0
	A1474118	Absent	Absent	0	0
	A1474120	Absent	Absent	0	0

GLP - CONFIDENTIAL - Non-Disclosure 2010

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 30

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474022	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474024	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474026	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474028	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474030	1	1	1	15	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 30

Males

Group	Animal No	BB	UN	UR	DE
Control	A1474022	Absent	Absent	0	0
	A1474024	Absent	Absent	0	0
	A1474026	Absent	Absent	0	0
	A1474028	Absent	Absent	0	0
	A1474030	Absent	Absent	0	0

For Internal Use Only - Document Control

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 30

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474052	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474054	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474056	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474058	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474060	1	1	1	15	1	Absent	Absent	Absent	Absent

DRAFT - NOT FOR DISTRIBUTION 2015

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 30

Males

Group	Animal No	BB	UN	UR	DE
2	A1474052	Absent	Absent	0	0
	A1474054	Absent	Absent	0	0
	A1474056	Absent	Absent	0	0
	A1474058	Absent	Absent	0	0
	A1474060	Absent	Absent	0	0

For Inspection Purposes Only

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 30

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474082	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474084	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474086	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474088	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474090	1	1	1	12	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 30

Males

Group	Animal No	BB	UN	UR	DE
3	A1474082	Absent	Absent	0	0
	A1474084	Absent	Absent	0	0
	A1474086	Absent	Absent	0	0
	A1474088	Absent	Absent	0	0
	A1474090	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 30

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474112	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474114	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474116	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474118	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474120	1	1	1	7	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 30

Males

Group	Animal No	BB	UN	UR	DE
4	A1474112	Absent	Absent	0	0
	A1474114	Absent	Absent	0	0
	A1474116	Absent	Absent	0	0
	A1474118	Absent	Absent	0	0
	A1474120	Absent	Absent	0	0

GLP - DRAFT - Test Universal Ltd

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 37

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474022	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474024	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474026	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474028	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474030	1	1	1	13	1	Absent	Absent	Absent	Absent

Property of Study Laboratory

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 37

Males

Group	Animal No	BB	UN	UR	DE
Control	A1474022	Absent	Absent	0	0
	A1474024	Absent	Absent	0	0
	A1474026	Absent	Absent	0	0
	A1474028	Absent	Absent	0	0
	A1474030	Absent	Absent	0	0

19 March 2014 Draft

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 37

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474052	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474054	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474056	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474058	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474060	1	1	1	13	1	Absent	Absent	Absent	Absent

Not Approved for Distribution

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 37

Males

Group	Animal No	BB	UN	UR	DE
2	A1474052	Absent	Absent	0	0
	A1474054	Absent	Absent	0	0
	A1474056	Absent	Absent	0	0
	A1474058	Absent	Absent	0	0
	A1474060	Absent	Absent	0	0

For GLP Use Only

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 37

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474082	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474084	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474086	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474088	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474090	1	1	1	12	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 37

Males

Group	Animal No	BB	UN	UR	DE
3	A1474082	Absent	Absent	0	0
	A1474084	Absent	Absent	0	0
	A1474086	Absent	Absent	0	0
	A1474088	Absent	Absent	0	0
	A1474090	Absent	Absent	0	0

GLP - DRAFT - Study Director Only

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 37

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474112	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474114	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474116	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474118	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474120	1	1	1	16	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 37

Males

Group	Animal No	BB	UN	UR	DE
4	A1474112	Absent	Absent	0	0
	A1474114	Absent	Absent	0	0
	A1474116	Absent	Absent	0	0
	A1474118	Absent	Absent	0	0
	A1474120	Absent	Absent	0	0

GLP - ORIGINAL - Valid (December 2010)

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 44

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474022	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474024	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474026	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474028	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474030	1	1	1	22	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 44

Males

Group	Animal No	BB	UN	UR	DE
Control	A1474022	Absent	Absent	0	0
	A1474024	Absent	Absent	0	0
	A1474026	Absent	Absent	0	0
	A1474028	Absent	Absent	0	0
	A1474030	Absent	Absent	0	0

GLP - DRAFT - 16th December 2016

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 44

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474052	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474054	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474056	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474058	1	1	1	22	1	Absent	Absent	Absent	Absent
	A1474060	1	1	1	24	1	Absent	Absent	Absent	Absent

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REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 44

Males

Group	Animal No	BB	UN	UR	DE
2	A1474052	Absent	Absent	0	0
	A1474054	Absent	Absent	0	0
	A1474056	Absent	Absent	0	0
	A1474058	Absent	Absent	0	0
	A1474060	Absent	Absent	0	0

Final - Locked - Final Unaudited 2012

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 44

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474082	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474084	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474086	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474088	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474090	1	1	1	11	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 44

Males

Group	Animal No	BB	UN	UR	DE
3	A1474082	Absent	Absent	0	0
	A1474084	Absent	Absent	0	0
	A1474086	Absent	Absent	0	0
	A1474088	Absent	Absent	0	0
	A1474090	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 44

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474112	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474114	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474116	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474118	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474120	1	1	1	11	1	Absent	Absent	Absent	Absent

Not Approved for Human Consumption 2016

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 44

Males

Group	Animal No	BB	UN	UR	DE
4	A1474112	Absent	Absent	0	0
	A1474114	Absent	Absent	0	0
	A1474116	Absent	Absent	0	0
	A1474118	Absent	Absent	0	0
	A1474120	Absent	Absent	0	0

DRAFT - NOT FOR DISTRIBUTION

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 51

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474022	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474024	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474026	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474028	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474030	1	1	1	13	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 51

Males

Group	Animal No	BB	UN	UR	DE
Control	A1474022	Absent	Absent	0	0
	A1474024	Absent	Absent	0	0
	A1474026	Absent	Absent	0	0
	A1474028	Absent	Absent	0	0
	A1474030	Absent	Absent	1	0

Draft - Not Dosed

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 51

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474052	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474054	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474056	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474058	1	1	1	9	1	Absent	Absent	Absent	Absent
	A1474060	1	1	1	9	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 51

Males

Group	Animal No	BB	UN	UR	DE
2	A1474052	Absent	Absent	0	0
	A1474054	Absent	Absent	0	0
	A1474056	Absent	Absent	0	0
	A1474058	Absent	Absent	0	0
	A1474060	Absent	Absent	0	0

Do Not Distribute - Confidential 2010

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 51

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474082	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474084	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474086	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474088	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474090	1	1	1	10	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 51

Males

Group	Animal No	BB	UN	UR	DE
3	A1474082	Absent	Absent	0	0
	A1474084	Absent	Absent	0	0
	A1474086	Absent	Absent	0	0
	A1474088	Absent	Absent	0	0
	A1474090	Absent	Absent	0	0

DRAFT

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 51

Males

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474112	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474114	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474116	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474118	1	1	1	9	1	Absent	Absent	Absent	Absent
	A1474120	1	1	1	12	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 51

Males

Group	Animal No	BB	UN	UR	DE
4	A1474112	Absent	Absent	0	0
	A1474114	Absent	Absent	0	0
	A1474116	Absent	Absent	0	0
	A1474118	Absent	Absent	0	0
	A1474120	Absent	Absent	0	0

FDA - DRAFT - Not Disclosable 2010

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 2

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474021	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474023	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474025	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474027	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474029	1	1	1	15	1	Absent	Absent	Absent	Absent

DRAFT - Not for Distribution

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 2

Females

Group	Animal No	BB	UN	UR	DE
Control	A1474021	Absent	Absent	0	0
	A1474023	Absent	Absent	0	0
	A1474025	Absent	Absent	0	0
	A1474027	Absent	Absent	0	0
	A1474029	Absent	Absent	0	0

Do Not Quote or Cite

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 2

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474051	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474053	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474055	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474057	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474059	1	1	1	15	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 2

Females

Group	Animal No	BB	UN	UR	DE
2	A1474051	Absent	Absent	0	0
	A1474053	Absent	Absent	0	0
	A1474055	Absent	Absent	0	0
	A1474057	Absent	Absent	0	0
	A1474059	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 2

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474081	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474083	1	1	1	9	1	Absent	Absent	Absent	Absent
	A1474085	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474087	1	1	1	8	1	Absent	Absent	Absent	Absent
	A1474089	1	1	1	13	1	Absent	Absent	Absent	Absent

X - COMPANY CONFIDENTIAL

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 2

Females

Group	Animal No	BB	UN	UR	DE
3	A1474081	Absent	Absent	0	0
	A1474083	Absent	Absent	0	0
	A1474085	Absent	Absent	0	0
	A1474087	Absent	Absent	0	0
	A1474089	Absent	Absent	0	0

GLP - DRAFT - Not Approved 24/19

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 2

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474111	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474113	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474115	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474117	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474119	1	1	1	10	1	Absent	Absent	Absent	Absent

For internal use only

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 2

Females

Group	Animal No	BB	UN	UR	DE
4	A1474111	Absent	Absent	0	0
	A1474113	Absent	Absent	0	0
	A1474115	Absent	Absent	0	0
	A1474117	Absent	Absent	0	0
	A1474119	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 9

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474021	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474023	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474025	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474027	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474029	1	1	1	13	1	Absent	Absent	Absent	Absent

Not Guideline Compliant

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 9

Females

Group	Animal No	BB	UN	UR	DE
Control	A1474021	Absent	Absent	0	0
	A1474023	Absent	Absent	0	0
	A1474025	Absent	Absent	0	0
	A1474027	Absent	Absent	0	0
	A1474029	Absent	Absent	0	0

29 - DRAFT - Not Dated/Signed 2016

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 9

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474051	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474053	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474055	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474057	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474059	1	1	1	17	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 9

Females

Group	Animal No	BB	UN	UR	DE
2	A1474051	Absent	Absent	0	0
	A1474053	Absent	Absent	0	0
	A1474055	Absent	Absent	0	0
	A1474057	Absent	Absent	0	0
	A1474059	Absent	Absent	0	0

GLP - DRAFT - Not Quality Assured

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 9

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474081	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474083	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474085	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474087	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474089	1	1	1	14	1	Absent	Absent	Absent	Absent

For GLP Study Use Only - Do Not Copy

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 9

Females

Group	Animal No	BB	UN	UR	DE
3	A1474081	Absent	Absent	0	0
	A1474083	Absent	Absent	0	0
	A1474085	Absent	Absent	0	0
	A1474087	Absent	Absent	0	0
	A1474089	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 9

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474111	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474113	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474115	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474117	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474119	1	1	1	17	1	Absent	Absent	Absent	Absent

For library use only

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 9

Females

Group	Animal No	BB	UN	UR	DE
4	A1474111	Absent	Absent	0	0
	A1474113	Absent	Absent	0	0
	A1474115	Absent	Absent	0	0
	A1474117	Absent	Absent	0	0
	A1474119	Absent	Absent	0	0

DRAFT - NOT FOR DISTRIBUTION

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 16

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474021	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474023	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474025	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474027	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474029	1	1	1	16	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 16

Females

Group	Animal No	BB	UN	UR	DE
Control	A1474021	Absent	Absent	0	0
	A1474023	Absent	Absent	0	0
	A1474025	Absent	Absent	0	0
	A1474027	Absent	Absent	0	0
	A1474029	Absent	Absent	0	0

GLP - IVMAS - Final December 2016

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 16

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474051	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474053	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474055	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474057	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474059	1	1	1	19	1	Absent	Absent	Absent	Absent

Final Version - 13 October 2015

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 16

Females

Group	Animal No	BB	UN	UR	DE
2	A1474051	Absent	Absent	0	0
	A1474053	Absent	Absent	0	0
	A1474055	Absent	Absent	0	0
	A1474057	Absent	Absent	0	0
	A1474059	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 16

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474081	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474083	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474085	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474087	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474089	1	1	1	16	1	Absent	Absent	Absent	Absent

For Study Director Review Only

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 16

Females

Group	Animal No	BB	UN	UR	DE
3	A1474081	Absent	Absent	0	0
	A1474083	Absent	Absent	0	0
	A1474085	Absent	Absent	0	0
	A1474087	Absent	Absent	0	0
	A1474089	Absent	Absent	0	0

Not - Drug - Test Treatment Group

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 16

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474111	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474113	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474115	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474117	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474119	1	1	1	13	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 16

Females

Group	Animal No	BB	UN	UR	DE
4	A1474111	Absent	Absent	0	0
	A1474113	Absent	Absent	0	0
	A1474115	Absent	Absent	0	0
	A1474117	Absent	Absent	0	0
	A1474119	Absent	Absent	0	0

GLP - Draft - 16th December 2015

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 23

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474021	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474023	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474025	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474027	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474029	1	1	1	16	1	Absent	Absent	Absent	Absent

Study Director Signature Date

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 23

Females

Group	Animal No	BB	UN	UR	DE
Control	A1474021	Absent	Absent	0	0
	A1474023	Absent	Absent	0	0
	A1474025	Absent	Absent	0	0
	A1474027	Absent	Absent	0	0
	A1474029	Absent	Absent	0	0

For Inspection Purposes Only

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 23

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474051	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474053	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474055	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474057	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474059	1	1	1	18	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 23

Females

Group	Animal No	BB	UN	UR	DE
2	A1474051	Absent	Absent	0	0
	A1474053	Absent	Absent	0	0
	A1474055	Absent	Absent	0	0
	A1474057	Absent	Absent	0	0
	A1474059	Absent	Absent	0	0

DRAFT - NOT FOR SIGNATURE

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 23

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474081	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474083	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474085	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474087	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474089	1	1	1	18	1	Absent	Absent	Absent	Absent

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 23

Females

Group	Animal No	BB	UN	UR	DE
3	A1474081	Absent	Absent	0	0
	A1474083	Absent	Absent	0	0
	A1474085	Absent	Absent	0	0
	A1474087	Absent	Absent	0	0
	A1474089	Absent	Absent	0	0

DRAFT - Not for Distribution 2016

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 23

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474111	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474113	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474115	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474117	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474119	1	1	1	16	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 23

Females

Group	Animal No	BB	UN	UR	DE
4	A1474111	Absent	Absent	0	0
	A1474113	Absent	Absent	0	0
	A1474115	Absent	Absent	0	0
	A1474117	Absent	Absent	0	0
	A1474119	Absent	Absent	0	0

Study - GLP/GCP - Not Guaranteed 2010

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 30

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474021	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474023	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474025	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474027	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474029	1	1	1	11	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 30

Females

Group	Animal No	BB	UN	UR	DE
Control	A1474021	Absent	Absent	0	0
	A1474023	Absent	Absent	0	0
	A1474025	Absent	Absent	0	0
	A1474027	Absent	Absent	0	0
	A1474029	Absent	Absent	0	0

FOR - DRAFT - NOT FOR SUBMISSION

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 30

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474051	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474053	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474055	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474057	1	1	1	9	1	Absent	Absent	Absent	Absent
	A1474059	1	1	1	15	1	Absent	Absent	Absent	Absent

Study Director Signature Date 2016

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 30

Females

Group	Animal No	BB	UN	UR	DE
2	A1474051	Absent	Absent	0	0
	A1474053	Absent	Absent	0	0
	A1474055	Absent	Absent	0	0
	A1474057	Absent	Absent	0	0
	A1474059	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 30

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474081	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474083	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474085	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474087	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474089	1	1	1	12	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 30

Females

Group	Animal No	BB	UN	UR	DE
3	A1474081	Absent	Absent	0	0
	A1474083	Absent	Absent	0	0
	A1474085	Absent	Absent	0	0
	A1474087	Absent	Absent	0	0
	A1474089	Absent	Absent	0	0

FOR ORIGINAL - Signed Document - 2010

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 30

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474111	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474113	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474115	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474117	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474119	1	1	1	15	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 30

Females

Group	Animal No	BB	UN	UR	DE
4	A1474111	Absent	Absent	0	0
	A1474113	Absent	Absent	0	0
	A1474115	Absent	Absent	0	0
	A1474117	Absent	Absent	0	0
	A1474119	Absent	Absent	0	0

FOR INTERNAL USE ONLY

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 37

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474021	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474023	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474025	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474027	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474029	1	1	1	10	1	Absent	Absent	Absent	Absent

Not Guideline Study

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 37

Females

Group	Animal No	BB	UN	UR	DE
Control	A1474021	Absent	Absent	0	0
	A1474023	Absent	Absent	0	0
	A1474025	Absent	Absent	0	0
	A1474027	Absent	Absent	0	0
	A1474029	Absent	Absent	0	0

DRAFT - Not Dissemination 2010

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 37

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474051	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474053	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474055	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474057	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474059	1	1	1	14	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 37

Females

Group	Animal No	BB	UN	UR	DE
2	A1474051	Absent	Absent	0	0
	A1474053	Absent	Absent	0	0
	A1474055	Absent	Absent	0	0
	A1474057	Absent	Absent	0	0
	A1474059	Absent	Absent	0	0

For DRAFT - Not Guideline

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 37

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474081	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474083	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474085	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474087	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474089	1	1	1	19	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 37

Females

Group	Animal No	BB	UN	UR	DE
3	A1474081	Absent	Absent	0	0
	A1474083	Absent	Absent	0	0
	A1474085	Absent	Absent	0	0
	A1474087	Absent	Absent	0	0
	A1474089	Absent	Absent	0	0

Not to be used for commercial purposes

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 37

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474111	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474113	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474115	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474117	1	1	1	10	1	Absent	Absent	Absent	Absent
	A1474119	1	1	1	12	1	Absent	Absent	Absent	Absent

For Official Use Only

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 37

Females

Group	Animal No	BB	UN	UR	DE
4	A1474111	Absent	Absent	0	0
	A1474113	Absent	Absent	0	0
	A1474115	Absent	Absent	0	0
	A1474117	Absent	Absent	0	0
	A1474119	Absent	Absent	0	0

GLP - Draft - Not Operational Data

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 44

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474021	1	1	1	21	1	Absent	Absent	Absent	Absent
	A1474023	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474025	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474027	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474029	1	1	1	23	1	Absent	Absent	Absent	Absent

Study Director Initial Date: 4/1/10

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 44

Females

Group	Animal No	BB	UN	UR	DE
Control	A1474021	Absent	Absent	0	0
	A1474023	Absent	Absent	0	0
	A1474025	Absent	Absent	0	0
	A1474027	Absent	Absent	0	0
	A1474029	Absent	Absent	0	0

For Client Review Only

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 44

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474051	1	1	1	11	1	Absent	Absent	Absent	Absent
	A1474053	1	1	1	25	1	Absent	Absent	Absent	Absent
	A1474055	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474057	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474059	1	1	1	17	1	Absent	Absent	Absent	Absent

For Internal Use Only 2010

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 44

Females

Group	Animal No	BB	UN	UR	DE
2	A1474051	Absent	Absent	0	0
	A1474053	Absent	Absent	0	0
	A1474055	Absent	Absent	0	0
	A1474057	Absent	Absent	0	0
	A1474059	Absent	Absent	0	0

GLP Quality Control Document

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 44

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474081	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474083	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474085	1	1	1	12	1	Absent	Absent	Absent	Absent
	A1474087	1	1	1	20	1	Absent	Absent	Absent	Absent
	A1474089	1	1	1	13	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 44

Females

Group	Animal No	BB	UN	UR	DE
3	A1474081	Absent	Absent	0	0
	A1474083	Absent	Absent	0	0
	A1474085	Absent	Absent	0	0
	A1474087	Absent	Absent	0	0
	A1474089	Absent	Absent	0	0

[illegible] 2016

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 44

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474111	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474113	1	1	1	13	1	Absent	Absent	Absent	Absent
	A1474115	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474117	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474119	1	1	1	15	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 44

Females

Group	Animal No	BB	UN	UR	DE
4	A1474111	Absent	Absent	0	0
	A1474113	Absent	Absent	0	0
	A1474115	Absent	Absent	0	0
	A1474117	Absent	Absent	0	0
	A1474119	Absent	Absent	0	0

DRAFT - NOT FOR DISTRIBUTION

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 51

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
Control	A1474021	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474023	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474025	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474027	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474029	1	1	1	16	1	Absent	Absent	Absent	Absent

Draft - Not for Distribution 2010

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 51

Females

Group	Animal No	BB	UN	UR	DE
Control	A1474021	Absent	Absent	0	0
	A1474023	Absent	Absent	1	0
	A1474025	Absent	Absent	0	0
	A1474027	Absent	Absent	0	0
	A1474029	Absent	Absent	0	0

FDA - DRAFT - Not for distribution 2010

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 51

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
2	A1474051	1	1	1	15	1	Absent	Absent	Absent	Absent
	A1474053	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474055	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474057	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474059	1	1	1	19	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 51

Females

Group	Animal No	BB	UN	UR	DE
2	A1474051	Absent	Absent	0	0
	A1474053	Absent	Absent	0	0
	A1474055	Absent	Absent	0	0
	A1474057	Absent	Absent	1	0
	A1474059	Absent	Absent	0	0

FOR INTERNAL USE ONLY

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 51

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
3	A1474081	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474083	1	1	1	18	1	Absent	Absent	Absent	Absent
	A1474085	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474087	1	1	1	17	1	Absent	Absent	Absent	Absent
	A1474089	1	1	1	15	1	Absent	Absent	Absent	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 51

Females

Group	Animal No	BB	UN	UR	DE
3	A1474081	Absent	Absent	0	0
	A1474083	Absent	Absent	0	0
	A1474085	Absent	Absent	0	0
	A1474087	Absent	Absent	0	0
	A1474089	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 51

Females

Group	Animal No	AR	MI	GA	RE	SP	MY	TR	VC	ST
4	A1474111	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474113	1	1	1	16	1	Absent	Absent	Absent	Absent
	A1474115	1	1	1	19	1	Absent	Absent	Absent	Absent
	A1474117	1	1	1	14	1	Absent	Absent	Absent	Absent
	A1474119	1	1	1	12	1	Absent	Absent	Absent	Absent

NOT ORIGINAL TERMINATION BODY

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 51

Females

Group	Animal No	BB	UN	UR	DE
4	A1474111	Absent	Absent	0	0
	A1474113	Absent	Absent	0	0
	A1474115	Absent	Absent	0	0
	A1474117	Absent	Absent	0	0
	A1474119	Absent	Absent	0	0

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Allocation Day 3

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474002	1	2	1	1	1	Absent
	A1474004	1	2	1	1	1	Absent
	A1474006	1	2	1	1	1	Absent
	A1474008	1	2	1	1	1	Absent
	A1474010	1	2	1	1	1	Absent
	A1474012	1	2	1	1	1	Absent
	A1474014	1	2	1	1	1	Absent
	A1474016	1	2	1	1	1	Absent
	A1474018	1	2	1	1	1	Absent
	A1474020	1	2	1	1	1	Absent
	A1474022	1	2	1	1	1	Absent
	A1474024	1	2	1	1	1	Absent
	A1474026	1	2	1	1	1	Absent
	A1474028	1	2	1	1	1	Absent
	A1474030	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Allocation Day 3

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474032	1	2	1	1	1	Absent
	A1474034	1	2	1	1	1	Absent
	A1474036	1	2	1	1	1	Absent
	A1474038	1	2	1	1	1	Absent
	A1474040	1	2	1	1	1	Absent
	A1474042	1	2	1	1	1	Absent
	A1474044	1	2	1	1	1	Absent
	A1474046	1	2	1	1	1	Absent
	A1474048	1	2	1	1	1	Absent
	A1474050	1	2	1	1	1	Absent
	A1474052	1	2	1	1	1	Absent
	A1474054	1	2	1	1	1	Absent
	A1474056	1	2	1	1	1	Absent
	A1474058	1	2	1	1	1	Absent
	A1474060	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Allocation Day 3

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474062	1	2	1	1	1	Absent
	A1474064	1	2	1	1	1	Absent
	A1474066	1	2	1	1	1	Absent
	A1474068	1	2	1	1	1	Absent
	A1474070	1	2	1	1	1	Absent
	A1474072	1	2	1	1	1	Absent
	A1474074	1	2	1	1	1	Absent
	A1474076	1	2	1	1	1	Absent
	A1474078	1	2	1	1	1	Absent
	A1474080	1	2	1	1	1	Absent
	A1474082	1	2	1	1	1	Absent
	A1474084	1	2	1	1	1	Absent
	A1474086	1	2	1	1	1	Absent
	A1474088	1	2	1	1	1	Absent
	A1474090	1	2	1	1	1	Absent

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Allocation Day 3

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474092	1	2	1	1	1	Absent
	A1474094	1	2	1	1	1	Absent
	A1474096	1	2	1	1	1	Absent
	A1474098	1	2	1	1	1	Absent
	A1474100	1	2	1	1	1	Absent
	A1474102	1	2	1	1	1	Absent
	A1474104	1	2	1	1	1	Absent
	A1474106	1	2	1	1	1	Absent
	A1474108	1	2	1	1	1	Absent
	A1474110	1	2	1	1	1	Absent
	A1474112	1	2	1	1	1	Absent
	A1474114	1	2	1	1	1	Absent
	A1474116	1	2	1	1	1	Absent
	A1474118	1	2	1	1	1	Absent
	A1474120	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Allocation Day 4

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474001	1	2	1	1	1	Absent
	A1474003	1	2	1	1	1	Absent
	A1474005	1	2	1	1	1	Absent
	A1474007	1	2	1	1	1	Absent
	A1474009	1	2	1	1	1	Absent
	A1474011	1	2	1	1	1	Absent
	A1474013	1	2	1	1	1	Absent
	A1474015	1	2	1	1	1	Absent
	A1474017	1	2	1	1	1	Absent
	A1474019	1	2	1	1	1	Absent
	A1474021	1	2	1	1	1	-
	A1474023	1	2	1	1	1	Absent
	A1474025	1	2	1	1	1	Absent
	A1474027	1	2	1	1	1	Absent
	A1474029	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Allocation Day 4

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474031	1	2	1	1	1	Absent
	A1474033	1	2	1	1	1	Absent
	A1474035	1	2	1	1	1	Absent
	A1474037	1	2	1	1	1	Absent
	A1474039	1	2	1	1	1	Absent
	A1474041	1	2	1	1	1	Absent
	A1474043	1	2	1	1	1	Absent
	A1474045	1	2	1	1	1	Absent
	A1474047	1	2	1	1	1	Absent
	A1474049	1	2	1	1	1	Absent
	A1474051	1	2	1	1	1	Absent
	A1474053	1	2	1	1	1	Absent
	A1474055	1	2	1	1	1	Absent
	A1474057	1	2	1	1	1	Absent
	A1474059	1	2	1	1	1	Absent

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Allocation Day 4

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474061	1	2	1	1	1	Absent
	A1474063	1	2	1	1	1	Absent
	A1474065	1	2	1	1	1	Absent
	A1474067	1	2	1	1	1	Absent
	A1474069	1	2	1	1	1	Absent
	A1474071	1	2	1	1	1	Absent
	A1474073	1	2	1	1	1	Absent
	A1474075	1	2	1	1	1	Absent
	A1474077	1	2	1	1	1	Absent
	A1474079	1	2	1	1	1	Absent
	A1474081	1	2	1	1	1	Absent
	A1474083	1	2	1	1	1	Absent
	A1474085	1	2	1	1	1	Absent
	A1474087	1	2	1	1	1	Absent
	A1474089	1	2	1	1	1	Absent

For Study Director Use Only

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Allocation Day 4

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474091	1	2	1	1	1	Absent
	A1474093	1	2	1	1	1	Absent
	A1474095	1	2	1	1	1	Absent
	A1474097	1	2	1	1	1	Absent
	A1474099	1	2	1	1	1	Absent
	A1474101	1	2	1	1	1	Absent
	A1474103	1	2	1	1	1	Absent
	A1474105	1	2	1	1	1	Absent
	A1474107	1	2	1	1	1	Absent
	A1474109	1	2	1	1	1	Absent
	A1474111	1	2	1	1	1	Absent
	A1474113	1	2	1	1	1	Absent
	A1474115	1	2	1	1	1	Absent
	A1474117	1	2	1	1	1	Absent
	A1474119	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 2

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474002	1	2	1	1	1	Absent
	A1474004	1	2	1	1	1	Absent
	A1474006	1	2	1	1	1	Absent
	A1474008	1	2	1	1	1	Absent
	A1474010	1	2	1	1	1	Absent
	A1474012	1	2	1	1	1	Absent
	A1474014	1	2	1	1	1	Absent
	A1474016	1	2	1	1	1	Absent
	A1474018	1	2	1	1	1	Absent
	A1474020	1	2	1	1	1	Absent
	A1474022	1	2	1	1	1	Absent
	A1474024	1	2	1	1	1	Absent
	A1474026	1	2	1	1	1	Absent
	A1474028	1	2	1	1	1	Absent
	A1474030	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 2

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474032	1	2	1	1	1	Absent
	A1474034	1	2	1	1	1	Absent
	A1474036	1	2	1	1	1	Absent
	A1474038	1	2	1	1	1	Absent
	A1474040	1	2	1	1	1	Absent
	A1474042	1	2	1	1	1	Absent
	A1474044	1	2	1	1	1	Absent
	A1474046	1	2	1	1	1	Absent
	A1474048	1	2	1	1	1	Absent
	A1474050	1	2	1	1	1	Absent
	A1474052	1	2	1	1	1	Absent
	A1474054	1	2	1	1	1	Absent
	A1474056	1	2	1	1	1	Absent
	A1474058	1	2	1	1	1	Absent
	A1474060	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 2

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474062	1	2	1	1	1	Absent
	A1474064	1	2	1	1	1	Absent
	A1474066	1	2	1	1	1	Absent
	A1474068	1	2	1	1	1	Absent
	A1474070	1	2	1	1	1	Absent
	A1474072	1	2	1	1	1	Absent
	A1474074	1	2	1	1	1	Absent
	A1474076	1	2	1	1	1	Absent
	A1474078	1	2	1	1	1	Absent
	A1474080	1	2	1	1	1	Absent
	A1474082	1	2	1	1	1	Absent
	A1474084	1	2	1	1	1	Absent
	A1474086	1	2	1	1	1	Absent
	A1474088	1	2	1	1	1	Absent
	A1474090	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 2

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474092	1	2	1	1	1	Absent
	A1474094	1	2	1	1	1	Absent
	A1474096	1	2	1	1	1	Absent
	A1474098	1	2	1	1	1	Absent
	A1474100	1	2	1	1	1	Absent
	A1474102	1	2	1	1	1	Absent
	A1474104	1	2	1	1	1	Absent
	A1474106	1	2	1	1	1	Absent
	A1474108	1	2	1	1	1	Absent
	A1474110	1	2	1	1	1	Absent
	A1474112	1	2	1	1	1	Absent
	A1474114	1	2	1	1	1	Absent
	A1474116	1	2	1	1	1	Absent
	A1474118	1	2	1	1	1	Absent
	A1474120	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 9

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474002	1	2	1	1	1	Absent
	A1474004	1	2	1	1	1	Absent
	A1474006	1	2	1	1	1	Absent
	A1474008	1	2	1	1	1	Absent
	A1474010	1	2	1	1	1	Absent
	A1474012	1	2	1	1	1	Absent
	A1474014	1	2	1	1	1	Absent
	A1474016	1	2	1	1	1	Absent
	A1474018	1	2	1	1	1	Absent
	A1474020	1	2	1	1	1	Absent
	A1474022	1	2	1	1	1	Absent
	A1474024	1	2	1	1	1	Absent
	A1474026	1	2	1	1	1	Absent
	A1474028	1	2	1	1	1	Absent
	A1474030	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 9

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474032	1	2	1	1	1	Absent
	A1474034	1	2	1	1	1	Absent
	A1474036	1	2	1	1	1	Absent
	A1474038	1	2	1	1	1	Absent
	A1474040	1	2	1	1	1	Absent
	A1474042	1	2	1	1	1	Absent
	A1474044	1	2	1	1	1	Absent
	A1474046	1	2	1	1	1	Absent
	A1474048	1	2	1	1	1	Absent
	A1474050	1	2	1	1	1	Absent
	A1474052	1	2	1	1	1	Absent
	A1474054	1	2	1	1	1	Absent
	A1474056	1	2	1	1	1	Absent
	A1474058	1	2	1	1	1	Absent
	A1474060	1	2	1	1	1	Absent

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 9

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474062	1	2	1	1	1	Absent
	A1474064	1	2	1	1	1	Absent
	A1474066	1	2	1	1	1	Absent
	A1474068	1	2	1	1	1	Absent
	A1474070	1	2	1	1	1	Absent
	A1474072	1	2	1	1	1	Absent
	A1474074	1	2	1	1	1	Absent
	A1474076	1	2	1	1	1	Absent
	A1474078	1	2	1	1	1	Absent
	A1474080	1	2	1	1	1	Absent
	A1474082	1	2	1	1	1	Absent
	A1474084	1	2	1	1	1	Absent
	A1474086	1	2	1	1	1	Absent
	A1474088	1	2	1	1	1	Absent
	A1474090	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 9

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474092	1	2	1	1	1	Absent
	A1474094	1	2	1	1	1	Absent
	A1474096	1	2	1	1	1	Absent
	A1474098	1	2	1	1	1	Absent
	A1474100	1	2	1	1	1	Absent
	A1474102	1	2	1	1	1	Absent
	A1474104	1	2	1	1	1	Absent
	A1474106	1	2	1	1	1	Absent
	A1474108	1	2	1	1	1	Absent
	A1474110	1	2	1	1	1	Absent
	A1474112	1	2	1	1	1	Absent
	A1474114	1	2	1	1	1	Absent
	A1474116	1	2	1	1	1	Absent
	A1474118	1	2	1	1	1	Absent
	A1474120	1	2	1	1	1	Absent

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 16

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474002	1	2	1	1	1	Absent
	A1474004	1	2	1	1	1	Absent
	A1474006	1	2	1	1	1	Absent
	A1474008	1	2	1	1	1	Absent
	A1474010	1	2	1	1	1	Absent
	A1474012	1	2	1	1	1	Absent
	A1474014	1	2	1	1	1	Absent
	A1474016	1	2	1	1	1	Absent
	A1474018	1	2	1	1	1	Absent
	A1474020	1	2	1	1	1	Absent
	A1474022	1	2	1	1	1	Absent
	A1474024	1	2	1	1	1	Absent
	A1474026	1	2	1	1	1	Absent
	A1474028	1	2	1	1	1	Absent
	A1474030	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 16

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474032	1	2	1	1	1	Absent
	A1474034	1	2	1	1	1	Absent
	A1474036	1	2	1	1	1	Absent
	A1474038	1	2	1	1	1	Absent
	A1474040	1	2	1	1	1	Absent
	A1474042	1	2	1	1	1	Absent
	A1474044	1	2	1	1	1	Absent
	A1474046	1	2	1	1	1	Absent
	A1474048	1	2	1	1	1	Absent
	A1474050	1	2	1	1	1	Absent
	A1474052	1	2	1	1	1	Absent
	A1474054	1	2	1	1	1	Absent
	A1474056	1	2	1	1	1	Absent
	A1474058	1	2	1	1	1	Absent
	A1474060	1	2	1	1	1	Absent

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 16

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474062	1	2	1	1	1	Absent
	A1474064	1	2	1	1	1	Absent
	A1474066	1	2	1	1	1	Absent
	A1474068	1	2	1	1	1	Absent
	A1474070	1	2	1	1	1	Absent
	A1474072	1	2	1	1	1	Absent
	A1474074	1	2	1	1	1	Absent
	A1474076	1	2	1	1	1	Absent
	A1474078	1	2	1	1	1	Absent
	A1474080	1	2	1	1	1	Absent
	A1474082	1	2	1	1	1	Absent
	A1474084	1	2	1	1	1	Absent
	A1474086	1	2	1	1	1	Absent
	A1474088	1	2	1	1	1	Absent
	A1474090	1	2	1	1	1	Absent

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REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 16

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474092	1	2	1	1	1	Absent
	A1474094	1	2	1	1	1	Absent
	A1474096	1	2	1	1	1	Absent
	A1474098	1	2	1	1	1	Absent
	A1474100	1	2	1	1	1	Absent
	A1474102	1	2	1	1	1	Absent
	A1474104	1	2	1	1	1	Absent
	A1474106	1	2	1	1	1	Absent
	A1474108	1	2	1	1	1	Absent
	A1474110	1	2	1	1	1	Absent
	A1474112	1	2	1	1	1	Absent
	A1474114	1	2	1	1	1	Absent
	A1474116	1	2	1	1	1	Absent
	A1474118	1	2	1	1	1	Absent
	A1474120	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 23

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474002	1	2	1	1	1	Absent
	A1474004	1	2	1	1	1	Absent
	A1474006	1	2	1	1	1	Absent
	A1474008	1	2	1	1	1	Absent
	A1474010	1	2	1	1	1	Absent
	A1474012	1	2	1	1	1	Absent
	A1474014	1	2	1	1	1	Absent
	A1474016	1	2	1	1	1	Absent
	A1474018	1	2	1	1	1	Absent
	A1474020	1	2	1	1	1	Absent
	A1474022	1	2	1	1	1	Absent
	A1474024	1	2	1	1	1	Absent
	A1474026	1	2	1	1	1	Absent
	A1474028	1	2	1	1	1	Absent
	A1474030	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 23

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474032	1	2	1	1	1	Absent
	A1474034	1	2	1	1	1	Absent
	A1474036	1	2	1	1	1	Absent
	A1474038	1	2	1	1	1	Absent
	A1474040	1	2	1	1	1	Absent
	A1474042	1	2	1	1	1	Absent
	A1474044	1	2	1	1	1	Absent
	A1474046	1	2	1	1	1	Absent
	A1474048	1	2	1	1	1	Absent
	A1474050	1	2	1	1	1	Absent
	A1474052	1	2	1	1	1	Absent
	A1474054	1	2	1	1	1	Absent
	A1474056	1	2	1	1	1	Absent
	A1474058	1	2	1	1	1	Absent
	A1474060	1	2	1	1	1	Absent

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REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 23

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474062	1	2	1	1	1	Absent
	A1474064	1	2	1	1	1	Absent
	A1474066	1	2	1	1	1	Absent
	A1474068	1	2	1	1	1	Absent
	A1474070	1	2	1	1	1	Absent
	A1474072	1	2	1	1	1	Absent
	A1474074	1	2	1	1	1	Absent
	A1474076	1	2	1	1	1	Absent
	A1474078	1	2	1	1	1	Absent
	A1474080	1	2	1	1	1	Absent
	A1474082	1	2	1	1	1	Absent
	A1474084	1	2	1	1	1	Absent
	A1474086	1	2	1	1	1	Absent
	A1474088	1	2	1	1	1	Absent
	A1474090	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 23

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474092	1	2	1	1	1	Absent
	A1474094	1	2	1	1	1	Absent
	A1474096	1	2	1	1	1	Absent
	A1474098	1	2	1	1	1	Absent
	A1474100	1	2	1	1	1	Absent
	A1474102	1	2	1	1	1	Absent
	A1474104	1	2	1	1	1	Absent
	A1474106	1	2	1	1	1	Absent
	A1474108	1	2	1	1	1	Absent
	A1474110	1	2	1	1	1	Absent
	A1474112	1	2	1	1	1	Absent
	A1474114	1	2	1	1	1	Absent
	A1474116	1	2	1	1	1	Absent
	A1474118	1	2	1	1	1	Absent
	A1474120	1	2	1	1	1	Absent

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 30

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474002	1	2	1	1	1	Absent
	A1474004	1	2	1	1	1	Absent
	A1474006	1	2	1	1	1	Absent
	A1474008	1	2	1	1	1	Absent
	A1474010	1	2	1	1	1	Absent
	A1474012	1	2	1	1	1	Absent
	A1474014	1	2	1	1	1	Absent
	A1474016	1	2	1	1	1	Absent
	A1474018	1	2	1	1	1	Absent
	A1474020	1	2	1	1	1	Absent
	A1474022	1	2	1	1	1	Absent
	A1474024	1	2	1	1	1	Absent
	A1474026	1	2	1	1	1	Absent
	A1474028	1	2	1	1	1	Absent
	A1474030	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 30

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474032	1	2	1	1	1	Absent
	A1474034	1	2	1	1	1	Absent
	A1474036	1	2	1	1	1	Absent
	A1474038	1	2	1	1	1	Absent
	A1474040	1	2	1	1	1	Absent
	A1474042	1	2	1	1	1	Absent
	A1474044	1	2	1	1	1	Absent
	A1474046	1	2	1	1	1	Absent
	A1474048	1	2	1	1	1	Absent
	A1474050	1	2	1	1	1	Absent
	A1474052	1	2	1	1	1	Absent
	A1474054	1	2	1	1	1	Absent
	A1474056	1	2	1	1	1	Absent
	A1474058	1	2	1	1	1	Absent
	A1474060	1	2	1	1	1	Absent

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REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 30

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474062	1	2	1	1	1	Absent
	A1474064	1	2	1	1	1	Absent
	A1474066	1	2	1	1	1	Absent
	A1474068	1	2	1	1	1	Absent
	A1474070	1	2	1	1	1	Absent
	A1474072	1	2	1	1	1	Absent
	A1474074	1	2	1	1	1	Absent
	A1474076	1	2	1	1	1	Absent
	A1474078	1	2	1	1	1	Absent
	A1474080	1	2	1	1	1	Absent
	A1474082	1	2	1	1	1	Absent
	A1474084	1	2	1	1	1	Absent
	A1474086	1	2	1	1	1	Absent
	A1474088	1	2	1	1	1	Absent
	A1474090	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 30

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474092	1	2	1	1	1	Absent
	A1474094	1	2	1	1	1	Absent
	A1474096	1	2	1	1	1	Absent
	A1474098	1	2	1	1	1	Absent
	A1474100	1	2	1	1	1	Absent
	A1474102	1	2	1	1	1	Absent
	A1474104	1	2	1	1	1	Absent
	A1474106	1	2	1	1	1	Absent
	A1474108	1	2	1	1	1	Absent
	A1474110	1	2	1	1	1	Absent
	A1474112	1	2	1	1	1	Absent
	A1474114	1	2	1	1	1	Absent
	A1474116	1	2	1	1	1	Absent
	A1474118	1	2	1	1	1	Absent
	A1474120	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 37

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474002	1	2	1	1	1	Absent
	A1474004	1	2	1	1	1	Absent
	A1474006	1	2	1	1	1	Absent
	A1474008	1	2	1	1	1	Absent
	A1474010	1	2	1	1	1	Absent
	A1474012	1	2	1	1	1	Absent
	A1474014	1	2	1	1	1	Absent
	A1474016	1	2	1	1	1	Absent
	A1474018	1	2	1	1	1	Absent
	A1474020	1	2	1	1	1	Absent
	A1474022	1	2	1	1	1	Absent
	A1474024	1	2	1	1	1	Absent
	A1474026	1	2	1	1	1	Absent
	A1474028	1	2	1	1	1	Absent
	A1474030	1	2	1	1	1	Absent

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 37

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474032	1	2	1	1	1	Absent
	A1474034	1	2	1	1	1	Absent
	A1474036	1	2	1	1	1	Absent
	A1474038	1	2	1	1	1	Absent
	A1474040	1	2	1	1	1	Absent
	A1474042	1	2	1	1	1	Absent
	A1474044	1	2	1	1	1	Absent
	A1474046	1	2	1	1	1	Absent
	A1474048	1	2	1	1	1	Absent
	A1474050	1	2	1	1	1	Absent
	A1474052	1	2	1	1	1	Absent
	A1474054	1	2	1	1	1	Absent
	A1474056	1	2	1	1	1	Absent
	A1474058	1	2	1	1	1	Absent
	A1474060	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 37

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474062	1	2	1	1	1	Absent
	A1474064	1	2	1	1	1	Absent
	A1474066	1	2	1	1	1	Absent
	A1474068	1	2	1	1	1	Absent
	A1474070	1	2	1	1	1	Absent
	A1474072	1	2	1	1	1	Absent
	A1474074	1	2	1	1	1	Absent
	A1474076	1	2	1	1	1	Absent
	A1474078	1	2	1	1	1	Absent
	A1474080	1	2	1	1	1	Absent
	A1474082	1	2	1	1	1	Absent
	A1474084	1	2	1	1	1	Absent
	A1474086	1	2	1	1	1	Absent
	A1474088	1	2	1	1	1	Absent
	A1474090	1	2	1	1	1	Absent

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 37

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474092	1	2	1	1	1	Absent
	A1474094	1	2	1	1	1	Absent
	A1474096	1	2	1	1	1	Absent
	A1474098	1	2	1	1	1	Absent
	A1474100	1	2	1	1	1	Absent
	A1474102	1	2	1	1	1	Absent
	A1474104	1	2	1	1	1	Absent
	A1474106	1	2	1	1	1	Absent
	A1474108	1	2	1	1	1	Absent
	A1474110	1	2	1	1	1	Absent
	A1474112	1	2	1	1	1	Absent
	A1474114	1	2	1	1	1	Absent
	A1474116	1	2	1	1	1	Absent
	A1474118	1	2	1	1	1	Absent
	A1474120	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 44

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474002	1	2	1	1	1	Absent
	A1474004	1	2	1	1	1	Absent
	A1474006	1	2	1	1	1	Absent
	A1474008	1	2	1	1	1	Absent
	A1474010	1	2	1	1	1	Absent
	A1474012	1	2	1	1	1	Absent
	A1474014	1	2	1	1	1	Absent
	A1474016	1	2	1	1	1	Absent
	A1474018	1	2	1	1	1	Absent
	A1474020	1	2	1	1	1	Absent
	A1474022	1	2	1	1	1	Absent
	A1474024	1	2	1	1	1	Absent
	A1474026	1	2	1	1	1	Absent
	A1474028	1	2	1	1	1	Absent
	A1474030	1	2	1	1	1	Absent

DRAFT - Not for Circulation

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 44

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474032	1	2	1	1	1	Absent
	A1474034	1	2	1	1	1	Absent
	A1474036	1	2	1	1	1	Absent
	A1474038	1	2	1	1	1	Absent
	A1474040	1	2	1	1	1	Absent
	A1474042	1	2	1	1	1	Absent
	A1474044	1	2	1	1	1	Absent
	A1474046	1	2	1	1	1	Absent
	A1474048	1	2	1	1	1	Absent
	A1474050	1	2	1	1	1	Absent
	A1474052	1	2	1	1	1	Absent
	A1474054	1	2	1	1	1	Absent
	A1474056	1	2	1	1	1	Absent
	A1474058	1	2	1	1	1	Absent
	A1474060	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 44

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474062	1	2	1	1	1	Absent
	A1474064	1	2	1	1	1	Absent
	A1474066	1	2	1	1	1	Absent
	A1474068	1	2	1	1	1	Absent
	A1474070	1	2	1	1	1	Absent
	A1474072	1	2	1	1	1	Absent
	A1474074	1	2	1	1	1	Absent
	A1474076	1	2	1	1	1	Absent
	A1474078	1	2	1	1	1	Absent
	A1474080	1	2	1	1	1	Absent
	A1474082	1	2	1	1	1	Absent
	A1474084	1	2	1	1	1	Absent
	A1474086	1	2	1	1	1	Absent
	A1474088	1	2	1	1	1	Absent
	A1474090	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 44

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474092	1	2	1	1	1	Absent
	A1474094	1	2	1	1	1	Absent
	A1474096	1	2	1	1	1	Absent
	A1474098	1	2	1	1	1	Absent
	A1474100	1	2	1	1	1	Absent
	A1474102	1	2	1	1	1	Absent
	A1474104	1	2	1	1	1	Absent
	A1474106	1	2	1	1	1	Absent
	A1474108	1	2	1	1	1	Absent
	A1474110	1	2	1	1	1	Absent
	A1474112	1	2	1	1	1	Absent
	A1474114	1	2	1	1	1	Absent
	A1474116	1	2	1	1	1	Absent
	A1474118	1	2	1	1	1	Absent
	A1474120	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 51

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474002	1	2	1	1	1	Absent
	A1474004	1	2	1	1	1	Absent
	A1474006	1	2	1	1	1	Absent
	A1474008	1	2	1	1	1	Absent
	A1474010	1	2	1	1	1	Absent
	A1474012	1	2	1	1	1	Absent
	A1474014	1	2	1	1	1	Absent
	A1474016	1	2	1	1	1	Absent
	A1474018	1	2	1	1	1	Absent
	A1474020	1	2	1	1	1	Absent
	A1474022	1	2	1	1	1	Absent
	A1474024	1	2	1	1	1	Absent
	A1474026	1	2	1	1	1	Absent
	A1474028	1	2	1	1	1	Absent
	A1474030	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 51

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474032	1	2	1	1	1	Absent
	A1474034	1	2	1	1	1	Absent
	A1474036	1	2	1	1	1	Absent
	A1474038	1	2	1	1	1	Absent
	A1474040	1	2	1	1	1	Absent
	A1474042	1	2	1	1	1	Absent
	A1474044	1	2	1	1	1	Absent
	A1474046	1	2	1	1	1	Absent
	A1474048	1	2	1	1	1	Absent
	A1474050	1	2	1	1	1	Absent
	A1474052	1	2	1	1	1	Absent
	A1474054	1	2	1	1	1	Absent
	A1474056	1	2	1	1	1	Absent
	A1474058	1	2	1	1	1	Absent
	A1474060	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 51

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474062	1	2	1	1	1	Absent
	A1474064	1	2	1	1	1	Absent
	A1474066	1	2	1	1	1	Absent
	A1474068	1	2	1	1	1	Absent
	A1474070	1	2	1	1	1	Absent
	A1474072	1	2	1	1	1	Absent
	A1474074	1	2	1	1	1	Absent
	A1474076	1	2	1	1	1	Absent
	A1474078	1	2	1	1	1	Absent
	A1474080	1	2	1	1	1	Absent
	A1474082	1	2	1	1	1	Absent
	A1474084	1	2	1	1	1	Absent
	A1474086	1	2	1	1	1	Absent
	A1474088	1	2	1	1	1	Absent
	A1474090	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 51

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474092	1	2	1	1	1	Absent
	A1474094	1	2	1	1	1	Absent
	A1474096	1	2	1	1	1	Absent
	A1474098	1	2	1	1	1	Absent
	A1474100	1	2	1	1	1	Absent
	A1474102	1	2	1	1	1	Absent
	A1474104	1	2	1	1	1	Absent
	A1474106	1	2	1	1	1	Absent
	A1474108	1	2	1	1	1	Absent
	A1474110	1	2	1	1	1	Absent
	A1474112	1	2	1	1	1	Absent
	A1474114	1	2	1	1	1	Absent
	A1474116	1	2	1	1	1	Absent
	A1474118	1	2	1	1	1	Absent
	A1474120	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 58

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474002	1	2	1	1	1	Absent
	A1474004	1	2	1	1	1	Absent
	A1474006	1	2	1	1	1	Absent
	A1474008	1	2	1	1	1	Absent
	A1474010	1	2	1	1	1	Absent
	A1474012	1	2	1	1	1	Absent
	A1474014	1	2	1	1	1	Absent
	A1474016	1	2	1	1	1	Absent
	A1474018	1	2	1	1	1	Absent
	A1474020	1	2	1	1	1	Absent
	A1474022	1	2	1	1	1	Absent
	A1474024	1	2	1	1	1	Absent
	A1474026	1	2	1	1	1	Absent
	A1474028	1	2	1	1	1	Absent
	A1474030	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 58

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474032	1	2	1	1	1	Absent
	A1474034	1	2	1	1	1	Absent
	A1474036	1	2	1	1	1	Absent
	A1474038	1	2	1	1	1	Absent
	A1474040	1	2	1	1	1	Absent
	A1474042	1	2	1	1	1	Absent
	A1474044	1	2	1	1	1	Absent
	A1474046	1	2	1	1	1	Absent
	A1474048	1	2	1	1	1	Absent
	A1474050	1	2	1	1	1	Absent
	A1474052	1	2	1	1	1	Absent
	A1474054	1	2	1	1	1	Absent
	A1474056	1	2	1	1	1	Absent
	A1474058	1	2	1	1	1	Absent
	A1474060	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 58

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474062	1	2	1	1	1	Absent
	A1474064	1	2	1	1	1	Absent
	A1474066	1	2	1	1	1	Absent
	A1474068	1	2	1	1	1	Absent
	A1474070	1	2	1	1	1	Absent
	A1474072	1	2	1	1	1	Absent
	A1474074	1	2	1	1	1	Absent
	A1474076	1	2	1	1	1	Absent
	A1474078	1	2	1	1	1	Absent
	A1474080	1	2	1	1	1	Absent
	A1474082	1	2	1	1	1	Absent
	A1474084	1	2	1	1	1	Absent
	A1474086	1	2	1	1	1	Absent
	A1474088	1	2	1	1	1	Absent
	A1474090	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 58

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474092	1	2	1	1	1	Absent
	A1474094	1	2	1	1	1	Absent
	A1474096	1	2	1	1	1	Absent
	A1474098	1	2	1	1	1	Absent
	A1474100	1	2	1	1	1	Absent
	A1474102	1	2	1	1	1	Absent
	A1474104	1	2	1	1	1	Absent
	A1474106	1	2	1	1	1	Absent
	A1474108	1	2	1	1	1	Absent
	A1474110	1	2	1	1	1	Absent
	A1474112	1	2	1	1	1	Absent
	A1474114	1	2	1	1	1	Absent
	A1474116	1	2	1	1	1	Absent
	A1474118	1	2	1	1	1	Absent
	A1474120	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 66

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474002	1	2	1	1	1	Absent
	A1474004	1	2	1	1	1	Absent
	A1474006	1	2	1	1	1	Absent
	A1474008	1	2	1	1	1	Absent
	A1474010	1	2	1	1	1	Absent
	A1474012	1	2	1	1	1	Absent
	A1474014	1	2	1	1	1	Absent
	A1474016	1	2	1	1	1	Absent
	A1474018	1	2	1	1	1	Absent
	A1474020	1	2	1	1	1	Absent
	A1474022	1	2	1	1	1	Absent
	A1474024	1	2	1	1	1	Absent
	A1474026	1	2	1	1	1	Absent
	A1474028	1	2	1	1	1	Absent
	A1474030	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 66

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474032	1	2	1	1	1	Absent
	A1474034	1	2	1	1	1	Absent
	A1474036	1	2	1	1	1	Absent
	A1474038	1	2	1	1	1	Absent
	A1474040	1	2	1	1	1	Absent
	A1474042	1	2	1	1	1	Absent
	A1474044	1	2	1	1	1	Absent
	A1474046	1	2	1	1	1	Absent
	A1474048	1	2	1	1	1	Absent
	A1474050	1	2	1	1	1	Absent
	A1474052	1	2	1	1	1	Absent
	A1474054	1	2	1	1	1	Absent
	A1474056	1	2	1	1	1	Absent
	A1474058	1	2	1	1	1	Absent
	A1474060	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 66

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474062	1	2	1	1	1	Absent
	A1474064	1	2	1	1	1	Absent
	A1474066	1	2	1	1	1	Absent
	A1474068	1	2	1	1	1	Absent
	A1474070	1	2	1	1	1	Absent
	A1474072	1	2	1	1	1	Absent
	A1474074	1	2	1	1	1	Absent
	A1474076	1	2	1	1	1	Absent
	A1474078	1	2	1	1	1	Absent
	A1474080	1	2	1	1	1	Absent
	A1474082	1	2	1	1	1	Absent
	A1474084	1	2	1	1	1	Absent
	A1474086	1	2	1	1	1	Absent
	A1474088	1	2	1	1	1	Absent
	A1474090	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 66

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474092	1	2	1	1	1	Absent
	A1474094	1	2	1	1	1	Absent
	A1474096	1	2	1	1	1	Absent
	A1474098	1	2	1	1	1	Absent
	A1474100	1	2	1	1	1	Absent
	A1474102	1	2	1	1	1	Absent
	A1474104	1	2	1	1	1	Absent
	A1474106	1	2	1	1	1	Absent
	A1474108	1	2	1	1	1	Absent
	A1474110	1	2	1	1	1	Absent
	A1474112	1	2	1	1	1	Absent
	A1474114	1	2	1	1	1	Absent
	A1474116	1	2	1	1	1	Absent
	A1474118	1	2	1	1	1	Absent
	A1474120	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 72

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474002	1	2	1	1	1	Absent
	A1474004	1	2	1	1	1	Absent
	A1474006	1	2	1	1	1	Absent
	A1474008	1	2	1	1	1	Absent
	A1474010	1	2	1	1	1	Absent
	A1474012	1	2	1	1	1	Absent
	A1474014	1	2	1	1	1	Absent
	A1474016	1	2	1	1	1	Absent
	A1474018	1	2	1	1	1	Absent
	A1474020	1	2	1	1	1	Absent
	A1474022	1	2	1	1	1	Absent
	A1474024	1	2	1	1	1	Absent
	A1474026	1	2	1	1	1	Absent
	A1474028	1	2	1	1	1	Absent
	A1474030	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 72

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474032	1	2	1	1	1	Absent
	A1474034	1	2	1	1	1	Absent
	A1474036	1	2	1	1	1	Absent
	A1474038	1	2	1	1	1	Absent
	A1474040	1	2	1	1	1	Absent
	A1474042	1	2	1	1	1	Absent
	A1474044	1	2	1	1	1	Absent
	A1474046	1	2	1	1	1	Absent
	A1474048	1	2	1	1	1	Absent
	A1474050	1	2	1	1	1	Absent
	A1474052	1	2	1	1	1	Absent
	A1474054	1	2	1	1	1	Absent
	A1474056	1	2	1	1	1	Absent
	A1474058	1	2	1	1	1	Absent
	A1474060	1	2	1	1	1	Absent

FDA DRAFT - Not for Distribution

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 72

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474062	1	2	1	1	1	Absent
	A1474064	1	2	1	1	1	Absent
	A1474066	1	2	1	1	1	Absent
	A1474068	1	2	1	1	1	Absent
	A1474070	1	2	1	1	1	Absent
	A1474072	1	2	1	1	1	Absent
	A1474074	1	2	1	1	1	Absent
	A1474076	1	2	1	1	1	Absent
	A1474078	1	2	1	1	1	Absent
	A1474080	1	2	1	1	1	Absent
	A1474082	1	2	1	1	1	Absent
	A1474084	1	2	1	1	1	Absent
	A1474086	1	2	1	1	1	Absent
	A1474088	1	2	1	1	1	Absent
	A1474090	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 72

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474092	1	2	1	1	1	Absent
	A1474094	1	2	1	1	1	Absent
	A1474096	1	2	1	1	1	Absent
	A1474098	1	2	1	1	1	Absent
	A1474100	1	2	1	1	1	Absent
	A1474102	1	2	1	1	1	Absent
	A1474104	1	2	1	1	1	Absent
	A1474106	1	2	1	1	1	Absent
	A1474108	1	2	1	1	1	Absent
	A1474110	1	2	1	1	1	Absent
	A1474112	1	2	1	1	1	Absent
	A1474114	1	2	1	1	1	Absent
	A1474116	1	2	1	1	1	Absent
	A1474118	1	2	1	1	1	Absent
	A1474120	1	2	1	1	1	Absent

DRAFT - NOT FOR DISTRIBUTION

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 79

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474002	1	2	1	1	1	Absent
	A1474004	1	2	1	1	1	Absent
	A1474006	1	2	1	1	1	Absent
	A1474008	1	2	1	1	1	Absent
	A1474010	1	2	1	1	1	Absent
	A1474012	1	2	1	1	1	Absent
	A1474014	1	2	1	1	1	Absent
	A1474016	1	2	1	1	1	Absent
	A1474018	1	2	1	1	1	Absent
	A1474020	1	2	1	1	1	Absent
	A1474022	1	2	1	1	1	Absent
	A1474024	1	2	1	1	1	Absent
	A1474026	1	2	1	1	1	Absent
	A1474028	1	2	1	1	1	Absent
	A1474030	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 79

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474032	1	2	1	1	1	Absent
	A1474034	1	2	1	1	1	Absent
	A1474036	1	2	1	1	1	Absent
	A1474038	1	2	1	1	1	Absent
	A1474040	1	2	1	1	1	Absent
	A1474042	1	2	1	1	1	Absent
	A1474044	1	2	1	1	1	Absent
	A1474046	1	2	1	1	1	Absent
	A1474048	1	2	1	1	1	Absent
	A1474050	1	2	1	1	1	Absent
	A1474052	1	2	1	1	1	Absent
	A1474054	1	2	1	1	1	Absent
	A1474056	1	2	1	1	1	Absent
	A1474058	1	2	1	1	1	Absent
	A1474060	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 79

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474062	1	2	1	1	1	Absent
	A1474064	1	2	1	1	1	Absent
	A1474066	1	2	1	1	1	Absent
	A1474068	1	2	1	1	1	Absent
	A1474070	1	2	1	1	1	Absent
	A1474072	1	2	1	1	1	Absent
	A1474074	1	2	1	1	1	Absent
	A1474076	1	2	1	1	1	Absent
	A1474078	1	2	1	1	1	Absent
	A1474080	1	2	1	1	1	Absent
	A1474082	1	2	1	1	1	Absent
	A1474084	1	2	1	1	1	Absent
	A1474086	1	2	1	1	1	Absent
	A1474088	1	2	1	1	1	Absent
	A1474090	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 79

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474092	1	2	1	1	1	Absent
	A1474094	1	2	1	1	1	Absent
	A1474096	1	2	1	1	1	Absent
	A1474098	1	2	1	1	1	Absent
	A1474100	1	2	1	1	1	Absent
	A1474102	1	2	1	1	1	Absent
	A1474104	1	2	1	1	1	Absent
	A1474106	1	2	1	1	1	Absent
	A1474108	1	2	1	1	1	Absent
	A1474110	1	2	1	1	1	Absent
	A1474112	1	2	1	1	1	Absent
	A1474114	1	2	1	1	1	Absent
	A1474116	1	2	1	1	1	Absent
	A1474118	1	2	1	1	1	Absent
	A1474120	1	2	1	1	1	Absent

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REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 86

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474002	1	2	1	1	1	Absent
	A1474004	1	2	1	1	1	Absent
	A1474006	1	2	1	1	1	Absent
	A1474008	1	2	1	1	1	Absent
	A1474010	1	2	1	1	1	Absent
	A1474012	1	2	1	1	1	Absent
	A1474014	1	2	1	1	1	Absent
	A1474016	1	2	1	1	1	Absent
	A1474018	1	2	1	1	1	Absent
	A1474020	1	2	1	1	1	Absent
	A1474022	1	2	1	1	1	Absent
	A1474024	1	2	1	1	1	Absent
	A1474026	1	2	1	1	1	Absent
	A1474028	1	2	1	1	1	Absent
	A1474030	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 86

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474032	1	2	1	1	1	Absent
	A1474034	1	2	1	1	1	Absent
	A1474036	1	2	1	1	1	Absent
	A1474038	1	2	1	1	1	Absent
	A1474040	1	2	1	1	1	Absent
	A1474042	1	2	1	1	1	Absent
	A1474044	1	2	1	1	1	Absent
	A1474046	1	2	1	1	1	Absent
	A1474048	1	2	1	1	1	Absent
	A1474050	1	2	1	1	1	Absent
	A1474052	1	2	1	1	1	Absent
	A1474054	1	2	1	1	1	Absent
	A1474056	1	2	1	1	1	Absent
	A1474058	1	2	1	1	1	Absent
	A1474060	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 86

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474062	1	2	1	1	1	Absent
	A1474064	1	2	1	1	1	Absent
	A1474066	1	2	1	1	1	Absent
	A1474068	1	2	1	1	1	Absent
	A1474070	1	2	1	1	1	Absent
	A1474072	1	2	1	1	1	Absent
	A1474074	1	2	1	1	1	Absent
	A1474076	1	2	1	1	1	Absent
	A1474078	1	2	1	1	1	Absent
	A1474080	1	2	1	1	1	Absent
	A1474082	1	2	1	1	1	Absent
	A1474084	1	2	1	1	1	Absent
	A1474086	1	2	1	1	1	Absent
	A1474088	1	2	1	1	1	Absent
	A1474090	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 86

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474092	1	2	1	1	1	Absent
	A1474094	1	2	1	1	1	Absent
	A1474096	1	2	1	1	1	Absent
	A1474098	1	2	1	1	1	Absent
	A1474100	1	2	1	1	1	Absent
	A1474102	1	2	1	1	1	Absent
	A1474104	1	2	1	1	1	Absent
	A1474106	1	2	1	1	1	Absent
	A1474108	1	2	1	1	1	Absent
	A1474110	1	2	1	1	1	Absent
	A1474112	1	2	1	1	1	Absent
	A1474114	1	2	1	1	1	Absent
	A1474116	1	2	1	1	1	Absent
	A1474118	1	2	1	1	1	Absent
	A1474120	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 3

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474001	1	2	1	1	1	Absent
	A1474003	1	2	1	1	1	Absent
	A1474005	1	2	1	1	1	Absent
	A1474007	1	2	1	1	1	Absent
	A1474009	1	2	1	1	1	Absent
	A1474011	1	2	1	1	1	Absent
	A1474013	1	2	1	1	1	Absent
	A1474015	1	2	1	1	1	Absent
	A1474017	1	2	1	1	1	Absent
	A1474019	1	2	1	1	1	Absent
	A1474021	1	2	1	1	1	Absent
	A1474023	1	2	1	1	1	Absent
	A1474025	1	2	1	1	1	Absent
	A1474027	1	2	1	1	1	Absent
	A1474029	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 3

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474031	1	2	1	1	1	Absent
	A1474033	1	2	1	1	1	Absent
	A1474035	1	2	1	1	1	Absent
	A1474037	1	2	1	1	1	Absent
	A1474039	1	2	1	1	1	Absent
	A1474041	1	2	1	1	1	Absent
	A1474043	1	2	1	1	1	Absent
	A1474045	1	2	1	1	1	Absent
	A1474047	1	2	1	1	1	Absent
	A1474049	1	2	1	1	1	Absent
	A1474051	1	2	1	1	1	Absent
	A1474053	1	2	1	1	1	Absent
	A1474055	1	2	1	1	1	Absent
	A1474057	1	2	1	1	1	Absent
	A1474059	1	2	1	1	1	Absent

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REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 3

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474061	1	2	1	1	1	Absent
	A1474063	1	2	1	1	1	Absent
	A1474065	1	2	1	1	1	Absent
	A1474067	1	2	1	1	1	Absent
	A1474069	1	2	1	1	1	Absent
	A1474071	1	2	1	1	1	Absent
	A1474073	1	2	1	1	1	Absent
	A1474075	1	2	1	1	1	Absent
	A1474077	1	2	1	1	1	Absent
	A1474079	1	2	1	1	1	Absent
	A1474081	1	2	1	1	1	Absent
	A1474083	1	2	1	1	1	Absent
	A1474085	1	2	1	1	1	Absent
	A1474087	1	2	1	1	1	Absent
	A1474089	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 3

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474091	1	2	1	1	1	Absent
	A1474093	1	2	1	1	1	Absent
	A1474095	1	2	1	1	1	Absent
	A1474097	1	2	1	1	1	Absent
	A1474099	1	2	1	1	1	Absent
	A1474101	1	2	1	1	1	Absent
	A1474103	1	2	1	1	1	Absent
	A1474105	1	2	1	1	1	Absent
	A1474107	1	2	1	1	1	Absent
	A1474109	1	2	1	1	1	Absent
	A1474111	1	2	1	1	1	Absent
	A1474113	1	2	1	1	1	Absent
	A1474115	1	2	1	1	1	Absent
	A1474117	1	2	1	1	1	Absent
	A1474119	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 10

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474001	1	2	1	1	1	Absent
	A1474003	1	2	1	1	1	Absent
	A1474005	1	2	1	1	1	Absent
	A1474007	1	2	1	1	1	Absent
	A1474009	1	2	1	1	1	Absent
	A1474011	1	2	1	1	1	Absent
	A1474013	1	2	1	1	1	Absent
	A1474015	1	2	1	1	1	Absent
	A1474017	1	2	1	1	1	Absent
	A1474019	1	2	1	1	1	Absent
	A1474021	1	2	1	1	1	Absent
	A1474023	1	2	1	1	1	Absent
	A1474025	1	2	1	1	1	Absent
	A1474027	1	2	1	1	1	Absent
	A1474029	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 10

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474031	1	2	1	1	1	Absent
	A1474033	1	2	1	1	1	Absent
	A1474035	1	2	1	1	1	Absent
	A1474037	1	2	1	1	1	Absent
	A1474039	1	2	1	1	1	Absent
	A1474041	1	2	1	1	1	Absent
	A1474043	1	2	1	1	1	Absent
	A1474045	1	2	1	1	1	Absent
	A1474047	1	2	1	1	1	Absent
	A1474049	1	2	1	1	1	Absent
	A1474051	1	2	1	1	1	Absent
	A1474053	1	2	1	1	1	Absent
	A1474055	1	2	1	1	1	Absent
	A1474057	1	2	1	1	1	Absent
	A1474059	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 10

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474061	1	2	1	1	1	Absent
	A1474063	1	2	1	1	1	Absent
	A1474065	1	2	1	1	1	Absent
	A1474067	1	2	1	1	1	Absent
	A1474069	1	2	1	1	1	Absent
	A1474071	1	2	1	1	1	Absent
	A1474073	1	2	1	1	1	Absent
	A1474075	1	2	1	1	1	Absent
	A1474077	1	2	1	1	1	Absent
	A1474079	1	2	1	1	1	Absent
	A1474081	1	2	1	1	1	Absent
	A1474083	1	2	1	1	1	Absent
	A1474085	1	2	1	1	1	Absent
	A1474087	1	2	1	1	1	Absent
	A1474089	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 10

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474091	1	2	1	1	1	Absent
	A1474093	1	2	1	1	1	Absent
	A1474095	1	2	1	1	1	Absent
	A1474097	1	2	1	1	1	Absent
	A1474099	1	2	1	1	1	Absent
	A1474101	1	2	1	1	1	Absent
	A1474103	1	2	1	1	1	Absent
	A1474105	1	2	1	1	1	Absent
	A1474107	1	2	1	1	1	Absent
	A1474109	1	2	1	1	1	Absent
	A1474111	1	2	1	1	1	Absent
	A1474113	1	2	1	1	1	Absent
	A1474115	1	2	1	1	1	Absent
	A1474117	1	2	1	1	1	Absent
	A1474119	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 17

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474001	1	2	1	1	1	Absent
	A1474003	1	2	1	1	1	Absent
	A1474005	1	2	1	1	1	Absent
	A1474007	1	2	1	1	1	Absent
	A1474009	1	2	1	1	1	Absent
	A1474011	1	2	1	1	1	Absent
	A1474013	1	2	1	1	1	Absent
	A1474015	1	2	1	1	1	Absent
	A1474017	1	2	1	1	1	Absent
	A1474019	1	2	1	1	1	Absent
	A1474021	1	2	1	1	1	Absent
	A1474023	1	2	1	1	1	Absent
	A1474025	1	2	1	1	1	Absent
	A1474027	1	2	1	1	1	Absent
	A1474029	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 17

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474031	1	2	1	1	1	Absent
	A1474033	1	2	1	1	1	Absent
	A1474035	1	2	1	1	1	Absent
	A1474037	1	2	1	1	1	Absent
	A1474039	1	2	1	1	1	Absent
	A1474041	1	2	1	1	1	Absent
	A1474043	1	2	1	1	1	Absent
	A1474045	1	2	1	1	1	Absent
	A1474047	1	2	1	1	1	Absent
	A1474049	1	2	1	1	1	Absent
	A1474051	1	2	1	1	1	Absent
	A1474053	1	2	1	1	1	Absent
	A1474055	1	2	1	1	1	Absent
	A1474057	1	2	1	1	1	Absent
	A1474059	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 17

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474061	1	2	1	1	1	Absent
	A1474063	1	2	1	1	1	Absent
	A1474065	1	2	1	1	1	Absent
	A1474067	1	2	1	1	1	Absent
	A1474069	1	2	1	1	1	Absent
	A1474071	1	2	1	1	1	Absent
	A1474073	1	2	1	1	1	Absent
	A1474075	1	2	1	1	1	Absent
	A1474077	1	2	1	1	1	Absent
	A1474079	1	2	1	1	1	Absent
	A1474081	1	2	1	1	1	Absent
	A1474083	1	2	1	1	1	Absent
	A1474085	1	2	1	1	1	Absent
	A1474087	1	2	1	1	1	Absent
	A1474089	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 17

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474091	1	2	1	1	1	Absent
	A1474093	1	2	1	1	1	Absent
	A1474095	1	2	1	1	1	Absent
	A1474097	1	2	1	1	1	Absent
	A1474099	1	2	1	1	1	Absent
	A1474101	1	2	1	1	1	Absent
	A1474103	1	2	1	1	1	Absent
	A1474105	1	2	1	1	1	Absent
	A1474107	1	2	1	1	1	Absent
	A1474109	1	2	1	1	1	Absent
	A1474111	1	2	1	1	1	Absent
	A1474113	1	2	1	1	1	Absent
	A1474115	1	2	1	1	1	Absent
	A1474117	1	2	1	1	1	Absent
	A1474119	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 24

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474001	1	2	1	1	1	Absent
	A1474003	1	2	1	1	1	Absent
	A1474005	1	2	1	1	1	Absent
	A1474007	1	2	1	1	1	Absent
	A1474009	1	2	1	1	1	Absent
	A1474011	1	2	1	1	1	Absent
	A1474013	1	2	1	1	1	Absent
	A1474015	1	2	1	1	1	Absent
	A1474017	1	2	1	1	1	Absent
	A1474019	1	2	1	1	1	Absent
	A1474021	1	2	1	1	1	Absent
	A1474023	1	2	1	1	1	Absent
	A1474025	1	2	1	1	1	Absent
	A1474027	1	2	1	1	1	Absent
	A1474029	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 24

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474031	1	2	1	1	1	Absent
	A1474033	1	2	1	1	1	Absent
	A1474035	1	2	1	1	1	Absent
	A1474037	1	2	1	1	1	Absent
	A1474039	1	2	1	1	1	Absent
	A1474041	1	2	1	1	1	Absent
	A1474043	1	2	1	1	1	Absent
	A1474045	1	2	1	1	1	Absent
	A1474047	1	2	1	1	1	Absent
	A1474049	1	2	1	1	1	Absent
	A1474051	1	2	1	1	1	Absent
	A1474053	1	2	1	1	1	Absent
	A1474055	1	2	1	1	1	Absent
	A1474057	1	2	1	1	1	Absent
	A1474059	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 24

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474061	1	2	1	1	1	Absent
	A1474063	1	2	1	1	1	Absent
	A1474065	1	2	1	1	1	Absent
	A1474067	1	2	1	1	1	Absent
	A1474069	1	2	1	1	1	Absent
	A1474071	1	2	1	1	1	Absent
	A1474073	1	2	1	1	1	Absent
	A1474075	1	2	1	1	1	Absent
	A1474077	1	2	1	1	1	Absent
	A1474079	1	2	1	1	1	Absent
	A1474081	1	2	1	1	1	Absent
	A1474083	1	2	1	1	1	Absent
	A1474085	1	2	1	1	1	Absent
	A1474087	1	2	1	1	1	Absent
	A1474089	1	2	1	1	1	Absent

Study A1474 Day 24 Females

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 24

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474091	1	2	1	1	1	Absent
	A1474093	1	2	1	1	1	Absent
	A1474095	1	2	1	1	1	Absent
	A1474097	1	2	1	1	1	Absent
	A1474099	1	2	1	1	1	Absent
	A1474101	1	2	1	1	1	Absent
	A1474103	1	2	1	1	1	Absent
	A1474105	1	2	1	1	1	Absent
	A1474107	1	2	1	1	1	Absent
	A1474109	1	2	1	1	1	Absent
	A1474111	1	2	1	1	1	Absent
	A1474113	1	2	1	1	1	Absent
	A1474115	1	2	1	1	1	Absent
	A1474117	1	2	1	1	1	Absent
	A1474119	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 31

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474001	1	2	1	1	1	Absent
	A1474003	1	2	1	1	1	Absent
	A1474005	1	2	1	1	1	Absent
	A1474007	1	2	1	1	1	Absent
	A1474009	1	2	1	1	1	Absent
	A1474011	1	2	1	1	1	Absent
	A1474013	1	2	1	1	1	Absent
	A1474015	1	2	1	1	1	Absent
	A1474017	1	2	1	1	1	Absent
	A1474019	1	2	1	1	1	Absent
	A1474021	1	2	1	1	1	Absent
	A1474023	1	2	1	1	1	Absent
	A1474025	1	2	1	1	1	Absent
	A1474027	1	2	1	1	1	Absent
	A1474029	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 31

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474031	1	2	1	1	1	Absent
	A1474033	1	2	1	1	1	Absent
	A1474035	1	2	1	1	1	Absent
	A1474037	1	2	1	1	1	Absent
	A1474039	1	2	1	1	1	Absent
	A1474041	1	2	1	1	1	Absent
	A1474043	1	2	1	1	1	Absent
	A1474045	1	2	1	1	1	Absent
	A1474047	1	2	1	1	1	Absent
	A1474049	1	2	1	1	1	Absent
	A1474051	1	2	1	1	1	Absent
	A1474053	1	2	1	1	1	Absent
	A1474055	1	2	1	1	1	Absent
	A1474057	1	2	1	1	1	Absent
	A1474059	1	2	1	1	1	Absent

DRAFT - NOT FOR DISTRIBUTION

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 31

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474061	1	2	1	1	1	Absent
	A1474063	1	2	1	1	1	Absent
	A1474065	1	2	1	1	1	Absent
	A1474067	1	2	1	1	1	Absent
	A1474069	1	2	1	1	1	Absent
	A1474071	1	2	1	1	1	Absent
	A1474073	1	2	1	1	1	Absent
	A1474075	1	2	1	1	1	Absent
	A1474077	1	2	1	1	1	Absent
	A1474079	1	2	1	1	1	Absent
	A1474081	1	2	1	1	1	Absent
	A1474083	1	2	1	1	1	Absent
	A1474085	1	2	1	1	1	Absent
	A1474087	1	2	1	1	1	Absent
	A1474089	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 31

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474091	1	2	1	1	1	Absent
	A1474093	1	2	1	1	1	Absent
	A1474095	1	2	1	1	1	Absent
	A1474097	1	2	1	1	1	Absent
	A1474099	1	2	1	1	1	Absent
	A1474101	1	2	1	1	1	Absent
	A1474103	1	2	1	1	1	Absent
	A1474105	1	2	1	1	1	Absent
	A1474107	1	2	1	1	1	Absent
	A1474109	1	2	1	1	1	Absent
	A1474111	1	2	1	1	1	Absent
	A1474113	1	2	1	1	1	Absent
	A1474115	1	2	1	1	1	Absent
	A1474117	1	2	1	1	1	Absent
	A1474119	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 38

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474001	1	2	1	1	1	Absent
	A1474003	1	2	1	1	1	Absent
	A1474005	1	2	1	1	1	Absent
	A1474007	1	2	1	1	1	Absent
	A1474009	1	2	1	1	1	Absent
	A1474011	1	2	1	1	1	Absent
	A1474013	1	2	1	1	1	Absent
	A1474015	1	2	1	1	1	Absent
	A1474017	1	2	1	1	1	Absent
	A1474019	1	2	1	1	1	Absent
	A1474021	1	2	1	1	1	Absent
	A1474023	1	2	1	1	1	Absent
	A1474025	1	2	1	1	1	Absent
	A1474027	1	2	1	1	1	Absent
	A1474029	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 38

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474031	1	2	1	1	1	Absent
	A1474033	1	2	1	1	1	Absent
	A1474035	1	2	1	1	1	Absent
	A1474037	1	2	1	1	1	Absent
	A1474039	1	2	1	1	1	Absent
	A1474041	1	2	1	1	1	Absent
	A1474043	1	2	1	1	1	Absent
	A1474045	1	2	1	1	1	Absent
	A1474047	1	2	1	1	1	Absent
	A1474049	1	2	1	1	1	Absent
	A1474051	1	2	1	1	1	Absent
	A1474053	1	2	1	1	1	Absent
	A1474055	1	2	1	1	1	Absent
	A1474057	1	2	1	1	1	Absent
	A1474059	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 38

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474061	1	2	1	1	1	Absent
	A1474063	1	2	1	1	1	Absent
	A1474065	1	2	1	1	1	Absent
	A1474067	1	2	1	1	1	Absent
	A1474069	1	2	1	1	1	Absent
	A1474071	1	2	1	1	1	Absent
	A1474073	1	2	1	1	1	Absent
	A1474075	1	2	1	1	1	Absent
	A1474077	1	2	1	1	1	Absent
	A1474079	1	2	1	1	1	Absent
	A1474081	1	2	1	1	1	Absent
	A1474083	1	2	1	1	1	Absent
	A1474085	1	2	1	1	1	Absent
	A1474087	1	2	1	1	1	Absent
	A1474089	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 38

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474091	1	2	1	1	1	Absent
	A1474093	1	2	1	1	1	Absent
	A1474095	1	2	1	1	1	Absent
	A1474097	1	2	1	1	1	Absent
	A1474099	1	2	1	1	1	Absent
	A1474101	1	2	1	1	1	Absent
	A1474103	1	2	1	1	1	Absent
	A1474105	1	2	1	1	1	Absent
	A1474107	1	2	1	1	1	Absent
	A1474109	1	2	1	1	1	Absent
	A1474111	1	2	1	1	1	Absent
	A1474113	1	2	1	1	1	Absent
	A1474115	1	2	1	1	1	Absent
	A1474117	1	2	1	1	1	Absent
	A1474119	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 45

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474001	1	2	1	1	1	Absent
	A1474003	1	2	1	1	1	Absent
	A1474005	1	2	1	1	1	Absent
	A1474007	1	2	1	1	1	Absent
	A1474009	1	2	1	1	1	Absent
	A1474011	1	2	1	1	1	Absent
	A1474013	1	2	1	1	1	Absent
	A1474015	1	2	1	1	1	Absent
	A1474017	1	2	1	1	1	Absent
	A1474019	1	2	1	1	1	Absent
	A1474021	1	2	1	1	1	Absent
	A1474023	1	2	1	1	1	Absent
	A1474025	1	2	1	1	1	Absent
	A1474027	1	2	1	1	1	Absent
	A1474029	1	2	1	1	1	Absent

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 45

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474031	1	2	1	1	1	Absent
	A1474033	1	2	1	1	1	Absent
	A1474035	1	2	1	1	1	Absent
	A1474037	1	2	1	1	1	Absent
	A1474039	1	2	1	1	1	Absent
	A1474041	1	2	1	1	1	Absent
	A1474043	1	2	1	1	1	Absent
	A1474045	1	2	1	1	1	Absent
	A1474047	1	2	1	1	1	Absent
	A1474049	1	2	1	1	1	Absent
	A1474051	1	2	1	1	1	Absent
	A1474053	1	2	1	1	1	Absent
	A1474055	1	2	1	1	1	Absent
	A1474057	1	2	1	1	1	Absent
	A1474059	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 45

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474061	1	2	1	1	1	Absent
	A1474063	1	2	1	1	1	Absent
	A1474065	1	2	1	1	1	Absent
	A1474067	1	2	1	1	1	Absent
	A1474069	1	2	1	1	1	Absent
	A1474071	1	2	1	1	1	Absent
	A1474073	1	2	1	1	1	Absent
	A1474075	1	2	1	1	1	Absent
	A1474077	1	2	1	1	1	Absent
	A1474079	1	2	1	1	1	Absent
	A1474081	1	2	1	1	1	Absent
	A1474083	1	2	1	1	1	Absent
	A1474085	1	2	1	1	1	Absent
	A1474087	1	2	1	1	1	Absent
	A1474089	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 45

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474091	1	2	1	1	1	Absent
	A1474093	1	2	1	1	1	Absent
	A1474095	1	2	1	1	1	Absent
	A1474097	1	2	1	1	1	Absent
	A1474099	1	2	1	1	1	Absent
	A1474101	1	2	1	1	1	Absent
	A1474103	1	2	1	1	1	Absent
	A1474105	1	2	1	1	1	Absent
	A1474107	1	2	1	1	1	Absent
	A1474109	1	2	1	1	1	Absent
	A1474111	1	2	1	1	1	Absent
	A1474113	1	2	1	1	1	Absent
	A1474115	1	2	1	1	1	Absent
	A1474117	1	2	1	1	1	Absent
	A1474119	1	2	1	1	1	Absent

DRAFT - NOT FOR SIGNATURE

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 52

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474001	1	2	1	1	1	Absent
	A1474003	1	2	1	1	1	Absent
	A1474005	1	2	1	1	1	Absent
	A1474007	1	2	1	1	1	Absent
	A1474009	1	2	1	1	1	Absent
	A1474011	1	2	1	1	1	Absent
	A1474013	1	2	1	1	1	Absent
	A1474015	1	2	1	1	1	Absent
	A1474017	1	2	1	1	1	Absent
	A1474019	1	2	1	1	1	Absent
	A1474021	1	2	1	1	1	Absent
	A1474023	1	2	1	1	1	Absent
	A1474025	1	2	1	1	1	Absent
	A1474027	1	2	1	1	1	Absent
	A1474029	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 52

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474031	1	2	1	1	1	Absent
	A1474033	1	2	1	1	1	Absent
	A1474035	1	2	1	1	1	Absent
	A1474037	1	2	1	1	1	Absent
	A1474039	1	2	1	1	1	Absent
	A1474041	1	2	1	1	1	Absent
	A1474043	1	2	1	1	1	Absent
	A1474045	1	2	1	1	1	Absent
	A1474047	1	2	1	1	1	Absent
	A1474049	1	2	1	1	1	Absent
	A1474051	1	2	1	1	1	Absent
	A1474053	1	2	1	1	1	Absent
	A1474055	1	2	1	1	1	Absent
	A1474057	1	2	1	1	2	Absent
	A1474059	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 52

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474061	1	2	1	1	1	Absent
	A1474063	1	2	1	1	1	Absent
	A1474065	1	2	1	1	1	Absent
	A1474067	1	2	1	1	1	Absent
	A1474069	1	2	1	1	1	Absent
	A1474071	1	2	1	1	1	Absent
	A1474073	1	2	1	1	1	Absent
	A1474075	1	2	1	1	1	Absent
	A1474077	1	2	1	1	1	Absent
	A1474079	1	2	1	1	1	Absent
	A1474081	1	2	1	1	1	Absent
	A1474083	1	2	1	1	1	Absent
	A1474085	1	2	1	1	1	Absent
	A1474087	1	2	1	1	1	Absent
	A1474089	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 52

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474091	1	2	1	1	1	Absent
	A1474093	1	2	1	1	1	Absent
	A1474095	1	2	1	1	1	Absent
	A1474097	1	2	1	1	1	Absent
	A1474099	1	2	1	1	1	Absent
	A1474101	1	2	1	1	1	Absent
	A1474103	1	2	1	1	1	Absent
	A1474105	1	2	1	1	1	Absent
	A1474107	1	2	1	1	1	Absent
	A1474109	1	2	1	1	1	Absent
	A1474111	1	2	1	1	1	Absent
	A1474113	1	2	1	1	1	Absent
	A1474115	1	2	1	1	1	Absent
	A1474117	1	2	1	1	1	Absent
	A1474119	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 59

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474001	1	2	1	1	1	Absent
	A1474003	1	2	1	1	1	Absent
	A1474005	1	2	1	1	1	Absent
	A1474007	1	2	1	1	1	Absent
	A1474009	1	2	1	1	1	Absent
	A1474011	1	2	1	1	1	Absent
	A1474013	1	2	1	1	1	Absent
	A1474015	1	2	1	1	1	Absent
	A1474017	1	2	1	1	1	Absent
	A1474019	1	2	1	1	1	Absent
	A1474021	1	2	1	1	1	Absent
	A1474023	1	2	1	1	1	Absent
	A1474025	1	2	1	1	1	Absent
	A1474027	1	2	1	1	1	Absent
	A1474029	1	2	1	1	1	Absent

28 DAY ORAL - RAT (GAVAGE) STUDY

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 59

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474031	1	2	1	1	1	Absent
	A1474033	1	2	1	1	1	Absent
	A1474035	1	2	1	1	1	Absent
	A1474037	1	2	1	1	1	Absent
	A1474039	1	2	1	1	1	Absent
	A1474041	1	2	1	1	1	Absent
	A1474043	1	2	1	1	1	Absent
	A1474045	1	2	1	1	1	Absent
	A1474047	1	2	1	1	1	Absent
	A1474049	1	2	1	1	1	Absent
	A1474051	1	2	1	1	1	Absent
	A1474053	1	2	1	1	1	Absent
	A1474055	1	2	1	1	1	Absent
	A1474057	1	2	1	1	1	Absent
	A1474059	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 59

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474061	1	2	1	1	1	Absent
	A1474063	1	2	1	1	1	Absent
	A1474065	1	2	1	1	1	Absent
	A1474067	1	2	1	1	1	Absent
	A1474069	1	2	1	1	1	Absent
	A1474071	1	2	1	1	1	Absent
	A1474073	1	2	1	1	1	Absent
	A1474075	1	2	1	1	1	Absent
	A1474077	1	2	1	1	1	Absent
	A1474079	1	2	1	1	1	Absent
	A1474081	1	2	1	1	1	Absent
	A1474083	1	2	1	1	1	Absent
	A1474085	1	2	1	1	1	Absent
	A1474087	1	2	1	1	1	Absent
	A1474089	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 59

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474091	1	2	1	1	1	Absent
	A1474093	1	2	1	1	1	Absent
	A1474095	1	2	1	1	1	Absent
	A1474097	1	2	1	1	1	Absent
	A1474099	1	2	1	1	1	Absent
	A1474101	1	2	1	1	1	Absent
	A1474103	1	2	1	1	1	Absent
	A1474105	1	2	1	1	1	Absent
	A1474107	1	2	1	1	1	Absent
	A1474109	1	2	1	1	1	Absent
	A1474111	1	2	1	1	1	Absent
	A1474113	1	2	1	1	1	Absent
	A1474115	1	2	1	1	1	Absent
	A1474117	1	2	1	1	1	Absent
	A1474119	1	2	1	1	1	Absent

GLP - DRAFT - Not Guaranteed

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 67

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474001	1	2	1	1	1	Absent
	A1474003	1	2	1	1	1	Absent
	A1474005	1	2	1	1	1	Absent
	A1474007	1	2	1	1	1	Absent
	A1474009	1	2	1	1	1	Absent
	A1474011	1	2	1	1	1	Absent
	A1474013	1	2	1	1	1	Absent
	A1474015	1	2	1	1	1	Absent
	A1474017	1	2	1	1	1	Absent
	A1474019	1	2	1	1	1	Absent
	A1474021	1	2	1	1	1	Absent
	A1474023	1	2	1	1	1	Absent
	A1474025	1	2	1	1	1	Absent
	A1474027	1	2	1	1	1	Absent
	A1474029	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 67

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474031	1	2	1	1	1	Absent
	A1474033	1	2	1	1	1	Absent
	A1474035	1	2	1	1	1	Absent
	A1474037	1	2	1	1	1	Absent
	A1474039	1	2	1	1	1	Absent
	A1474041	1	2	1	1	1	Absent
	A1474043	1	2	1	1	1	Absent
	A1474045	1	2	1	1	1	Absent
	A1474047	1	2	1	1	1	Absent
	A1474049	1	2	1	1	1	Absent
	A1474051	1	2	1	1	1	Absent
	A1474053	1	2	1	1	1	Absent
	A1474055	1	2	1	1	1	Absent
	A1474057	1	2	1	1	1	Absent
	A1474059	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 67

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474061	1	2	1	1	1	Absent
	A1474063	1	2	1	1	1	Absent
	A1474065	1	2	1	1	1	Absent
	A1474067	1	2	1	1	1	Absent
	A1474069	1	2	1	1	1	Absent
	A1474071	1	2	1	1	1	Absent
	A1474073	1	2	1	1	1	Absent
	A1474075	1	2	1	1	1	Absent
	A1474077	1	2	1	1	1	Absent
	A1474079	1	2	1	1	1	Absent
	A1474081	1	2	1	1	1	Absent
	A1474083	1	2	1	1	1	Absent
	A1474085	1	2	1	1	1	Absent
	A1474087	1	2	1	1	1	Absent
	A1474089	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 67

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474091	1	2	1	1	1	Absent
	A1474093	1	2	1	1	1	Absent
	A1474095	1	2	1	1	1	Absent
	A1474097	1	2	1	1	1	Absent
	A1474099	1	2	1	1	1	Absent
	A1474101	1	2	1	1	1	Absent
	A1474103	1	2	1	1	1	Absent
	A1474105	1	2	1	1	1	Absent
	A1474107	1	2	1	1	1	Absent
	A1474109	1	2	1	1	1	Absent
	A1474111	1	2	1	1	1	Absent
	A1474113	1	2	1	1	1	Absent
	A1474115	1	2	1	1	1	Absent
	A1474117	1	2	1	1	1	Absent
	A1474119	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 73

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474001	1	2	1	1	1	Absent
	A1474003	1	2	1	1	1	Absent
	A1474005	1	2	1	1	1	Absent
	A1474007	1	2	1	1	1	Absent
	A1474009	1	2	1	1	1	Absent
	A1474011	1	2	1	1	1	Absent
	A1474013	1	2	1	1	1	Absent
	A1474015	1	2	1	1	1	Absent
	A1474017	1	2	1	1	1	Absent
	A1474019	1	2	1	1	1	Absent
	A1474021	1	2	1	1	1	Absent
	A1474023	1	2	1	1	1	Absent
	A1474025	1	2	1	1	1	Absent
	A1474027	1	2	1	1	1	Absent
	A1474029	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 73

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474031	1	2	1	1	1	Absent
	A1474033	1	2	1	1	1	Absent
	A1474035	1	2	1	1	1	Absent
	A1474037	1	2	1	1	1	Absent
	A1474039	1	2	1	1	1	Absent
	A1474041	1	2	1	1	1	Absent
	A1474043	1	2	1	1	1	Absent
	A1474045	1	2	1	1	1	Absent
	A1474047	1	2	1	1	1	Absent
	A1474049	1	2	1	1	1	Absent
	A1474051	1	2	1	1	1	Absent
	A1474053	1	2	1	1	1	Absent
	A1474055	1	2	1	1	1	Absent
	A1474057	1	2	1	1	1	Absent
	A1474059	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 73

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474061	1	2	1	1	1	Absent
	A1474063	1	2	1	1	1	Absent
	A1474065	1	2	1	1	1	Absent
	A1474067	1	2	1	1	1	Absent
	A1474069	1	2	1	1	1	Absent
	A1474071	1	2	1	1	1	Absent
	A1474073	1	2	1	1	1	Absent
	A1474075	1	2	1	1	1	Absent
	A1474077	1	2	1	1	1	Absent
	A1474079	1	2	1	1	1	Absent
	A1474081	1	2	1	1	1	Absent
	A1474083	1	2	1	1	1	Absent
	A1474085	1	2	1	1	1	Absent
	A1474087	1	2	1	1	1	Absent
	A1474089	1	2	1	1	1	Absent

For Study Purposes Only

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 73

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474091	1	2	1	1	1	Absent
	A1474093	1	2	1	1	1	Absent
	A1474095	1	2	1	1	1	Absent
	A1474097	1	2	1	1	1	Absent
	A1474099	1	2	1	1	1	Absent
	A1474101	1	2	1	1	1	Absent
	A1474103	1	2	1	1	1	Absent
	A1474105	1	2	1	1	1	Absent
	A1474107	1	2	1	1	1	Absent
	A1474109	1	2	1	1	1	Absent
	A1474111	1	2	1	1	1	Absent
	A1474113	1	2	1	1	1	Absent
	A1474115	1	2	1	1	1	Absent
	A1474117	1	2	1	1	1	Absent
	A1474119	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 80

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474001	1	2	1	1	1	Absent
	A1474003	1	2	1	1	1	Absent
	A1474005	1	2	1	1	1	Absent
	A1474007	1	2	1	1	1	Absent
	A1474009	1	2	1	1	1	Absent
	A1474011	1	2	1	1	1	Absent
	A1474013	1	2	1	1	1	Absent
	A1474015	1	2	1	1	1	Absent
	A1474017	1	2	1	1	1	Absent
	A1474019	1	2	1	1	1	Absent
	A1474021	1	2	1	1	1	Absent
	A1474023	1	2	1	1	1	Absent
	A1474025	1	2	1	1	1	Absent
	A1474027	1	2	1	1	1	Absent
	A1474029	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 80

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474031	1	2	1	1	1	Absent
	A1474033	1	2	1	1	1	Absent
	A1474035	1	2	1	1	1	Absent
	A1474037	1	2	1	1	1	Absent
	A1474039	1	2	1	1	1	Absent
	A1474041	1	2	1	1	1	Absent
	A1474043	1	2	1	1	1	Absent
	A1474045	1	2	1	1	1	Absent
	A1474047	1	2	1	1	1	Absent
	A1474049	1	2	1	1	1	Absent
	A1474051	1	2	1	1	1	Absent
	A1474053	1	2	1	1	1	Absent
	A1474055	1	2	1	1	1	Absent
	A1474057	1	2	1	1	1	Absent
	A1474059	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 80

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474061	1	2	1	1	1	Absent
	A1474063	1	2	1	1	1	Absent
	A1474065	1	2	1	1	1	Absent
	A1474067	1	2	1	1	1	Absent
	A1474069	1	2	1	1	1	Absent
	A1474071	1	2	1	1	1	Absent
	A1474073	1	2	1	1	1	Absent
	A1474075	1	2	1	1	1	Absent
	A1474077	1	2	1	1	1	Absent
	A1474079	1	2	1	1	1	Absent
	A1474081	1	2	1	1	1	Absent
	A1474083	1	2	1	1	1	Absent
	A1474085	1	2	1	1	1	Absent
	A1474087	1	2	1	1	1	Absent
	A1474089	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 80

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474091	1	2	1	1	1	Absent
	A1474093	1	2	1	1	1	Absent
	A1474095	1	2	1	1	1	Absent
	A1474097	1	2	1	1	1	Absent
	A1474099	1	2	1	1	1	Absent
	A1474101	1	2	1	1	1	Absent
	A1474103	1	2	1	1	1	Absent
	A1474105	1	2	1	1	1	Absent
	A1474107	1	2	1	1	1	Absent
	A1474109	1	2	1	1	1	Absent
	A1474111	1	2	1	1	1	Absent
	A1474113	1	2	1	1	1	Absent
	A1474115	1	2	1	1	1	Absent
	A1474117	1	2	1	1	1	Absent
	A1474119	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 87

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474001	1	2	1	1	1	Absent
	A1474003	1	2	1	1	1	Absent
	A1474005	1	2	1	1	1	Absent
	A1474007	1	2	1	1	1	Absent
	A1474009	1	2	1	1	1	Absent
	A1474011	1	2	1	1	1	Absent
	A1474013	1	2	1	1	1	Absent
	A1474015	1	2	1	1	1	Absent
	A1474017	1	2	1	1	1	Absent
	A1474019	1	2	1	1	1	Absent
	A1474021	1	2	1	1	1	Absent
	A1474023	1	2	1	1	1	Absent
	A1474025	1	2	1	1	1	Absent
	A1474027	1	2	1	1	1	Absent
	A1474029	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 87

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474031	1	2	1	1	1	Absent
	A1474033	1	2	1	1	1	Absent
	A1474035	1	2	1	1	1	Absent
	A1474037	1	2	1	1	1	Absent
	A1474039	1	2	1	1	1	Absent
	A1474041	1	2	1	1	1	Absent
	A1474043	1	2	1	1	1	Absent
	A1474045	1	2	1	1	1	Absent
	A1474047	1	2	1	1	1	Absent
	A1474049	1	2	1	1	1	Absent
	A1474051	1	2	1	1	1	Absent
	A1474053	1	2	1	1	1	Absent
	A1474055	1	2	1	1	1	Absent
	A1474057	1	2	1	1	1	Absent
	A1474059	1	2	1	1	1	Absent

DRAFT - NOT FOR SIGNATURE

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 87

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474061	1	2	1	1	1	Absent
	A1474063	1	2	1	1	1	Absent
	A1474065	1	2	1	1	1	Absent
	A1474067	1	2	1	1	1	Absent
	A1474069	1	2	1	1	1	Absent
	A1474071	1	2	1	1	1	Absent
	A1474073	1	2	1	1	1	Absent
	A1474075	1	2	1	1	1	Absent
	A1474077	1	2	1	1	1	Absent
	A1474079	1	2	1	1	1	Absent
	A1474081	1	2	1	1	1	Absent
	A1474083	1	2	1	1	1	Absent
	A1474085	1	2	1	1	1	Absent
	A1474087	1	2	1	1	1	Absent
	A1474089	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 87

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474091	1	2	1	1	1	Absent
	A1474093	1	2	1	1	1	Absent
	A1474095	1	2	1	1	1	Absent
	A1474097	1	2	1	1	1	Absent
	A1474099	1	2	1	1	1	Absent
	A1474101	1	2	1	1	1	Absent
	A1474103	1	2	1	1	1	Absent
	A1474105	1	2	1	1	1	Absent
	A1474107	1	2	1	1	1	Absent
	A1474109	1	2	1	1	1	Absent
	A1474111	1	2	1	1	1	Absent
	A1474113	1	2	1	1	1	Absent
	A1474115	1	2	1	1	1	Absent
	A1474117	1	2	1	1	1	Absent
	A1474119	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 2

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474022	1	2	1	1	1	Absent
	A1474024	1	2	1	1	1	Absent
	A1474026	1	2	1	1	1	Absent
	A1474028	1	2	1	1	1	Absent
	A1474030	1	2	1	1	1	Absent

Not to be used for regulatory purposes

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 2

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474052	1	2	1	1	1	Absent
	A1474054	1	2	1	1	1	Absent
	A1474056	1	2	1	1	1	Absent
	A1474058	1	2	1	1	1	Absent
	A1474060	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 2

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474082	1	2	1	1	1	Absent
	A1474084	1	2	1	1	1	Absent
	A1474086	1	2	1	1	1	Absent
	A1474088	1	2	1	1	1	Absent
	A1474090	1	2	1	1	1	Absent

For Internal Use Only

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 2

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474112	1	2	1	1	1	Absent
	A1474114	1	2	1	1	1	Absent
	A1474116	1	2	1	1	1	Absent
	A1474118	1	2	1	1	1	Absent
	A1474120	1	2	1	1	1	Absent

Not Official Study Document

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 9

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474022	1	2	1	1	1	Absent
	A1474024	1	2	1	1	1	Absent
	A1474026	1	2	1	1	1	Absent
	A1474028	1	2	1	1	1	Absent
	A1474030	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 9

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474052	1	2	1	1	1	Absent
	A1474054	1	2	1	1	1	Absent
	A1474056	1	2	1	1	1	Absent
	A1474058	1	2	1	1	1	Absent
	A1474060	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 9

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474082	1	2	1	1	1	Absent
	A1474084	1	2	1	1	1	Absent
	A1474086	1	2	1	1	1	Absent
	A1474088	1	2	1	1	1	Absent
	A1474090	1	2	1	1	1	Absent

THIS DRAFT WAS UNDER GMP

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 9

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474112	1	2	1	1	1	Absent
	A1474114	1	2	1	1	1	Absent
	A1474116	1	2	1	1	1	Absent
	A1474118	1	2	1	1	1	Absent
	A1474120	1	2	1	1	1	Absent

FOR PMRA REVIEW - OCT 2016

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 16

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474022	1	2	1	1	1	Absent
	A1474024	1	2	1	1	1	Absent
	A1474026	1	2	1	1	1	Absent
	A1474028	1	2	1	1	1	Absent
	A1474030	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 16

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474052	1	2	1	1	1	Absent
	A1474054	1	2	1	1	1	Absent
	A1474056	1	2	1	1	1	Absent
	A1474058	1	2	1	1	1	Absent
	A1474060	1	2	1	1	1	Absent

DRAFT - NOT FOR SIGNATURE 2018

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 16

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474082	1	2	1	1	1	Absent
	A1474084	1	2	1	1	1	Absent
	A1474086	1	2	1	1	1	Absent
	A1474088	1	2	1	1	1	Absent
	A1474090	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 16

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474112	1	2	1	1	1	Absent
	A1474114	1	2	1	1	1	Absent
	A1474116	1	2	1	1	1	Absent
	A1474118	1	2	1	1	1	Absent
	A1474120	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 23

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474022	1	2	1	1	1	Absent
	A1474024	1	2	1	1	1	Absent
	A1474026	1	2	1	1	1	Absent
	A1474028	1	2	1	1	1	Absent
	A1474030	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 23

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474052	1	2	1	1	1	Absent
	A1474054	1	2	1	1	1	Absent
	A1474056	1	2	1	1	1	Absent
	A1474058	1	2	1	1	1	Absent
	A1474060	1	2	1	1	1	Absent

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REDACTED AS TO TRADE NAMES

Study: A1474
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FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 23

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474082	1	2	1	1	1	Absent
	A1474084	1	2	1	1	1	Absent
	A1474086	1	2	1	1	1	Absent
	A1474088	1	2	1	1	1	Absent
	A1474090	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 23

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474112	1	2	1	1	1	Absent
	A1474114	1	2	1	1	1	Absent
	A1474116	1	2	1	1	1	Absent
	A1474118	1	2	1	1	1	Absent
	A1474120	1	2	1	1	1	Absent

UNAUTHORIZED DISCLOSURE PROHIBITED

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 30

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474022	1	2	1	1	1	Absent
	A1474024	1	2	1	1	1	Absent
	A1474026	1	2	1	1	1	Absent
	A1474028	1	2	1	1	1	Absent
	A1474030	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 30

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474052	1	2	1	1	1	Absent
	A1474054	1	2	1	1	1	Absent
	A1474056	1	2	1	1	1	Absent
	A1474058	1	2	1	1	1	Absent
	A1474060	1	2	1	1	1	Absent

DRAFT - NOT FOR DISTRIBUTION

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 30

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474082	1	2	1	1	1	Absent
	A1474084	1	2	1	1	1	Absent
	A1474086	1	2	1	1	1	Absent
	A1474088	1	2	1	1	1	Absent
	A1474090	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 30

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474112	1	2	1	1	1	Absent
	A1474114	1	2	1	1	1	Absent
	A1474116	1	2	1	1	1	Absent
	A1474118	1	2	1	1	1	Absent
	A1474120	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 37

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474022	1	2	1	1	1	Absent
	A1474024	1	2	1	1	1	Absent
	A1474026	1	2	1	1	1	Absent
	A1474028	1	2	1	1	1	Absent
	A1474030	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 37

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474052	1	2	1	1	1	Absent
	A1474054	1	2	1	1	1	Absent
	A1474056	1	2	1	1	1	Absent
	A1474058	1	2	1	1	1	Absent
	A1474060	1	2	1	1	1	Absent

Non-GLP - Not Dose-Ranging

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 37

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474082	1	2	1	1	1	Absent
	A1474084	1	2	1	1	1	Absent
	A1474086	1	2	1	1	1	Absent
	A1474088	1	2	1	1	1	Absent
	A1474090	1	2	1	1	1	Absent

Not Used for Regulatory Purposes 2015

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 37

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474112	1	2	1	1	1	Absent
	A1474114	1	2	1	1	1	Absent
	A1474116	1	2	1	1	1	Absent
	A1474118	1	2	1	1	1	Absent
	A1474120	1	2	1	1	1	Absent

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 44

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474022	1	2	1	1	1	Absent
	A1474024	1	2	1	1	1	Absent
	A1474026	1	2	1	1	1	Absent
	A1474028	1	2	1	1	1	Absent
	A1474030	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 44

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474052	1	2	1	1	1	Absent
	A1474054	1	2	1	1	1	Absent
	A1474056	1	2	1	1	1	Absent
	A1474058	1	2	1	1	1	Absent
	A1474060	1	2	1	1	1	Absent

Not Official Until Signed December 2016

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 44

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474082	1	2	1	1	1	Absent
	A1474084	1	2	1	1	1	Absent
	A1474086	1	2	1	1	1	Absent
	A1474088	1	2	1	1	1	Absent
	A1474090	1	2	1	1	1	Absent

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REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 44

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474112	1	2	1	1	1	Absent
	A1474114	1	2	1	1	1	Absent
	A1474116	1	2	1	1	1	Absent
	A1474118	1	2	1	1	1	Absent
	A1474120	1	2	1	1	1	Absent

GLP - DRAFT - Not Guaranteed - 2010

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 51

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474022	1	2	1	1	1	Absent
	A1474024	1	2	1	1	1	Absent
	A1474026	1	2	1	1	1	Absent
	A1474028	1	2	1	1	1	Absent
	A1474030	1	2	1	1	1	Absent

Study Director Signature Date

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 51

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474052	1	2	1	1	1	Absent
	A1474054	1	2	1	1	1	Absent
	A1474056	1	2	1	1	1	Absent
	A1474058	1	2	1	1	1	Absent
	A1474060	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 51

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474082	1	2	1	1	1	Absent
	A1474084	1	2	1	1	1	Absent
	A1474086	1	2	1	1	1	Absent
	A1474088	1	2	1	1	1	Absent
	A1474090	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 51

Males

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474112	1	2	1	1	1	Absent
	A1474114	1	2	1	1	1	Absent
	A1474116	1	2	1	1	1	Absent
	A1474118	1	2	1	1	1	Absent
	A1474120	1	2	1	1	1	Absent

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REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 2

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474021	1	2	1	1	1	Absent
	A1474023	1	2	1	1	1	Absent
	A1474025	1	2	1	1	1	Absent
	A1474027	1	2	1	1	1	Absent
	A1474029	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 2

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474051	1	2	1	1	1	Absent
	A1474053	1	2	1	1	1	Absent
	A1474055	1	2	1	1	1	Absent
	A1474057	1	2	1	1	1	Absent
	A1474059	1	2	1	1	1	Absent

EX-COMMERCIAL USE ONLY

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 2

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474081	1	2	1	1	1	Absent
	A1474083	1	2	1	1	1	Absent
	A1474085	1	2	1	1	1	Absent
	A1474087	1	2	1	1	1	Absent
	A1474089	1	2	1	1	1	Absent

Not Valid for Use Outside OECD

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 2

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474111	1	2	1	1	1	Absent
	A1474113	1	2	1	1	1	Absent
	A1474115	1	2	1	1	1	Absent
	A1474117	1	2	1	1	1	Absent
	A1474119	1	2	1	1	1	Absent

GLP - DRAFT - Not to be cited - December 2016

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 9

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474021	1	2	1	1	1	Absent
	A1474023	1	2	1	1	1	Absent
	A1474025	1	2	1	1	1	Absent
	A1474027	1	2	1	1	1	Absent
	A1474029	1	2	1	1	1	Absent

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Study: A1474
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Recovery Day 9

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474051	1	2	1	1	1	Absent
	A1474053	1	2	1	1	1	Absent
	A1474055	1	2	1	1	1	Absent
	A1474057	1	2	1	1	1	Absent
	A1474059	1	2	1	1	1	Absent

30 - DRAFT - Not Guideline - 2016

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 9

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474081	1	2	1	1	1	Absent
	A1474083	1	2	1	1	1	Absent
	A1474085	1	2	1	1	1	Absent
	A1474087	1	2	1	1	1	Absent
	A1474089	1	2	1	1	1	Absent

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Study: A1474
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Recovery Day 9

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474111	1	2	1	1	1	Absent
	A1474113	1	2	1	1	1	Absent
	A1474115	1	2	1	1	1	Absent
	A1474117	1	2	1	1	1	Absent
	A1474119	1	2	1	1	1	Absent

Final Document 2010

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 16

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474021	1	2	1	1	1	Absent
	A1474023	1	2	1	1	1	Absent
	A1474025	1	2	1	1	1	Absent
	A1474027	1	2	1	1	1	Absent
	A1474029	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
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Recovery Day 16

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474051	1	2	1	1	1	Absent
	A1474053	1	2	1	1	1	Absent
	A1474055	1	2	1	1	1	Absent
	A1474057	1	2	1	1	1	Absent
	A1474059	1	2	1	1	1	Absent

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Study: A1474
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Recovery Day 16

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474081	1	2	1	1	1	Absent
	A1474083	1	2	1	1	1	Absent
	A1474085	1	2	1	1	1	Absent
	A1474087	1	2	1	1	1	Absent
	A1474089	1	2	1	1	1	Absent

Not Guaranteed for Submission

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 16

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474111	1	2	1	1	1	Absent
	A1474113	1	2	1	1	1	Absent
	A1474115	1	2	1	1	1	Absent
	A1474117	1	2	1	1	1	Absent
	A1474119	1	2	1	1	1	Absent

DRAFT - NOT FOR SIGNATURE

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 23

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474021	1	2	1	1	1	Absent
	A1474023	1	2	1	1	1	Absent
	A1474025	1	2	1	1	1	Absent
	A1474027	1	2	1	1	1	Absent
	A1474029	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 23

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474051	1	2	1	1	1	Absent
	A1474053	1	2	1	1	1	Absent
	A1474055	1	2	1	1	1	Absent
	A1474057	1	2	1	1	1	Absent
	A1474059	1	2	1	1	1	Absent

Re-issued - Final Report (2016)

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 23

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474081	1	2	1	1	1	Absent
	A1474083	1	2	1	1	1	Absent
	A1474085	1	2	1	1	1	Absent
	A1474087	1	2	1	1	1	Absent
	A1474089	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 23

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474111	1	2	1	1	1	Absent
	A1474113	1	2	1	1	1	Absent
	A1474115	1	2	1	1	1	Absent
	A1474117	1	2	1	1	1	Absent
	A1474119	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 30

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474021	1	2	1	1	1	Absent
	A1474023	1	2	1	1	1	Absent
	A1474025	1	2	1	1	1	Absent
	A1474027	1	2	1	1	1	Absent
	A1474029	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 30

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474051	1	2	1	1	1	Absent
	A1474053	1	2	1	1	1	Absent
	A1474055	1	2	1	1	1	Absent
	A1474057	1	2	1	1	1	Absent
	A1474059	1	2	1	1	1	Absent

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REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 30

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474081	1	2	1	1	1	Absent
	A1474083	1	2	1	1	1	Absent
	A1474085	1	2	1	1	1	Absent
	A1474087	1	2	1	1	1	Absent
	A1474089	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 30

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474111	1	2	1	1	1	Absent
	A1474113	1	2	1	1	1	Absent
	A1474115	1	2	1	1	1	Absent
	A1474117	1	2	1	1	1	Absent
	A1474119	1	2	1	1	1	Absent

Not Intended for Human Consumption (NIHC)

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 37
Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474021	1	2	1	1	1	Absent
	A1474023	1	2	1	1	1	Absent
	A1474025	1	2	1	1	1	Absent
	A1474027	1	2	1	1	1	Absent
	A1474029	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 37

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474051	1	2	1	1	1	Absent
	A1474053	1	2	1	1	1	Absent
	A1474055	1	2	1	1	1	Absent
	A1474057	1	2	1	1	1	Absent
	A1474059	1	2	1	1	1	Absent

FOR DRAFT - NOT FOR RELEASE (DRAFT)

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 37

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474081	1	2	1	1	1	Absent
	A1474083	1	2	1	1	1	Absent
	A1474085	1	2	1	1	1	Absent
	A1474087	1	2	1	1	1	Absent
	A1474089	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 37

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474111	1	2	1	1	1	Absent
	A1474113	1	2	1	1	1	Absent
	A1474115	1	2	1	1	1	Absent
	A1474117	1	2	1	1	1	Absent
	A1474119	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 44

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474021	1	2	1	1	1	Absent
	A1474023	1	2	1	1	1	Absent
	A1474025	1	2	1	1	1	Absent
	A1474027	1	2	1	1	1	Absent
	A1474029	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 44

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474051	1	2	1	1	1	Absent
	A1474053	1	2	1	1	1	Absent
	A1474055	1	2	1	1	1	Absent
	A1474057	1	2	1	1	1	Absent
	A1474059	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 44

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474081	1	2	1	1	1	Absent
	A1474083	1	2	1	1	1	Absent
	A1474085	1	2	1	1	1	Absent
	A1474087	1	2	1	1	1	Absent
	A1474089	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 44

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474111	1	2	1	1	1	Absent
	A1474113	1	2	1	1	1	Absent
	A1474115	1	2	1	1	1	Absent
	A1474117	1	2	1	1	1	Absent
	A1474119	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 51

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
Control	A1474021	1	2	1	1	1	Absent
	A1474023	1	2	1	1	1	Absent
	A1474025	1	2	1	1	1	Absent
	A1474027	1	2	1	1	1	Absent
	A1474029	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Removal from the cage - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 51

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
2	A1474051	1	2	1	1	1	Absent
	A1474053	1	2	1	1	1	Absent
	A1474055	1	2	1	1	1	Absent
	A1474057	1	2	1	1	1	Absent
	A1474059	1	2	1	1	1	Absent

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 51

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
3	A1474081	1	2	1	1	1	Absent
	A1474083	1	2	1	1	1	Absent
	A1474085	1	2	1	1	1	Absent
	A1474087	1	2	1	1	1	Absent
	A1474089	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 51

Females

Group	Animal No	Removal	HAN	LA	PA	SA	PI
4	A1474111	1	2	1	1	1	Absent
	A1474113	1	2	1	1	1	Absent
	A1474115	1	2	1	1	1	Absent
	A1474117	1	2	1	1	1	Absent
	A1474119	1	2	1	1	1	Absent

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

At the end of treatment

Males

Group	Animal No	LAN1 (cm)	LAN2 (cm)	LAM (cm)
Control	A1474002	11.0	8.0	9.50
	A1474004	8.0	9.3	8.65
	A1474006	9.0	9.5	9.25
	A1474008	8.5	8.5	8.50
	A1474010	4.5	5.0	4.75
	A1474012	3.5	5.0	4.25
	A1474014	3.5	4.0	3.75
	A1474016	6.5	7.0	6.75
	A1474018	6.6	7.2	6.90
	A1474020	8.0	7.5	7.75
	A1474022	4.5	3.5	4.00
	A1474024	5.0	6.0	5.50
	A1474026	5.5	5.0	5.25
	A1474028	8.0	7.0	7.50
	A1474030	9.0	9.2	9.10

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

At the end of treatment

Males

Group	Animal No	LAN1 (cm)	LAN2 (cm)	LAM (cm)
2	A1474032	5.0	5.5	5.25
	A1474034	5.0	4.5	4.75
	A1474036	8.5	6.5	7.50
	A1474038	8.5	9.0	8.75
	A1474040	4.9	6.0	5.45
	A1474042	5.0	4.0	4.50
	A1474044	4.5	5.0	4.75
	A1474046	4.0	5.0	4.50
	A1474048	5.5	5.0	5.25
	A1474050	6.5	7.5	7.00
	A1474052	3.5	4.5	4.00
	A1474054	4.5	4.5	4.50
	A1474056	7.5	6.5	7.00
	A1474058	8.0	7.5	7.75
	A1474060	4.0	4.5	4.25

Not Used - HED Document 2694

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

At the end of treatment

Males

Group	Animal No	LAN1 (cm)	LAN2 (cm)	LAM (cm)
3	A1474062	5.0	4.5	4.75
	A1474064	6.5	5.0	5.75
	A1474066	8.5	6.0	7.25
	A1474068	7.0	5.0	6.00
	A1474070	8.5	6.5	7.50
	A1474072	5.5	6.5	6.00
	A1474074	6.5	6.0	6.25
	A1474076	5.0	5.0	5.00
	A1474078	4.5	3.5	4.00
	A1474080	5.5	6.0	5.75
	A1474082	5.0	5.6	5.30
	A1474084	4.5	4.0	4.25
	A1474086	5.0	4.5	4.75
	A1474088	6.5	5.0	5.75
	A1474090	4.5	5.0	4.75

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

At the end of treatment

Males

Group	Animal No	LAN1 (cm)	LAN2 (cm)	LAM (cm)
4	A1474092	4.0	4.5	4.25
	A1474094	4.8	4.2	4.50
	A1474096	6.0	6.5	6.25
	A1474098	4.5	5.9	5.20
	A1474100	7.0	9.5	8.25
	A1474102	9.5	8.5	9.00
	A1474104	6.5	5.5	6.00
	A1474106	12.0	10.0	11.00
	A1474108	7.0	6.5	6.75
	A1474110	8.0	2.5	5.25
	A1474112	9.7	6.7	8.20
	A1474114	7.5	4.5	6.00
	A1474116	5.5	4.5	5.00
	A1474118	7.6	7.0	7.30
	A1474120	5.5	4.5	5.00

Landing foot splay - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

At the and of treatment

Females

Group	Animal No	LAN1 (cm)	LAN2 (cm)	LAM (cm)
Control	A1474001	7.5	7.0	7.25
	A1474003	6.9	6.0	6.45
	A1474005	6.5	5.0	5.75
	A1474007	6.4	8.2	7.30
	A1474009	4.0	7.2	5.60
	A1474011	2.5	3.8	3.15
	A1474013	6.0	5.7	5.85
	A1474015	4.9	3.2	4.05
	A1474017	5.8	6.7	6.25
	A1474019	5.7	4.3	5.00
	A1474021	5.2	6.0	5.60
	A1474023	4.3	5.7	5.00
	A1474025	3.0	2.8	2.90
	A1474027	5.7	6.5	6.10
	A1474029	4.8	6.7	5.75

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

At the end of treatment

Females

Group	Animal No	LAN1 (cm)	LAN2 (cm)	LAM (cm)
2	A1474031	5.8	6.4	6.10
	A1474033	6.3	4.1	5.20
	A1474035	4.2	5.0	4.60
	A1474037	4.7	2.9	3.80
	A1474039	2.8	3.2	3.00
	A1474041	5.3	6.2	5.75
	A1474043	3.0	3.2	3.10
	A1474045	6.9	4.3	5.60
	A1474047	6.4	5.5	5.95
	A1474049	5.4	3.8	4.60
	A1474051	3.8	3.4	3.60
	A1474053	7.2	6.5	6.85
	A1474055	3.2	4.5	3.85
	A1474057	6.5	4.2	5.35
	A1474059	5.7	5.3	5.50

[illegible]

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

At the end of treatment

Females

Group	Animal No	LAN1 (cm)	LAN2 (cm)	LAM (cm)
3	A1474061	5.6	5.0	5.30
	A1474063	2.5	2.0	2.25
	A1474065	3.2	3.1	3.15
	A1474067	2.1	1.8	1.95
	A1474069	5.4	7.6	6.50
	A1474071	4.7	4.2	4.45
	A1474073	5.7	3.2	4.45
	A1474075	4.8	3.9	4.35
	A1474077	3.0	5.2	4.10
	A1474079	5.1	3.9	4.50
	A1474081	4.7	4.3	4.50
	A1474083	5.0	5.4	5.20
	A1474085	5.0	5.4	5.20
	A1474087	3.5	4.5	4.00
	A1474089	4.7	6.4	5.55

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

At the end of treatment

Females

Group	Animal No	LAN1 (cm)	LAN2 (cm)	LAM (cm)
4	A1474091	4.6	5.1	4.85
	A1474093	8.0	5.8	6.90
	A1474095	5.8	4.3	5.05
	A1474097	6.5	4.9	5.70
	A1474099	5.5	5.9	5.70
	A1474101	5.2	6.3	5.75
	A1474103	4.4	5.3	4.85
	A1474105	6.8	4.7	5.75
	A1474107	7.0	6.5	6.75
	A1474109	6.7	6.0	6.35
	A1474111	4.0	2.5	3.25
	A1474113	5.7	6.4	6.05
	A1474115	5.0	4.3	4.65
	A1474117	2.5	3.5	3.00
	A1474119	6.0	5.2	5.60

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

At the end of recovery

Males

Group	Animal No	LAN1 (cm)	LAN2 (cm)	LAM (cm)
Control	A1474022	6.5	6.0	6.25
	A1474024	4.5	6.0	5.25
	A1474026	10.5	8.0	9.25
	A1474028	8.5	8.0	8.25
	A1474030	8.5	10.0	9.25

For Internal Use Only

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

At the end of recovery

Males

Group	Animal No	LAN1 (cm)	LAN2 (cm)	LAM (cm)
2	A1474052	5.0	4.5	4.75
	A1474054	4.5	4.0	4.25
	A1474056	7.5	7.0	7.25
	A1474058	7.5	7.0	7.25
	A1474060	7.5	5.0	6.25

For DSMRT - IRM Operational Use

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

At the end of recovery

Males

Group	Animal No	LAN1 (cm)	LAN2 (cm)	LAM (cm)
3	A1474082	4.5	4.0	4.25
	A1474084	6.2	5.0	5.60
	A1474086	8.5	7.0	7.75
	A1474088	9.0	6.0	7.50
	A1474090	6.0	5.0	5.50

For Internal Use Only

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

At the end of recovery

Males

Group	Animal No	LAN1 (cm)	LAN2 (cm)	LAM (cm)
4	A1474112	5.5	5.0	5.25
	A1474114	7.0	5.0	6.00
	A1474116	4.0	3.5	3.75
	A1474118	5.0	4.5	4.75
	A1474120	4.8	5.0	4.90

For Regulatory Use Only - Not for Distribution

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

At the end of recovery

Females

Group	Animal No	LAN1 (cm)	LAN2 (cm)	LAM (cm)
Control	A1474021	4.0	3.5	3.75
	A1474023	7.5	7.5	7.50
	A1474025	7.0	6.5	6.75
	A1474027	6.0	6.5	6.25
	A1474029	8.0	6.5	7.25

FOR SPONSOR INTERNAL USE ONLY

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

At the end of recovery

Females

Group	Animal No	LAN1 (cm)	LAN2 (cm)	LAM (cm)
2	A1474051	4.5	5.0	4.75
	A1474053	5.0	4.5	4.75
	A1474055	7.0	7.0	7.00
	A1474057	6.0	6.5	6.25
	A1474059	6.5	5.0	5.75

For GLP Purposes - Final Document Only

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

At the end of recovery

Females

Group	Animal No	LAN1 (cm)	LAN2 (cm)	LAM (cm)
3	A1474081	3.5	3.0	3.25
	A1474083	3.5	2.8	3.15
	A1474085	4.0	4.2	4.10
	A1474087	5.0	6.0	5.50
	A1474089	4.0	3.0	3.50

Landing foot splay - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

At the end of recovery

Females

Group	Animal No	LAN1 (cm)	LAN2 (cm)	LAM (cm)
4	A1474111	3.8	3.0	3.40
	A1474113	4.0	4.5	4.25
	A1474115	5.2	3.8	4.50
	A1474117	4.9	3.7	4.30
	A1474119	4.9	3.2	4.05

For OECD 407 - Initial Submission 2010

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

At the end of treatment

Males

Group	Animal No	APP	TO	CLI	TPR	PU	ARR	GR1 (g)	GR2 (g)	GRM (g)
Control	A1474002	1	2	1	1	Passed	1	10.2	6.5	8.35
	A1474004	1	1	1	1	Passed	1	9.2	9.0	9.10
	A1474006	1	2	1	1	Passed	1	7.4	2.2	4.80
	A1474008	1	2	1	1	Passed	1	5.7	7.0	6.35
	A1474010	1	2	1	1	Passed	1	4.3	4.2	4.25
	A1474012	1	2	1	1	Passed	1	2.3	9.5	5.90
	A1474014	1	2	1	1	Passed	1	7.7	8.0	7.85
	A1474016	1	2	1	1	Passed	1	7.9	8.8	8.35
	A1474018	1	2	1	1	Passed	1	11.5	11.0	11.25
	A1474020	1	1	1	2	Passed	1	3.0	7.9	5.45
	A1474022	1	1	1	1	Passed	1	11.1	2.6	6.85
	A1474024	1	2	1	1	Passed	1	12.1	7.1	9.60
	A1474026	1	1	1	1	Passed	1	7.2	8.6	7.90
	A1474028	1	1	1	1	Passed	1	4.7	3.8	4.25
	A1474030	1	1	1	1	Passed	1	9.6	6.1	7.85

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

At the end of treatment

Males

Group	Animal No	APP	TO	CLI	TPR	PU	ARR	GR1 (g)	GR2 (g)	GRM (g)
2	A1474032	1	1	1	1	Passed	1	1.3	7.9	4.60
	A1474034	1	2	1	1	Passed	1	1.1	5.1	3.10
	A1474036	1	1	1	1	Passed	1	8.0	4.2	6.10
	A1474038	1	1	1	1	Passed	1	9.5	7.2	8.35
	A1474040	1	2	1	1	Passed	1	8.1	8.9	8.50
	A1474042	1	2	1	1	Passed	1	6.1	3.7	4.90
	A1474044	1	1	1	1	Passed	1	10.0	8.9	9.45
	A1474046	1	2	1	1	Passed	1	8.5	5.5	7.00
	A1474048	1	1	1	1	Passed	1	6.6	8.0	7.30
	A1474050	1	2	1	1	Passed	1	10.4	8.3	9.35
	A1474052	1	2	1	1	Passed	1	7.8	10.9	9.35
	A1474054	1	1	1	1	Passed	1	10.7	2.2	6.45
	A1474056	1	1	1	1	Passed	1	7.8	9.6	8.70
	A1474058	1	2	1	1	Passed	1	7.0	13.3	10.15
	A1474060	1	2	1	1	Passed	1	14.2	8.6	11.40

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

At the end of treatment

Males

Group	Animal No	APP	TO	CLI	TPR	PU	ARR	GR1 (g)	GR2 (g)	GRM (g)
3	A1474062	1	2	1	1	Passed	1	6.6	9.2	7.90
	A1474064	1	1	1	1	Passed	1	13.1	11.5	12.30
	A1474066	1	1	1	1	Passed	1	9.7	10.1	9.90
	A1474068	1	2	1	1	Passed	1	8.7	11.9	10.30
	A1474070	1	1	1	1	Passed	1	10.2	12.5	11.35
	A1474072	1	1	1	1	Passed	1	8.8	13.2	11.00
	A1474074	1	2	1	1	Passed	1	11.3	14.0	12.65
	A1474076	1	1	1	1	Passed	1	9.2	12.6	10.90
	A1474078	1	2	1	1	Passed	1	10.8	13.5	12.15
	A1474080	1	2	1	1	Passed	1	11.7	14.8	13.25
	A1474082	1	1	1	1	Passed	1	7.9	7.5	7.70
	A1474084	1	2	1	1	Passed	1	6.4	4.4	5.40
	A1474086	1	1	1	1	Passed	1	10.0	8.9	9.45
	A1474088	1	1	1	1	Passed	1	12.8	9.4	11.10
	A1474090	1	1	1	1	Passed	1	11.7	11.5	11.60

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

At the end of treatment

Males

Group	Animal No	APP	TO	CLI	TPR	PU	ARR	GR1 (g)	GR2 (g)	GRM (g)
4	A1474092	1	1	1	1	Passed	1	4.3	5.9	5.10
	A1474094	1	1	1	1	Passed	1	11.3	14.6	12.95
	A1474096	1	2	1	1	Passed	1	14.5	13.5	14.00
	A1474098	1	2	1	1	Passed	1	5.2	17.9	11.55
	A1474100	1	1	1	1	Passed	1	10.3	13.6	11.95
	A1474102	1	1	1	1	Passed	1	11.2	13.0	12.10
	A1474104	1	2	1	1	Passed	1	5.3	14.2	9.75
	A1474106	1	1	1	1	Passed	1	13.5	17.0	15.25
	A1474108	1	2	1	1	Passed	1	13.1	17.8	15.45
	A1474110	1	1	1	1	Passed	1	4.5	11.9	8.20
	A1474112	1	2	1	1	Passed	1	16.3	10.2	13.25
	A1474114	1	2	1	1	Passed	1	9.3	6.3	7.80
	A1474116	1	1	1	1	Passed	1	7.7	4.3	6.00
	A1474118	1	2	1	1	Passed	1	5.5	10.9	8.20
	A1474120	1	1	1	1	Passed	1	3.2	8.4	5.80

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

At the end of treatment

Females

Group	Animal No	APP	TO	CLI	TPR	PU	ARR	GR1 (g)	GR2 (g)	GRM (g)
Control	A1474001	1	1	1	1	Passed	1	8.9	3.2	6.05
	A1474003	1	1	1	1	Passed	1	12.7	13.8	13.25
	A1474005	1	1	1	1	Passed	1	15.1	12.0	13.55
	A1474007	1	1	1	1	Passed	1	12.7	12.6	12.65
	A1474009	1	1	1	1	Passed	1	10.4	14.2	12.30
	A1474011	1	2	1	1	Passed	1	10.3	17.4	13.85
	A1474013	1	1	1	1	Passed	1	14.4	16.4	15.40
	A1474015	1	1	1	1	Passed	1	12.4	17.3	14.85
	A1474017	1	2	1	1	Passed	1	12.9	16.0	14.45
	A1474019	1	1	1	1	Passed	1	13.2	15.1	14.15
	A1474021	1	1	1	1	Passed	1	12.8	10.3	11.55
	A1474023	1	2	1	1	Passed	1	12.3	16.2	14.25
	A1474025	1	1	1	1	Passed	1	6.8	9.4	8.10
	A1474027	1	2	1	1	Passed	1	12.7	10.1	11.40
	A1474029	1	1	1	1	Passed	1	11.5	12.5	12.00

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

At the end of treatment

Females

Group	Animal No	APP	TO	CLI	TPR	PU	ARR	GR1 (g)	GR2 (g)	GRM (g)
2	A1474031	1	1	1	1	Passed	1	12.9	15.7	14.30
	A1474033	1	2	1	1	Passed	1	11.8	13.4	12.60
	A1474035	1	1	1	1	Passed	1	12.6	8.2	10.40
	A1474037	1	1	1	1	Passed	1	9.2	8.6	8.90
	A1474039	1	1	1	1	Passed	1	11.7	12.9	12.30
	A1474041	1	1	1	1	Passed	1	8.0	16.1	12.05
	A1474043	1	2	1	1	Passed	1	6.9	9.1	8.00
	A1474045	1	1	1	1	Passed	1	7.0	10.8	8.90
	A1474047	1	1	1	1	Passed	1	7.7	16.0	11.85
	A1474049	1	1	1	1	Passed	1	9.2	15.9	12.55
	A1474051	1	1	1	1	Passed	1	7.3	14.1	10.70
	A1474053	1	2	1	1	Passed	1	6.6	15.7	11.15
	A1474055	1	1	1	1	Passed	1	7.0	13.1	10.05
	A1474057	1	1	1	1	Passed	1	12.0	11.5	11.75
	A1474059	1	2	1	1	Passed	1	10.1	16.3	13.20

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

At the end of treatment

Females

Group	Animal No	APP	TO	CLI	TPR	PU	ARR	GR1 (g)	GR2 (g)	GRM (g)
3	A1474061	1	1	1	1	Passed	1	14.9	8.5	11.70
	A1474063	1	1	1	1	Passed	1	12.3	11.8	12.05
	A1474065	1	1	1	1	Passed	1	7.3	9.8	8.55
	A1474067	1	2	1	1	Passed	1	12.3	14.1	13.20
	A1474069	1	2	1	1	Passed	1	15.4	9.3	12.35
	A1474071	1	2	1	1	Passed	1	7.8	10.1	8.95
	A1474073	1	1	1	1	Passed	1	12.3	13.1	12.70
	A1474075	1	2	1	1	Passed	1	10.8	12.8	11.80
	A1474077	1	2	1	1	Passed	1	14.5	8.6	11.55
	A1474079	1	1	1	1	Passed	1	12.6	11.1	11.85
	A1474081	1	1	1	1	Passed	1	13.4	15.1	14.25
	A1474083	1	2	1	1	Passed	1	11.0	8.7	9.85
	A1474085	1	1	1	1	Passed	1	12.0	9.5	10.75
	A1474087	1	1	1	1	Passed	1	11.5	15.6	13.55
	A1474089	1	2	1	1	Passed	1	16.1	8.4	12.25

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

At the end of treatment

Females

Group	Animal No	APP	TO	CLI	TPR	PU	ARR	GR1 (g)	GR2 (g)	GRM (g)
4	A1474091	1	1	1	1	Passed	1	16.1	10.9	13.50
	A1474093	1	2	1	1	Passed	1	12.4	11.8	12.10
	A1474095	1	1	1	1	Passed	1	11.3	10.4	10.85
	A1474097	1	2	1	1	Passed	1	12.4	10.5	11.45
	A1474099	1	1	1	1	Passed	1	14.5	11.8	13.15
	A1474101	1	1	1	1	Passed	1	14.1	8.4	11.25
	A1474103	1	2	1	1	Passed	1	12.4	15.1	13.75
	A1474105	1	1	1	1	Passed	1	11.0	8.3	9.65
	A1474107	1	1	1	1	Passed	1	12.0	9.0	10.50
	A1474109	1	1	1	1	Passed	1	8.9	10.0	9.45
	A1474111	1	2	1	1	Passed	1	9.0	9.5	9.25
	A1474113	1	1	1	1	Passed	1	10.5	11.6	11.05
	A1474115	1	1	1	1	Passed	1	10.4	12.3	11.35
	A1474117	1	1	1	1	Passed	1	11.4	10.8	11.10
	A1474119	1	1	1	1	Passed	1	9.2	10.7	9.95

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

At the end of recovery

Males

Group	Animal No	APP	TO	CLI	TPR	PU	ARR	GR1 (g)	GR2 (g)	GRM (g)
Control	A1474022	1	2	1	2	Passed	1	5.6	6.8	6.20
	A1474024	1	2	1	2	Passed	1	2.0	5.2	3.60
	A1474026	1	2	1	2	Passed	1	16.3	4.2	10.25
	A1474028	1	2	1	2	Passed	1	2.6	6.9	4.75
	A1474030	1	2	1	2	Passed	1	3.6	6.7	5.15

Sensory reactivity - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

At the end of recovery

Males

Group	Animal No	APP	TO	CLI	TPR	PU	ARR	GR1 (g)	GR2 (g)	GRM (g)
2	A1474052	1	1	1	2	Passed	1	2.1	1.6	1.85
	A1474054	1	1	1	2	Passed	1	3.6	5.6	4.60
	A1474056	1	1	1	2	Passed	1	5.0	5.1	5.05
	A1474058	1	1	1	2	Passed	1	1.4	7.1	4.25
	A1474060	1	1	1	2	Passed	1	5.3	7.0	6.15

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

At the end of recovery

Males

Group	Animal No	APP	TO	CLI	TPR	PU	ARR	GR1 (g)	GR2 (g)	GRM (g)
3	A1474082	1	1	1	2	Passed	1	2.0	2.9	2.45
	A1474084	1	1	1	2	Passed	1	1.7	0.9	1.30
	A1474086	1	1	1	2	Passed	1	2.2	4.5	3.35
	A1474088	1	1	1	2	Passed	1	1.2	4.5	2.85
	A1474090	1	1	1	2	Passed	1	5.2	5.0	5.10

Sensory reactivity - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

At the end of recovery

Males

Group	Animal No	APP	TO	CLI	TPR	PU	ARR	GR1 (g)	GR2 (g)	GRM (g)
4	A1474112	1	1	1	2	Passed	1	5.2	3.4	4.30
	A1474114	1	1	1	2	Passed	1	1.3	1.9	1.60
	A1474116	1	1	1	2	Passed	1	5.5	5.7	5.60
	A1474118	1	1	1	2	Passed	1	0.6	1.3	0.95
	A1474120	1	1	1	2	Passed	1	4.2	3.4	3.80

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

At the end of recovery

Females

Group	Animal No	APP	TO	CLI	TPR	PU	ARR	GR1 (g)	GR2 (g)	GRM (g)
Control	A1474021	1	1	1	2	Passed	1	3.4	5.0	4.20
	A1474023	1	1	1	2	Passed	1	1.3	2.7	2.00
	A1474025	1	1	1	2	Passed	1	5.6	5.7	5.65
	A1474027	1	1	1	2	Passed	1	1.7	5.4	3.55
	A1474029	1	1	1	2	Passed	1	2.9	4.9	3.90

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

At the end of recovery

Females

Group	Animal No	APP	TO	CLI	TPR	PU	ARR	GR1 (g)	GR2 (g)	GRM (g)
2	A1474051	1	1	1	2	Passed	1	2.8	1.1	1.95
	A1474053	1	1	1	2	Passed	1	2.0	1.8	1.90
	A1474055	1	1	1	2	Passed	1	9.4	4.9	7.15
	A1474057	1	1	1	2	Passed	1	3.2	2.0	2.60
	A1474059	1	1	1	2	Passed	1	3.0	4.3	3.65

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

At the end of recovery

Females

Group	Animal No	APP	TO	CLI	TPR	PU	ARR	GR1 (g)	GR2 (g)	GRM (g)
3	A1474081	1	1	1	2	Passed	1	3.3	3.0	3.15
	A1474083	1	1	1	2	Passed	1	2.8	3.4	3.10
	A1474085	1	1	1	2	Passed	1	2.9	4.9	3.90
	A1474087	1	1	1	2	Passed	1	4.6	1.4	3.00
	A1474089	1	1	1	2	Passed	1	3.6	5.3	4.45

Sensory reactivity - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

At the end of recovery

Females

Group	Animal No	APP	TO	CLI	TPR	PU	ARR	GR1 (g)	GR2 (g)	GRM (g)
4	A1474111	1	1	1	2	Passed	1	2.8	4.0	3.40
	A1474113	1	1	1	2	Passed	1	2.7	4.2	3.45
	A1474115	1	1	1	2	Passed	1	1.2	2.5	1.85
	A1474117	1	1	1	2	Passed	1	0.8	4.6	2.70
	A1474119	1	1	1	2	Passed	1	2.5	3.7	3.10

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 78

Males

Group	Animal No	CD
Control	A1474002	102
	A1474004	830
	A1474006	1240
	A1474008	1244
	A1474010	1060
	A1474012	998
	A1474014	801
	A1474016	1003
	A1474018	644
	A1474020	839
	A1474022	451
	A1474024	1106
	A1474026	1066
	A1474028	1314
	A1474030	1004

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 78

Males

Group	Animal No	CD
2	A1474032	1030
	A1474034	942
	A1474036	756
	A1474038	1038
	A1474040	895
	A1474042	779
	A1474044	1397
	A1474046	1226
	A1474048	799
	A1474050	1061
	A1474052	945
	A1474054	926
	A1474056	1145
	A1474058	954
	A1474060	924

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 78

Males

Group	Animal No	CD
3	A1474062	690
	A1474064	1150
	A1474066	1208
	A1474068	1152
	A1474070	1282
	A1474072	572
	A1474074	710
	A1474076	755
	A1474078	926
	A1474080	865
	A1474082	1013
	A1474084	1250
	A1474086	606
	A1474088	1378
	A1474090	1152

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REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 78

Males

Group	Animal No	CD
4	A1474092	1130
	A1474094	1065
	A1474096	1080
	A1474098	1213
	A1474100	1277
	A1474102	1332
	A1474104	1170
	A1474106	922
	A1474108	853
	A1474110	826
	A1474112	992
	A1474114	553
	A1474116	1115
	A1474118	1234
	A1474120	1026

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 78

Females

Group	Animal No	CD
Control	A1474001	1017
	A1474003	938
	A1474005	741
	A1474007	803
	A1474009	1328
	A1474011	1062
	A1474013	1069
	A1474015	959
	A1474017	1027
	A1474019	1174
	A1474021	976
	A1474023	1160
	A1474025	1055
	A1474027	1115
	A1474029	910

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 78

Females

Group	Animal No	CD
2	A1474031	1209
	A1474033	940
	A1474035	1279
	A1474037	1000
	A1474039	410
	A1474041	983
	A1474043	797
	A1474045	1083
	A1474047	1088
	A1474049	1127
	A1474051	1152
	A1474053	1176
	A1474055	855
	A1474057	1060
	A1474059	1161

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 78

Females

Group	Animal No	CD
3	A1474061	380
	A1474063	898
	A1474065	852
	A1474067	1253
	A1474069	1118
	A1474071	1326
	A1474073	1040
	A1474075	914
	A1474077	724
	A1474079	762
	A1474081	1224
	A1474083	1009
	A1474085	1242
	A1474087	1122
	A1474089	855

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 78

Females

Group	Animal No	CD
4	A1474091	1151
	A1474093	1129
	A1474095	1317
	A1474097	612
	A1474099	1046
	A1474101	1098
	A1474103	1006
	A1474105	1314
	A1474107	1163
	A1474109	1129
	A1474111	475
	A1474113	1241
	A1474115	978
	A1474117	1165
	A1474119	1003

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REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 50

Males

Group	Animal No	CD
Control	A1474022	296
	A1474024	938
	A1474026	820
	A1474028	1399
	A1474030	483

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REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 50

Males

Group	Animal No	CD
2	A1474052	1098
	A1474054	1104
	A1474056	1115
	A1474058	1207
	A1474060	572

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REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 50

Males

Group	Animal No	CD
3	A1474082	1090
	A1474084	1208
	A1474086	676
	A1474088	1077
	A1474090	985

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 50

Males

Group	Animal No	CD
4	A1474112	1081
	A1474114	1690
	A1474116	671
	A1474118	1412
	A1474120	1182

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 50

Females

Group	Animal No	CD
Control	A1474021	967
	A1474023	1003
	A1474025	944
	A1474027	1645
	A1474029	1261

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 50

Females

Group	Animal No	CD
2	A1474051	1297
	A1474053	1166
	A1474055	888
	A1474057	1004
	A1474059	830

EU - Private - Until Deceased + 10 y

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 50

Females

Group	Animal No	CD
3	A1474081	963
	A1474083	1182
	A1474085	1087
	A1474087	909
	A1474089	1032

GLP - IACUC - RTC Approved 2010

REDACTED AS TO TRADE NAMES

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FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 50

Females

Group	Animal No	CD
4	A1474111	973
	A1474113	1028
	A1474115	999
	A1474117	1310
	A1474119	1065

[illegible]

Body weight (g) - Individual data

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No	Animal No	Quarantine Day: 12	Dosing Day: 1	Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43
Control	A1474002	181.5	230.1	276.8	316.5	338.0	361.9	388.6	408.9
	A1474004	173.7	223.7	274.7	318.1	351.0	375.3	398.8	417.6
	A1474006	186.6	233.2	279.8	319.7	349.2	374.5	398.8	418.7
	A1474008	179.8	228.5	275.7	312.0	337.7	360.7	381.2	404.9
	A1474010	184.7	238.9	283.8	332.4	362.9	378.8	403.0	420.6
	A1474012	187.3	237.4	281.2	314.9	341.1	357.8	374.2	385.0
	A1474014	175.9	214.7	263.6	305.4	333.0	350.6	372.0	388.5
	A1474016	174.1	202.8	243.4	280.5	298.6	303.8	321.1	333.6
	A1474018	172.3	230.7	275.4	311.9	345.4	367.7	395.3	414.3
	A1474020	165.7	205.6	245.5	276.1	305.1	328.0	336.2	352.4
	A1474022	179.0	224.5	275.8	310.5	341.4	362.7	385.7	394.0
	A1474024	167.5	215.9	262.8	296.0	319.1	343.8	351.6	357.8
	A1474026	184.3	212.6	258.4	292.4	319.2	346.2	371.8	381.4
	A1474028	182.7	228.8	276.7	311.2	339.6	357.0	373.6	384.3
	A1474030	177.6	220.0	263.0	289.8	314.2	327.8	347.0	356.8
	(n)	15	15	15	15	15	15	15	15
	Mean	178.18	223.16	269.11	305.83	333.03	353.11	373.26	387.92
	SD	6.630	10.979	12.515	15.653	18.047	20.581	24.474	27.399

Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No	Animal No	Dosing Day: 50	Day: 57	Day: 64	Day: 71	Day: 78	Day: 85	Day: 92
Control	A1474002	419.7	440.0	450.6	464.0	479.6	471.8	457.4
	A1474004	426.4	439.7	450.2	459.4	479.2	475.1	467.8
	A1474006	428.7	440.1	452.7	463.2	477.0	475.9	468.7
	A1474008	413.6	428.9	440.9	450.0	471.2	472.0	463.7
	A1474010	434.9	439.8	446.8	460.8	471.1	470.8	461.0
	A1474012	390.6	404.8	413.6	418.1	433.9	432.8	423.1
	A1474014	400.4	410.7	425.8	434.3	451.9	450.7	441.2
	A1474016	345.7	360.4	364.1	378.2	393.3	391.1	381.5
	A1474018	425.5	431.3	440.8	451.8	469.9	478.3	467.4
	A1474020	361.7	375.0	386.1	393.7	408.8	407.6	396.0
	A1474022	410.7	422.3	427.3	440.6	434.4	446.7	453.0
	A1474024	368.8	375.0	389.9	395.1	406.6	401.4	411.8
	A1474026	394.3	405.5	420.2	429.7	446.6	450.7	458.4
	A1474028	399.7	412.6	424.3	428.7	441.4	442.7	455.0
	A1474030	376.7	387.3	393.1	404.9	416.8	417.0	423.2
	(n)	15	15	15	15	15	15	15
	Mean	399.83	411.56	421.76	431.50	445.45	445.64	441.95
	SD	26.898	26.702	27.398	28.076	29.188	29.625	28.096

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FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No	Animal No	Quarantine Day: 12	Dosing Day: 1	Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43
2	A1474032	174.2	224.2	271.1	294.9	331.8	350.9	368.1	379.1
	A1474034	187.8	219.6	256.4	293.3	324.4	341.3	363.4	382.2
	A1474036	176.9	224.8	273.2	318.8	345.0	364.9	386.2	406.1
	A1474038	177.6	225.6	266.6	297.0	330.1	345.1	365.0	375.0
	A1474040	179.7	216.9	261.3	297.0	325.9	349.0	364.6	380.2
	A1474042	173.9	218.6	259.5	297.6	332.6	351.5	375.2	392.9
	A1474044	179.1	226.3	272.2	308.1	343.6	363.2	383.9	397.9
	A1474046	180.9	229.6	276.8	322.8	351.9	372.8	395.1	411.2
	A1474048	186.1	235.9	277.1	315.5	348.9	379.6	388.9	402.9
	A1474050	174.9	216.7	261.5	291.9	320.9	339.9	356.3	369.0
	A1474052	182.4	226.9	273.8	309.1	336.7	364.0	386.7	399.4
	A1474054	173.0	223.1	269.4	305.4	339.6	341.6	377.4	392.4
	A1474056	168.3	218.7	272.0	310.8	341.3	370.8	389.0	405.1
	A1474058	184.7	230.3	272.3	313.2	349.0	364.8	386.8	391.9
	A1474060	184.2	221.6	262.7	295.9	327.4	362.4	368.9	383.7
	(n)	15	15	15	15	15	15	15	15
	Mean	178.91	223.92	268.39	304.81	336.61	357.45	377.03	391.27
	SD	5.514	5.454	6.581	10.025	9.876	12.640	11.937	12.618

Body weight (g) - Individual data

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FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No	Animal No	Dosing Day: 50	Day: 57	Day: 64	Day: 71	Day: 78	Day: 85	Day: 92
2	A1474032	397.0	402.9	409.7	424.8	433.5	432.3	425.6
	A1474034	392.5	400.9	416.3	422.7	443.8	447.5	436.7
	A1474036	412.6	433.1	443.3	450.7	467.6	473.5	461.6
	A1474038	393.4	406.1	411.7	424.0	442.4	450.2	433.0
	A1474040	397.9	398.2	407.6	413.9	430.6	432.2	419.0
	A1474042	406.6	433.7	421.5	438.7	448.2	450.8	438.3
	A1474044	407.4	420.9	429.6	438.1	459.1	463.2	443.6
	A1474046	425.6	433.6	444.4	456.3	468.2	477.0	465.0
	A1474048	420.6	423.7	441.9	460.1	468.9	476.9	462.6
	A1474050	384.5	390.2	403.0	413.1	419.9	421.9	408.4
	A1474052	413.9	425.6	439.9	453.4	467.9	471.6	483.3
	A1474054	410.7	431.1	438.2	447.8	458.4	459.5	473.8
	A1474056	420.0	427.0	439.9	448.2	460.5	466.8	469.5
	A1474058	398.5	411.4	421.2	425.6	443.9	450.0	459.6
	A1474060	395.6	405.4	413.5	425.8	440.7	445.6	453.4
	(n)	15	15	15	15	15	15	15
	Mean	405.12	416.25	425.45	436.27	450.24	454.60	448.89
	SD	12.031	14.766	14.798	15.723	15.490	17.210	21.696

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Males

Group No	Animal No	Quarantine Day: 12	Dosing Day: 1	Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43
3	A1474062	173.1	221.2	267.1	299.0	329.5	347.2	368.1	377.5
	A1474064	177.2	221.0	272.7	314.6	350.4	373.4	391.9	402.0
	A1474066	180.4	217.8	271.5	310.9	339.5	365.1	392.4	409.2
	A1474068	167.3	224.5	273.8	310.0	338.0	361.1	377.7	393.9
	A1474070	178.3	222.6	267.7	307.4	337.1	361.7	383.1	391.8
	A1474072	184.1	230.9	273.1	311.5	348.6	368.4	405.7	403.3
	A1474074	176.0	235.5	284.4	327.6	361.1	381.6	404.5	420.4
	A1474076	172.2	222.5	265.1	305.9	340.9	366.7	381.7	403.5
	A1474078	180.8	230.0	274.7	318.2	346.2	365.2	383.6	398.9
	A1474080	184.3	221.7	257.4	290.0	314.4	321.9	337.1	353.4
	A1474082	174.3	211.3	257.0	292.8	320.1	343.6	356.0	374.2
	A1474084	185.1	232.4	276.0	307.4	330.1	341.7	354.5	356.5
	A1474086	185.8	235.1	280.7	321.3	352.4	376.1	390.7	403.1
	A1474088	178.3	227.2	272.7	314.6	347.4	375.3	389.1	407.1
	A1474090	188.4	237.8	284.1	321.7	348.3	373.4	399.0	410.6
	(n)	15	15	15	15	15	15	15	15
	Mean	179.04	226.10	271.87	310.19	340.27	361.49	381.01	393.69
	SD	5.882	7.419	8.163	10.466	12.579	16.207	19.527	19.721

REDACTED AS TO TRADE NAMES

Study: A1474
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FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No	Animal No	Dosing Day: 50	Day: 57	Day: 64	Day: 71	Day: 78	Day: 85	Day: 92
3	A1474062	386.9	401.2	410.6	421.1	433.2	432.3	421.2
	A1474064	417.0	428.2	440.5	450.0	463.4	466.2	451.0
	A1474066	435.6	445.9	460.4	466.8	476.4	483.2	468.1
	A1474068	410.0	421.6	438.2	448.6	459.7	462.3	444.5
	A1474070	404.8	416.9	422.1	432.0	450.0	454.9	443.5
	A1474072	417.5	430.7	443.4	449.0	465.7	463.2	451.0
	A1474074	434.8	441.9	453.4	464.1	480.7	471.2	463.3
	A1474076	414.4	426.4	436.9	449.3	457.1	460.1	449.8
	A1474078	413.0	422.5	431.1	444.2	456.7	458.6	446.2
	A1474080	363.8	370.1	374.9	388.5	407.0	401.0	389.1
	A1474082	387.6	401.1	413.2	414.1	429.1	431.4	441.4
	A1474084	365.0	374.9	387.6	394.3	413.6	415.0	418.2
	A1474086	415.2	415.3	424.6	439.7	445.1	450.5	452.9
	A1474088	416.9	430.6	442.1	448.6	460.6	473.7	477.7
	A1474090	422.1	429.3	441.1	450.0	457.9	458.2	473.5
	(n)	15	15	15	15	15	15	15
	Mean	406.97	417.11	428.01	437.35	450.41	452.12	446.09
	SD	21.892	21.911	23.409	23.238	21.287	22.657	22.860

REDACTED AS TO TRADE NAMES

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Males

Group No	Animal No	Quarantine Day: 12	Dosing Day: 1	Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43
4	A1474092	177.2	225.9	273.7	312.7	343.0	366.2	385.0	398.0
	A1474094	179.2	238.6	284.0	316.9	340.1	357.0	374.2	388.5
	A1474096	188.9	205.7	250.4	286.1	314.1	337.9	358.9	370.5
	A1474098	185.5	233.7	285.0	316.7	341.4	367.8	391.4	404.3
	A1474100	181.5	239.9	289.5	337.5	377.7	389.5	412.2	433.8
	A1474102	177.5	228.0	279.3	324.4	350.0	371.1	396.1	411.4
	A1474104	179.2	223.3	268.5	307.9	325.3	346.8	368.0	383.1
	A1474106	170.7	242.5	289.5	330.8	365.1	382.4	403.8	418.8
	A1474108	184.5	239.8	285.1	321.6	347.5	367.8	392.0	411.8
	A1474110	173.1	217.1	260.5	292.9	321.3	345.7	362.6	377.8
	A1474112	180.7	250.9	301.0	336.2	360.9	390.3	411.7	422.8
	A1474114	185.2	231.4	277.9	314.5	347.1	365.5	380.7	396.5
	A1474116	174.6	221.5	274.3	310.1	343.4	363.1	385.2	400.0
	A1474118	171.2	212.2	256.6	280.3	311.8	329.7	349.4	362.7
	A1474120	174.7	233.0	285.0	319.3	337.6	356.8	376.5	391.8
	(n)	15	15	15	15	15	15	15	15
	Mean	178.91	229.57	277.35	313.86	341.75	362.51	383.18	398.12
	SD	5.516	12.232	13.685	16.798	18.340	17.573	18.740	19.832

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Males

Group No	Animal No	Dosing Day: 50	Day: 57	Day: 64	Day: 71	Day: 78	Day: 85	Day: 92
4	A1474092	412.4	422.5	403.3	398.2	437.4	448.8	458.2
	A1474094	405.6	416.0	418.9	429.7	437.7	442.6	441.1
	A1474096	379.4	394.9	405.4	415.8	423.1	424.0	429.9
	A1474098	415.0	422.4	437.8	440.2	447.6	456.1	464.1
	A1474100	450.5	463.1	478.4	492.3	495.7	505.0	498.6
	A1474102	420.8	424.4	437.1	447.1	464.6	467.5	441.7
	A1474104	400.1	405.5	406.1	422.8	430.4	435.9	421.4
	A1474106	432.3	444.9	452.1	464.7	471.9	474.8	456.6
	A1474108	429.7	439.4	448.0	466.4	473.4	478.6	464.9
	A1474110	387.4	390.5	409.9	408.1	419.3	422.9	408.4
	A1474112	441.1	450.2	459.3	468.7	473.1	466.1	460.9
	A1474114	408.7	421.3	429.6	446.4	449.0	457.3	448.8
	A1474116	410.6	421.0	440.0	448.7	461.3	466.5	461.4
	A1474118	372.8	382.5	390.5	402.0	408.5	413.0	402.5
	A1474120	404.3	413.1	422.6	436.8	446.3	447.3	444.7
	(n)	15	15	15	15	15	15	15
	Mean	411.38	420.78	429.27	439.19	449.29	453.76	446.88
	SD	21.703	22.315	24.273	27.032	24.032	24.225	24.470

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Females

Group No	Animal No	Quarantine Day: 12	Dosing Day: 1	Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43
Control	A1474001	147.8	175.9	192.9	212.4	225.4	239.0	245.4	255.6
	A1474003	147.3	183.4	207.6	226.3	246.3	252.7	263.4	271.1
	A1474005	150.3	173.7	189.9	203.9	226.2	230.7	241.8	249.7
	A1474007	145.8	160.2	167.2	185.0	203.2	207.7	214.2	206.3
	A1474009	155.9	171.2	188.1	201.0	226.2	232.0	241.8	250.6
	A1474011	157.0	174.6	191.0	204.6	231.9	240.2	248.7	256.9
	A1474013	153.9	176.3	198.0	215.7	229.3	250.1	249.2	255.3
	A1474015	156.2	174.7	197.3	215.0	236.8	249.1	255.8	265.2
	A1474017	155.0	192.5	205.3	235.8	251.9	257.2	274.3	277.8
	A1474019	153.9	172.1	199.3	215.6	241.5	243.0	249.4	261.2
	A1474021	160.7	187.0	215.5	232.4	245.6	257.7	263.9	270.6
	A1474023	149.7	170.6	204.3	207.6	225.3	249.0	249.3	256.7
	A1474025	146.3	171.3	192.6	208.1	219.6	237.9	239.5	248.1
	A1474027	142.3	163.9	181.9	200.2	215.3	218.3	238.5	241.9
	A1474029	152.0	179.4	181.9	213.3	231.7	243.3	256.3	262.5
	(n)	15	15	15	15	15	15	15	15
	Mean	151.61	175.12	194.19	211.79	230.41	240.53	248.77	255.30
	SD	5.074	8.205	11.983	13.006	12.779	13.944	13.879	16.616

REDACTED AS TO TRADE NAMES

Body weight (g) - Individual data

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Females

Group No	Animal No	Dosing Day: 50	Day: 57	Day: 64	Day: 71	Day: 78	Day: 85	Day: 92
Control	A1474001	262.1	261.4	276.4	274.6	284.4	281.6	280.2
	A1474003	273.2	275.5	282.2	285.2	297.4	312.9	302.2
	A1474005	255.7	259.2	267.1	270.9	275.6	279.0	280.5
	A1474007	222.1	224.2	221.7	233.4	240.8	237.1	257.9
	A1474009	254.9	255.0	263.4	263.0	274.1	274.4	274.2
	A1474011	254.1	269.2	270.7	271.1	286.8	287.8	285.7
	A1474013	262.2	264.7	269.7	270.6	281.7	280.0	279.0
	A1474015	286.4	272.4	280.3	289.5	296.8	289.8	296.7
	A1474017	292.7	299.0	304.1	306.5	308.1	304.8	310.8
	A1474019	264.7	270.6	279.7	276.4	288.0	284.1	290.7
	A1474021	286.7	293.0	293.3	302.8	308.7	305.8	308.8
	A1474023	265.9	262.3	276.0	274.3	283.4	281.9	291.0
	A1474025	246.2	250.3	256.8	256.9	266.9	264.0	274.7
	A1474027	247.8	249.3	257.8	255.6	282.1	273.4	280.1
	A1474029	267.4	274.3	270.1	282.2	290.5	282.4	293.7
	(n)	15	15	15	15	15	15	15
	Mean	262.81	265.36	271.29	274.33	284.35	282.60	287.08
	SD	17.951	17.968	18.546	18.116	16.766	18.165	14.155

REDACTED AS TO TRADE NAMES

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FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No	Animal No	Quarantine Day: 12	Dosing Day: 1	Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43
2	A1474031	157.2	162.9	179.1	195.1	225.5	233.0	247.4	247.5
	A1474033	155.4	148.2	161.9	170.8	189.4	193.6	196.8	206.6
	A1474035	152.5	171.1	192.7	213.3	237.4	252.6	253.3	258.3
	A1474037	154.1	177.6	199.5	221.1	243.0	259.1	284.0	281.8
	A1474039	146.3	165.9	181.0	195.0	219.1	226.9	240.2	244.3
	A1474041	160.4	183.5	203.8	217.3	239.2	247.6	253.3	264.1
	A1474043	149.7	175.2	194.7	213.9	235.5	240.5	249.2	261.4
	A1474045	153.7	168.3	185.9	204.6	227.2	249.0	239.7	250.5
	A1474047	144.2	167.1	183.2	201.8	211.0	226.8	232.3	242.2
	A1474049	148.3	176.1	194.6	210.9	231.9	237.9	246.7	250.8
	A1474051	145.4	173.8	199.6	220.5	225.4	233.9	239.6	263.3
	A1474053	150.3	180.8	209.1	210.6	235.8	240.8	246.2	257.8
	A1474055	156.3	184.3	209.5	226.6	254.1	252.5	278.9	279.1
	A1474057	154.8	185.7	185.7	225.9	235.6	250.8	266.3	260.8
	A1474059	147.1	172.7	186.3	200.2	213.0	224.4	227.3	235.8
	(n)	15	15	15	15	15	15	15	15
	Mean	151.71	172.88	191.11	208.51	228.21	237.96	246.75	253.62
	SD	4.815	9.725	12.634	14.602	15.598	16.271	20.911	18.125

REDACTED AS TO TRADE NAMES

Body weight (g) - Individual data

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No	Animal No	Dosing Day: 50	Day: 57	Day: 64	Day: 71	Day: 78	Day: 85	Day: 92
2	A1474031	248.7	262.2	258.9	267.4	272.9	274.0	288.2
	A1474033	213.9	220.6	221.9	229.7	234.6	237.1	241.1
	A1474035	266.7	264.3	275.8	281.6	284.4	286.9	291.4
	A1474037	284.4	292.5	295.3	310.2	306.3	305.4	305.9
	A1474039	251.3	262.7	264.1	272.0	276.8	271.8	287.9
	A1474041	257.4	263.2	258.3	270.2	275.4	280.9	287.1
	A1474043	268.2	267.7	281.0	280.5	290.1	283.3	290.7
	A1474045	248.0	262.0	264.9	276.5	288.7	270.5	278.8
	A1474047	245.4	240.8	248.6	252.1	270.6	258.3	271.0
	A1474049	261.7	260.4	263.2	274.9	275.3	275.2	277.3
	A1474051	271.3	269.6	271.6	271.0	279.3	267.0	279.9
	A1474053	263.7	262.9	266.8	269.0	274.7	283.7	280.5
	A1474055	280.9	287.2	309.9	300.9	305.2	296.4	315.7
	A1474057	277.6	273.5	278.8	282.1	285.3	280.1	292.5
	A1474059	241.8	240.7	252.5	249.1	260.9	257.0	256.4
	(n)	15	15	15	15	15	15	15
	Mean	258.73	262.02	267.44	272.48	278.70	275.17	282.96
	SD	18.123	17.759	20.395	19.512	17.265	16.612	18.037

REDACTED AS TO TRADE NAMES

Body weight (g) - Individual data

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No	Animal No	Quarantine Day: 12	Dosing Day: 1	Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43
3	A1474061	157.2	188.7	197.4	215.0	236.9	241.3	251.0	263.0
	A1474063	149.7	173.6	190.9	213.5	228.3	243.5	253.7	262.6
	A1474065	158.9	181.1	199.8	223.0	239.2	254.3	258.1	272.7
	A1474067	150.0	167.5	180.5	201.0	242.7	231.4	237.7	260.3
	A1474069	146.1	168.0	187.4	206.8	220.2	232.3	244.6	254.7
	A1474071	147.4	167.3	179.6	194.4	204.2	213.9	224.2	236.9
	A1474073	151.0	171.0	187.0	208.5	223.4	234.9	244.6	251.2
	A1474075	153.9	176.4	189.3	215.9	236.8	245.2	258.8	278.0
	A1474077	155.4	175.5	196.0	214.4	238.3	249.5	260.6	277.4
	A1474079	156.6	173.4	189.7	228.4	234.9	245.2	258.9	267.0
	A1474081	154.6	174.4	191.7	212.2	234.6	234.8	247.9	254.6
	A1474083	155.1	180.2	194.4	221.0	237.7	233.5	251.3	249.7
	A1474085	141.2	171.8	178.3	205.4	228.3	259.1	249.4	248.5
	A1474087	147.7	174.6	191.5	211.9	223.4	235.9	255.2	256.9
	A1474089	146.1	166.6	189.8	198.6	216.4	223.4	247.3	243.1
	(n)	15	15	15	15	15	15	15	15
	Mean	151.39	174.01	189.55	211.39	229.69	238.55	249.55	258.44
	SD	5.057	6.010	6.329	9.149	10.526	11.644	9.496	12.007

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No	Animal No	Dosing Day: 50	Day: 57	Day: 64	Day: 71	Day: 78	Day: 85	Day: 92
3	A1474061	259.6	266.9	271.2	275.9	279.4	279.4	283.8
	A1474063	270.1	262.8	276.0	271.6	298.4	284.1	287.0
	A1474065	267.3	283.9	284.6	291.3	299.0	296.5	305.2
	A1474067	260.6	253.5	263.4	268.1	277.2	273.6	275.5
	A1474069	267.3	255.0	264.1	264.0	275.6	271.2	282.2
	A1474071	234.1	241.1	254.6	262.1	257.0	256.5	264.3
	A1474073	250.9	260.4	261.3	268.0	278.0	270.4	286.5
	A1474075	265.5	276.0	281.8	285.2	294.3	287.5	292.6
	A1474077	273.6	279.4	280.7	293.9	290.1	294.4	304.1
	A1474079	271.6	275.3	295.5	283.3	288.3	286.9	288.0
	A1474081	255.1	268.3	266.4	275.7	278.5	280.6	286.5
	A1474083	265.7	267.5	261.3	278.1	281.3	284.8	286.9
	A1474085	271.9	269.1	269.4	268.2	281.7	274.7	283.3
	A1474087	261.1	265.5	273.0	270.9	275.9	280.4	281.6
	A1474089	245.8	250.8	263.4	263.4	261.4	266.3	276.6
	(n)	15	15	15	15	15	15	15
	Mean	261.35	265.03	271.11	274.65	281.07	279.15	285.61
	SD	10.975	11.528	10.918	9.993	11.916	10.664	10.209

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FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No	Animal No	Quarantine Day: 12	Dosing Day: 1	Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43
4	A1474091	154.7	176.0	194.7	216.9	230.1	234.1	250.7	256.1
	A1474093	155.3	162.1	179.0	191.9	210.1	208.9	225.1	237.3
	A1474095	158.6	187.0	203.5	229.5	254.4	251.3	275.0	278.0
	A1474097	156.9	182.8	189.9	212.3	236.4	238.0	258.4	266.3
	A1474099	158.2	176.5	194.4	210.5	231.9	238.7	248.4	260.1
	A1474101	147.5	163.5	194.1	207.4	234.1	255.3	243.2	257.5
	A1474103	145.3	166.0	188.2	202.1	218.1	229.1	238.5	249.2
	A1474105	147.5	173.2	205.7	207.5	224.7	232.3	247.8	250.8
	A1474107	150.8	176.9	201.1	223.0	251.8	245.0	264.4	277.0
	A1474109	155.2	164.2	182.5	198.2	219.1	239.3	232.7	257.1
	A1474111	153.1	174.5	191.4	209.8	216.5	229.1	235.7	245.3
	A1474113	145.3	180.3	195.5	211.1	225.8	233.0	233.6	254.5
	A1474115	153.1	169.1	191.1	199.6	220.0	227.0	239.5	246.9
	A1474117	146.9	182.6	198.2	209.4	235.8	249.4	241.2	247.4
	A1474119	149.3	171.0	187.7	214.2	229.2	241.2	250.8	252.9
	(n)	15	15	15	15	15	15	15	15
	Mean	151.85	173.71	193.13	209.56	229.20	236.78	245.67	255.76
	SD	4.641	7.669	7.316	9.521	12.367	11.477	13.062	11.201

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FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No	Animal No	Dosing Day: 50	Day: 57	Day: 64	Day: 71	Day: 78	Day: 85	Day: 92
4	A1474091	263.2	263.7	271.6	271.6	274.4	276.4	277.5
	A1474093	235.6	243.9	250.5	254.4	254.9	254.9	260.8
	A1474095	287.3	291.8	289.4	302.3	300.3	303.1	308.6
	A1474097	276.7	282.7	263.0	294.4	300.1	298.6	302.2
	A1474099	261.0	261.7	261.7	269.0	278.2	274.1	285.0
	A1474101	268.6	276.0	270.1	275.3	294.0	284.5	287.7
	A1474103	252.2	262.1	267.5	275.6	273.6	283.4	281.9
	A1474105	259.0	261.3	267.9	279.6	293.8	296.2	298.3
	A1474107	265.4	274.4	273.5	285.8	300.5	225.9	293.0
	A1474109	256.0	255.2	260.0	274.3	276.9	276.5	291.7
	A1474111	248.7	250.8	261.8	261.3	269.4	267.5	267.5
	A1474113	269.0	260.3	269.8	274.0	280.9	273.8	279.0
	A1474115	249.8	260.7	269.2	269.6	278.1	276.4	283.1
	A1474117	254.3	258.1	260.0	269.1	269.1	278.4	287.8
	A1474119	259.7	259.7	271.8	274.5	280.0	278.9	277.2
	(n)	15	15	15	15	15	15	15
	Mean	260.43	264.16	267.19	275.39	281.41	276.57	285.42
	SD	12.405	12.318	8.670	11.901	13.282	18.566	12.562

Body weight (g) - Individual data

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FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No	Animal No	Recovery Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
Control	A1474022	461.0	462.3	465.2	474.4	475.5	481.8	486.8	477.1
	A1474024	414.3	418.8	425.2	428.6	429.7	438.0	441.7	431.7
	A1474026	454.9	455.8	456.2	464.2	468.4	478.1	479.0	470.3
	A1474028	455.3	460.2	464.0	472.6	479.0	487.5	486.9	473.9
	A1474030	429.8	430.0	439.6	444.2	453.9	454.2	465.1	451.2
	(n)	5	5	5	5	5	5	5	5
	Mean	443.06	445.42	450.04	456.80	461.30	467.92	471.90	460.84
	SD	20.092	19.733	17.239	19.800	20.116	20.995	19.077	19.148

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FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No	Animal No	Recovery Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
2	A1474052	481.8	482.0	495.2	495.5	507.8	514.3	514.7	499.5
	A1474054	475.0	484.5	495.9	499.1	514.3	519.6	515.6	502.7
	A1474056	470.8	473.0	472.9	480.8	485.6	485.8	491.7	476.2
	A1474058	456.2	457.4	453.3	460.3	469.2	478.6	479.2	459.1
	A1474060	456.1	458.9	464.0	466.2	473.1	479.6	492.1	467.0
	(n)	5	5	5	5	5	5	5	5
	Mean	467.98	471.16	476.26	480.38	490.00	495.58	498.66	480.90
	SD	11.491	12.634	18.929	17.201	20.279	19.791	15.925	19.441

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Body weight (g) - Individual data

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Study: A1474
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FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No	Animal No	Recovery Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
3	A1474082	442.7	442.9	450.9	453.9	457.4	459.7	464.7	446.7
	A1474084	420.7	423.6	429.2	432.5	439.3	444.8	447.2	434.8
	A1474086	455.6	464.9	467.4	467.6	479.9	473.0	477.9	460.0
	A1474088	489.9	492.6	504.2	498.9	509.4	510.3	524.7	497.6
	A1474090	473.1	480.8	484.4	490.6	500.0	499.4	507.9	491.9
	(n)	5	5	5	5	5	5	5	5
	Mean	456.40	460.96	467.22	468.30	477.20	477.44	484.48	466.20
	SD	26.758	27.983	29.046	26.480	29.122	27.211	31.585	27.618

Body weight (g) - Individual data

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FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No	Animal No	Recovery Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
4	A1474112	477.9	483.4	489.3	501.5	507.7	509.8	516.5	498.1
	A1474114	469.6	476.6	483.2	489.6	502.9	499.5	505.8	494.5
	A1474116	476.8	477.8	481.1	488.3	497.5	497.7	507.0	490.0
	A1474118	420.8	427.1	428.5	439.1	443.5	441.2	453.3	434.5
	A1474120	460.3	467.0	472.2	478.5	482.9	484.3	497.6	477.2
	(n)	5	5	5	5	5	5	5	5
	Mean	461.08	466.38	470.86	479.40	486.90	486.50	496.04	478.86
	SD	23.589	22.737	24.461	23.961	25.983	26.899	24.815	26.026

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Study: A1474
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FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No	Animal No	Recovery Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
Control	A1474021	309.8	315.2	322.1	345.1	330.0	337.8	334.0	339.3
	A1474023	282.1	281.5	281.3	289.3	309.6	303.6	301.7	312.0
	A1474025	283.9	273.2	279.7	289.4	307.9	304.0	298.4	299.4
	A1474027	271.1	276.1	277.7	281.0	277.4	284.2	291.3	311.9
	A1474029	288.8	292.6	297.2	296.6	306.4	304.1	306.1	307.7
	(n)	5	5	5	5	5	5	5	5
	Mean	287.14	287.72	291.60	300.28	306.26	306.74	306.30	314.06
	SD	14.225	17.055	18.725	25.657	18.777	19.346	16.400	15.011

Body weight (g) - Individual data

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Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No	Animal No	Recovery Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
2	A1474051	282.1	277.8	282.5	281.1	296.0	284.8	289.9	318.5
	A1474053	286.9	286.3	287.8	290.7	291.9	288.9	295.5	290.2
	A1474055	311.3	311.6	323.5	311.7	322.0	328.8	325.8	327.3
	A1474057	295.9	297.7	300.1	293.3	293.7	302.6	306.5	292.1
	A1474059	260.7	260.7	259.5	261.6	267.2	269.0	265.6	266.3
	(n)	5	5	5	5	5	5	5	5
	Mean	287.38	286.82	290.68	287.68	294.16	294.82	296.66	298.88
	SD	18.606	19.341	23.523	18.311	19.433	22.457	22.123	24.369

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REDACTED AS TO TRADE NAMES

Body weight (g) - Individual data

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No	Animal No	Recovery Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
3	A1474081	279.6	285.9	289.5	292.8	297.3	299.1	302.5	304.7
	A1474083	294.0	292.3	290.9	297.5	299.6	307.2	300.1	305.4
	A1474085	286.0	282.8	293.0	288.5	298.1	303.9	320.9	307.5
	A1474087	285.4	284.5	294.4	295.1	295.2	306.0	300.1	305.9
	A1474089	293.5	277.2	283.3	280.8	297.3	290.9	280.7	281.4
	(n)	5	5	5	5	5	5	5	5
	Mean	287.70	284.54	290.22	290.94	297.50	301.42	300.86	300.98
	SD	6.065	5.454	4.303	6.568	1.592	6.644	14.247	10.994

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Study: A1474
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FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No	Animal No	Recovery Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
4	A1474111	274.8	275.2	280.0	283.2	287.3	283.7	290.0	287.6
	A1474113	290.4	287.5	293.8	296.2	297.4	298.1	315.1	308.7
	A1474115	280.2	288.3	288.8	294.0	292.2	302.8	300.1	303.4
	A1474117	281.9	275.8	286.4	288.0	294.2	295.6	294.6	305.1
	A1474119	283.1	284.4	285.5	296.9	300.9	289.5	293.5	291.7
	(n)	5	5	5	5	5	5	5	5
	Mean	282.08	282.24	286.90	291.66	294.40	293.94	298.66	299.30
	SD	5.631	6.326	5.026	5.885	5.161	7.469	9.880	9.130

REDACTED AS TO TRADE NAMES

Absolute body weight gain (g) - Individual data

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No	Animal No	Dosing Day: 1	Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
Control	A1474002	0.0	46.7	86.4	107.9	131.8	158.5	178.8	189.6	209.9
	A1474004	0.0	51.0	94.4	127.3	151.6	175.1	193.9	202.7	216.0
	A1474006	0.0	46.6	86.5	116.0	141.3	165.6	185.5	195.5	206.9
	A1474008	0.0	47.2	83.5	109.2	132.2	152.7	176.4	185.1	200.4
	A1474010	0.0	44.9	93.5	124.0	139.9	164.1	181.7	196.0	200.9
	A1474012	0.0	43.8	77.5	103.7	120.4	136.8	147.6	153.2	167.4
	A1474014	0.0	48.9	90.7	118.3	135.9	157.3	173.8	185.7	196.0
	A1474016	0.0	40.6	77.7	95.8	101.0	118.3	130.8	142.9	157.6
	A1474018	0.0	44.7	81.2	114.7	137.0	164.6	183.6	194.8	200.6
	A1474020	0.0	39.9	70.5	99.5	122.4	130.6	146.8	156.1	169.4
	A1474022	0.0	51.3	86.0	116.9	138.2	161.2	169.5	186.2	197.8
	A1474024	0.0	46.9	80.1	103.2	127.9	135.7	141.9	152.9	159.1
	A1474026	0.0	45.8	79.8	106.6	133.6	159.2	168.8	181.7	192.9
	A1474028	0.0	47.9	82.4	110.8	128.2	144.8	155.5	170.9	183.8
	A1474030	0.0	43.0	69.8	94.2	107.8	127.0	136.8	156.7	167.3
	(n)	15	15	15	15	15	15	15	15	15
	Mean	0.00	45.95	82.67	109.87	129.95	150.10	164.76	176.67	188.40
	SD	0.000	3.288	7.280	9.763	12.972	16.785	19.883	19.424	19.378

REDACTED AS TO TRADE NAMES

Absolute body weight gain (g) - Individual data

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Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No	Animal No	Dosing Day: 64	Day: 71	Day: 78	Day: 85	Day: 92
Control	A1474002	220.5	233.9	249.5	241.7	227.3
	A1474004	226.5	235.7	255.5	251.4	244.1
	A1474006	219.5	230.0	243.8	242.?	235.5
	A1474008	212.4	221.5	242.7	243.5	235.2
	A1474010	207.9	221.9	232.2	231.9	222.1
	A1474012	176.2	180.7	196.5	195.4	185.7
	A1474014	211.1	219.6	237.2	236.0	226.5
	A1474016	161.3	175.4	190.5	188.3	178.7
	A1474018	210.1	221.1	239.2	247.6	236.7
	A1474020	180.5	188.1	203.2	202.0	190.4
	A1474022	202.8	216.1	209.9	222.2	228.5
	A1474024	174.0	179.2	190.7	185.5	195.9
	A1474026	207.6	217.1	234.0	238.1	245.8
	A1474028	195.5	199.9	212.6	213.9	226.2
	A1474030	173.1	184.9	196.8	197.0	203.2
	(n)	15	15	15	15	15
	Mean	198.60	208.34	222.29	222.48	218.79
	SD	20.432	21.353	22.993	23.321	22.050

REDACTED AS TO TRADE NAMES

Absolute body weight gain (g) - Individual data

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Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No	Animal No	Dosing Day: 1	Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
2	A1474032	0.0	46.9	70.7	107.6	126.7	143.9	154.9	172.8	178.7
	A1474034	0.0	36.8	73.7	104.8	121.7	143.8	162.6	172.9	181.3
	A1474036	0.0	48.4	94.0	120.2	140.1	161.4	181.3	187.8	208.3
	A1474038	0.0	41.0	72.3	104.5	119.5	139.4	149.4	167.8	180.5
	A1474040	0.0	44.4	80.1	109.0	132.1	147.7	163.3	181.0	181.3
	A1474042	0.0	40.9	79.0	114.0	132.9	156.6	174.3	188.0	215.1
	A1474044	0.0	45.9	81.8	117.3	136.9	157.6	171.6	181.1	194.6
	A1474046	0.0	47.2	93.2	122.3	143.2	165.5	181.6	196.0	204.0
	A1474048	0.0	41.2	79.6	113.0	143.7	153.0	167.0	184.7	187.8
	A1474050	0.0	44.8	75.2	104.2	123.2	139.6	152.3	167.8	173.5
	A1474052	0.0	46.9	82.2	109.8	137.1	159.8	172.5	187.0	198.7
	A1474054	0.0	46.3	82.3	116.5	118.5	154.3	169.3	187.6	208.0
	A1474056	0.0	53.3	92.1	122.6	152.1	170.3	186.4	201.3	208.3
	A1474058	0.0	42.0	82.9	118.7	134.5	156.5	161.6	168.2	181.1
	A1474060	0.0	41.1	74.3	105.8	140.8	147.3	162.1	174.0	183.8
	(n)	15	15	15	15	15	15	15	15	15
	Mean	0.00	44.47	80.89	112.69	133.53	153.11	167.35	181.20	192.33
	SD	0.000	4.053	7.410	6.641	9.933	9.307	10.891	10.417	13.625

Absolute body weight gain (g) - Individual data

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Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No	Animal No	Dosing Day: 64	Day: 71	Day: 78	Day: 85	Day: 92
2	A1474032	185.5	200.6	209.3	208.1	201.4
	A1474034	196.7	203.1	224.2	227.9	217.1
	A1474036	218.5	225.9	242.8	248.7	236.8
	A1474038	186.1	199.3	216.8	224.6	207.4
	A1474040	190.7	197.0	213.7	215.3	202.1
	A1474042	202.9	220.1	229.6	232.2	219.7
	A1474044	203.3	211.8	232.8	236.9	217.3
	A1474046	214.8	226.7	238.6	247.4	235.4
	A1474048	206.0	224.2	233.0	241.0	226.7
	A1474050	186.3	196.4	203.2	205.2	191.7
	A1474052	213.0	226.5	241.0	244.7	256.4
	A1474054	215.1	224.7	235.3	236.4	250.7
	A1474056	221.2	229.5	241.8	248.1	250.8
	A1474058	190.9	195.3	213.6	219.7	229.3
	A1474060	191.9	204.2	219.1	224.0	231.8
	(n)	15	15	15	15	15
	Mean	201.53	212.35	226.32	230.68	224.97
	SD	12.720	13.305	12.951	14.368	19.414

Absolute body weight gain (g) - Individual data

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Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No	Animal No	Dosing Day: 1	Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
3	A1474062	0.0	45.9	77.8	108.3	126.0	146.9	156.3	165.7	180.0
	A1474064	0.0	51.7	93.6	129.4	152.4	170.9	181.0	196.0	207.2
	A1474066	0.0	53.7	93.1	121.7	147.3	174.6	191.4	217.8	228.1
	A1474068	0.0	49.3	85.5	113.5	136.6	153.2	169.4	185.5	197.1
	A1474070	0.0	45.1	84.8	114.5	139.1	160.5	169.2	182.2	194.3
	A1474072	0.0	42.2	80.6	117.7	137.5	174.8	172.4	186.6	199.8
	A1474074	0.0	48.9	92.1	125.6	146.1	169.0	184.9	199.3	206.4
	A1474076	0.0	42.6	83.4	118.4	144.2	159.2	181.0	191.9	203.9
	A1474078	0.0	44.7	88.2	116.2	135.2	153.6	168.9	183.0	192.5
	A1474080	0.0	35.7	68.3	92.7	100.2	115.4	131.7	142.1	148.4
	A1474082	0.0	45.7	81.5	108.8	132.3	144.7	162.9	176.3	189.8
	A1474084	0.0	43.6	75.0	97.7	109.3	122.1	124.1	132.6	142.5
	A1474086	0.0	45.6	86.2	117.3	141.0	155.6	168.0	180.1	180.2
	A1474088	0.0	45.5	87.4	120.2	148.1	161.9	179.9	189.7	203.4
	A1474090	0.0	46.3	83.9	110.5	135.6	161.2	172.8	184.3	191.5
	(n)	15	15	15	15	15	15	15	15	15
	Mean	0.00	45.77	84.09	114.17	135.39	154.91	167.59	180.87	191.01
	SD	0.000	4.236	6.874	9.671	14.275	17.293	18.448	21.195	21.926

REDACTED AS TO TRADE NAMES

Absolute body weight gain (g) - Individual data

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Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No	Animal No	Dosing Day: 64	Day: 71	Day: 78	Day: 85	Day: 92
3	A1474062	189.4	199.9	212.0	211.1	200.0
	A1474064	219.5	229.0	242.4	245.2	230.0
	A1474066	242.6	249.0	258.6	265.4	250.3
	A1474068	213.7	224.1	235.2	237.8	220.0
	A1474070	199.5	209.4	227.4	232.3	220.9
	A1474072	212.5	218.1	234.8	232.3	220.1
	A1474074	217.9	228.6	245.2	235.7	227.8
	A1474076	214.4	226.8	234.6	237.6	227.3
	A1474078	201.1	214.2	226.7	228.6	216.2
	A1474080	153.2	166.8	185.3	179.3	167.4
	A1474082	201.9	202.8	217.8	220.1	230.1
	A1474084	155.2	161.9	181.2	182.6	185.8
	A1474086	189.5	204.6	210.0	215.4	217.8
	A1474088	214.9	221.4	233.4	246.5	250.5
	A1474090	203.3	212.2	220.1	220.4	235.7
	(n)	15	15	15	15	15
	Mean	201.91	211.25	224.31	226.02	219.99
	SD	23.406	22.783	20.991	22.773	21.986

REDACTED AS TO TRADE NAMES

Absolute body weight gain (g) - Individual data

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Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No	Animal No	Dosing Day: 1	Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
4	A1474092	0.0	47.8	86.8	117.1	140.3	159.1	172.1	186.5	196.6
	A1474094	0.0	45.4	78.3	101.5	118.4	135.6	149.9	167.0	177.4
	A1474096	0.0	44.7	80.4	108.4	132.2	153.2	164.8	173.7	189.2
	A1474098	0.0	51.3	83.0	107.7	134.1	157.7	170.6	181.3	188.7
	A1474100	0.0	49.6	97.6	137.8	149.6	172.3	193.9	210.6	223.2
	A1474102	0.0	51.3	96.4	122.0	143.1	168.1	183.4	192.8	196.4
	A1474104	0.0	45.2	84.6	102.0	123.5	144.7	159.8	176.8	182.2
	A1474106	0.0	47.0	88.3	122.6	139.9	161.3	176.3	189.8	202.4
	A1474108	0.0	45.3	81.8	107.7	128.0	152.2	172.0	189.9	199.6
	A1474110	0.0	43.4	75.8	104.2	128.6	145.5	160.7	170.3	173.4
	A1474112	0.0	50.1	85.3	110.0	139.4	160.8	171.9	190.2	199.3
	A1474114	0.0	46.5	83.1	115.7	134.1	149.3	165.1	177.3	189.9
	A1474116	0.0	52.8	88.6	121.9	141.6	163.7	178.5	189.1	199.5
	A1474118	0.0	44.4	68.1	99.6	117.5	137.2	150.5	160.6	170.3
	A1474120	0.0	52.0	86.3	104.6	123.8	143.5	158.8	171.3	180.1
	(n)	15	15	15	15	15	15	15	15	15
	Mean	0.00	47.79	84.29	112.19	132.94	153.61	168.55	181.81	191.21
	SD	0.000	3.132	7.389	10.518	9.521	10.956	11.937	12.672	13.551

Absolute body weight gain (g) - Individual data

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Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No	Animal No	Dosing Day: 64	Day: 71	Day: 78	Day: 85	Day: 92
4	A1474092	177.4	172.3	211.5	222.9	232.3
	A1474094	180.3	191.1	199.1	204.0	202.5
	A1474096	199.7	210.1	217.4	218.3	224.2
	A1474098	204.1	206.5	213.9	222.4	230.4
	A1474100	238.5	252.4	255.8	265.1	258.7
	A1474102	209.1	219.1	236.6	239.5	213.7
	A1474104	182.8	199.5	207.1	212.6	198.1
	A1474106	209.6	222.2	229.4	232.3	214.1
	A1474108	208.2	226.6	233.6	238.8	225.1
	A1474110	192.8	191.0	202.2	205.8	191.3
	A1474112	208.4	217.8	222.2	215.2	210.0
	A1474114	198.2	215.0	217.6	225.9	217.4
	A1474116	218.5	227.2	239.8	245.0	239.9
	A1474118	178.3	189.8	196.3	200.8	190.3
	A1474120	189.6	203.8	213.3	214.3	211.7
	(n)	15	15	15	15	15
	Mean	199.70	209.63	219.72	224.19	217.31
	SD	16.864	19.627	16.637	17.462	18.575

Absolute body weight gain (g) - Individual data

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Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No	Animal No	Dosing Day: 1	Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
Control	A1474001	0.0	17.0	36.5	49.5	63.1	69.5	79.7	86.2	85.5
	A1474003	0.0	24.2	42.9	62.9	69.3	80.0	87.7	89.8	92.1
	A1474005	0.0	16.2	30.2	52.5	57.0	68.1	76.0	82.0	85.5
	A1474007	0.0	7.0	24.8	43.0	47.5	54.0	46.1	61.9	64.0
	A1474009	0.0	16.9	29.8	55.0	60.8	70.6	79.4	83.7	83.8
	A1474011	0.0	16.4	30.0	57.3	65.6	74.1	82.3	79.5	94.6
	A1474013	0.0	21.7	39.4	53.0	73.8	72.9	79.0	85.9	88.4
	A1474015	0.0	22.6	40.3	62.1	74.4	81.1	90.5	111.7	97.7
	A1474017	0.0	12.8	43.3	59.4	64.7	81.8	85.3	100.2	106.5
	A1474019	0.0	27.2	43.5	69.4	70.9	77.3	89.1	92.6	98.5
	A1474021	0.0	28.5	45.4	58.6	70.7	76.9	83.6	99.7	106.0
	A1474023	0.0	33.7	37.0	54.7	78.4	78.7	86.1	95.3	91.7
	A1474025	0.0	21.3	36.8	48.3	66.6	68.2	76.8	74.9	79.0
	A1474027	0.0	18.0	36.3	51.4	54.4	74.6	78.0	83.9	85.4
	A1474029	0.0	2.5	33.9	52.3	63.9	76.9	83.1	88.0	94.9
	(n)	15	15	15	15	15	15	15	15	15
	Mean	0.00	19.07	36.67	55.29	65.41	73.65	80.18	87.69	90.24
	SD	0.000	8.039	6.028	6.580	8.180	7.056	10.440	11.734	10.727

REDACTED AS TO TRADE NAMES

Absolute body weight gain (g) - Individual data

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Pristima® Version 6.3.2 Build 22

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Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No	Animal No	Dosing Day: 64	Day: 71	Day: 78	Day: 85	Day: 92
Control	A1474001	100.5	98.7	108.5	105.7	104.3
	A1474003	98.8	101.8	114.0	120.5	118.8
	A1474005	93.4	97.2	101.9	105.3	106.8
	A1474007	61.5	75.2	80.6	76.9	97.7
	A1474009	92.2	91.8	102.9	103.2	103.0
	A1474011	96.1	96.5	112.2	113.2	111.1
	A1474013	93.4	94.3	105.4	103.7	102.7
	A1474015	105.6	114.8	122.1	115.1	122.0
	A1474017	111.6	114.0	115.6	112.3	118.3
	A1474019	107.6	104.3	115.9	112.0	118.6
	A1474021	106.3	115.8	121.7	118.8	121.8
	A1474023	105.4	103.7	112.8	111.3	120.4
	A1474025	85.5	85.6	95.6	92.7	103.4
	A1474027	93.9	91.7	118.2	109.5	116.2
	A1474029	90.7	102.8	111.1	103.0	114.3
	(n)	15	15	15	15	15
	Mean	96.17	99.21	109.23	107.48	111.96
	SD	12.110	11.057	10.853	11.893	8.247

REDACTED AS TO TRADE NAMES

Absolute body weight gain (g) - Individual data

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No	Animal No	Dosing Day: 1	Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
2	A1474031	0.0	16.2	32.2	62.6	70.1	84.5	84.6	85.8	99.3
	A1474033	0.0	13.7	22.6	41.2	45.4	48.6	58.4	65.7	72.4
	A1474035	0.0	21.6	42.2	66.3	81.5	82.2	87.2	95.6	93.2
	A1474037	0.0	21.9	43.5	65.4	81.5	106.4	104.2	106.8	114.9
	A1474039	0.0	15.1	29.1	53.2	61.0	74.3	78.4	85.4	96.8
	A1474041	0.0	20.3	33.8	55.7	64.1	69.8	80.6	73.9	79.7
	A1474043	0.0	19.5	38.7	60.3	65.3	74.0	86.2	93.0	92.5
	A1474045	0.0	17.6	36.3	58.9	80.7	71.4	82.2	79.7	93.7
	A1474047	0.0	16.1	34.7	43.9	59.7	65.2	75.1	78.3	73.7
	A1474049	0.0	18.5	34.8	55.8	61.8	70.6	74.7	85.6	84.3
	A1474051	0.0	25.8	46.7	51.6	60.1	65.8	89.5	97.5	95.8
	A1474053	0.0	28.3	29.8	55.0	60.0	65.4	77.0	82.9	82.1
	A1474055	0.0	25.2	42.3	69.8	68.2	94.6	94.8	96.6	102.9
	A1474057	0.0	0.0	40.2	49.9	65.1	80.6	75.1	91.9	87.8
	A1474059	0.0	13.6	27.5	40.3	51.7	54.6	63.1	69.1	68.0
	(n)	15	15	15	15	15	15	15	15	15
	Mean	0.00	18.23	35.63	55.33	65.08	73.87	80.74	85.85	89.14
	SD	0.000	6.715	6.719	8.968	10.325	14.568	11.474	11.358	12.641

REDACTED AS TO TRADE NAMES

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Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No	Animal No	Dosing Day: 64	Day: 71	Day: 78	Day: 85	Day: 92
2	A1474031	96.0	104.5	110.0	111.1	125.3
	A1474033	73.7	81.5	86.4	88.9	92.9
	A1474035	104.7	110.5	113.3	115.8	120.3
	A1474037	117.7	132.6	128.7	127.8	128.3
	A1474039	98.2	106.1	110.9	105.9	122.0
	A1474041	74.8	86.7	91.9	97.4	103.6
	A1474043	105.8	105.3	114.9	108.1	115.5
	A1474045	96.6	108.2	120.4	102.2	110.5
	A1474047	81.5	85.0	103.5	91.2	103.9
	A1474049	87.1	98.8	99.2	99.1	101.2
	A1474051	97.8	97.2	105.5	93.2	106.1
	A1474053	86.0	88.2	93.9	102.9	99.7
	A1474055	125.6	116.6	120.9	112.1	131.4
	A1474057	93.1	96.4	99.6	94.4	106.8
	A1474059	79.8	76.4	88.2	84.3	83.7
	(n)	15	15	15	15	15
	Mean	94.56	99.60	105.82	102.29	110.08
	SD	14.888	14.788	12.696	11.524	13.572

REDACTED AS TO TRADE NAMES

Absolute body weight gain (g) - Individual data

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Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No	Animal No	Dosing Day: 1	Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
3	A1474061	0.0	8.7	26.3	48.2	52.6	62.3	74.3	70.9	78.2
	A1474063	0.0	17.3	39.9	54.7	69.9	80.1	89.0	96.5	89.2
	A1474065	0.0	18.7	41.9	58.1	73.2	77.0	91.6	86.2	102.8
	A1474067	0.0	13.0	34.4	75.2	63.9	70.2	92.8	93.1	86.0
	A1474069	0.0	19.4	38.8	52.2	64.3	76.6	86.7	99.3	87.0
	A1474071	0.0	12.3	27.1	36.9	46.6	56.9	69.6	66.8	73.8
	A1474073	0.0	16.0	37.5	52.4	63.9	73.6	80.2	79.9	89.4
	A1474075	0.0	12.9	39.5	60.4	68.8	82.4	101.6	89.1	99.6
	A1474077	0.0	20.5	38.9	62.8	74.0	85.1	101.9	98.1	103.9
	A1474079	0.0	16.3	55.0	61.5	71.8	85.5	93.6	98.2	101.9
	A1474081	0.0	17.3	37.8	60.2	60.4	73.5	80.2	80.7	93.9
	A1474083	0.0	14.2	40.8	57.5	53.3	71.1	69.5	85.5	87.3
	A1474085	0.0	6.5	33.6	56.5	87.3	77.6	76.7	100.1	97.3
	A1474087	0.0	16.9	37.3	48.8	61.3	80.6	82.3	86.5	90.9
	A1474089	0.0	23.2	32.0	49.8	56.8	80.7	76.5	79.2	84.2
	(n)	15	15	15	15	15	15	15	15	15
	Mean	0.00	15.55	37.39	55.68	64.54	75.55	84.43	87.34	91.03
	SD	0.000	4.401	6.753	8.588	10.216	8.005	10.488	10.430	8.916

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No	Animal No	Dosing Day: 64	Day: 71	Day: 78	Day: 85	Day: 92
3	A1474061	82.5	87.2	90.7	90.7	95.1
	A1474063	102.4	98.0	124.8	110.5	113.4
	A1474065	103.5	110.2	117.9	115.2	124.1
	A1474067	95.9	100.6	109.7	106.1	108.0
	A1474069	96.1	96.0	107.6	103.2	114.2
	A1474071	87.3	94.8	89.7	89.2	97.0
	A1474073	90.3	97.0	107.0	99.4	115.5
	A1474075	105.4	108.8	117.9	111.1	116.2
	A1474077	105.2	118.4	114.6	118.9	128.6
	A1474079	122.1	109.9	114.9	113.5	114.6
	A1474081	92.0	101.3	104.1	106.2	112.1
	A1474083	81.1	97.9	101.1	104.6	106.7
	A1474085	97.6	96.4	109.9	102.9	111.5
	A1474087	98.4	96.3	101.3	105.8	107.0
	A1474089	96.8	96.8	94.8	99.7	110.0
	(n)	15	15	15	15	15
	Mean	97.11	100.64	107.07	105.15	111.60
	SD	10.249	7.906	10.282	8.304	8.648

REDACTED AS TO TRADE NAMES

Absolute body weight gain (g) - Individual data

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Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No	Animal No	Dosing Day: 1	Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
4	A1474091	0.0	18.7	40.9	54.1	58.1	74.7	80.1	87.2	87.7
	A1474093	0.0	16.9	29.8	48.0	46.8	63.0	75.2	73.5	81.8
	A1474095	0.0	16.5	42.5	67.4	64.3	88.0	91.0	100.3	104.8
	A1474097	0.0	7.1	29.5	53.6	55.2	75.6	83.5	93.9	99.9
	A1474099	0.0	17.9	34.0	55.4	62.2	71.9	83.6	84.5	85.2
	A1474101	0.0	30.6	43.9	70.6	91.8	79.7	94.0	105.1	112.5
	A1474103	0.0	22.2	36.1	52.1	63.1	72.5	83.2	86.2	96.1
	A1474105	0.0	32.5	34.3	51.5	59.1	74.6	77.6	85.8	88.1
	A1474107	0.0	24.2	46.1	74.9	68.1	87.5	100.1	88.5	97.5
	A1474109	0.0	18.3	34.0	54.9	75.1	68.5	92.9	91.8	91.0
	A1474111	0.0	16.9	35.3	42.0	54.6	61.2	70.8	74.2	76.3
	A1474113	0.0	15.2	30.8	45.5	52.7	53.3	74.2	88.7	80.0
	A1474115	0.0	22.0	30.5	50.9	57.9	70.4	77.8	80.7	91.6
	A1474117	0.0	15.6	26.8	53.2	66.8	58.6	64.8	71.7	75.5
	A1474119	0.0	16.7	43.2	58.2	70.2	79.8	81.9	88.7	88.7
	(n)	15	15	15	15	15	15	15	15	15
	Mean	0.00	19.42	35.85	55.49	63.07	71.95	82.05	86.72	90.45
	SD	0.000	6.269	6.072	9.070	10.809	9.947	9.436	9.298	10.407

REDACTED AS TO TRADE NAMES

Absolute body weight gain (g) - Individual data

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Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No	Animal No	Dosing Day: 64	Day: 71	Day: 78	Day: 85	Day: 92
4	A1474091	95.6	95.6	98.4	100.4	101.5
	A1474093	88.4	92.3	92.8	92.8	98.7
	A1474095	102.4	115.3	113.3	116.1	121.6
	A1474097	80.2	111.6	117.3	115.8	119.4
	A1474099	85.2	92.5	101.7	97.6	108.5
	A1474101	106.6	111.8	130.5	121.0	124.2
	A1474103	101.5	109.6	107.6	117.4	115.9
	A1474105	94.7	106.4	117.6	123.0	125.1
	A1474107	96.6	108.9	123.6	49.0	116.1
	A1474109	95.8	110.1	112.7	112.3	127.5
	A1474111	87.3	86.8	94.9	93.0	93.0
	A1474113	89.5	93.7	100.6	93.5	98.7
	A1474115	100.1	100.5	109.0	107.3	114.0
	A1474117	77.4	86.5	86.5	95.8	105.2
	A1474119	100.8	103.5	109.0	107.9	106.2
	(n)	15	15	15	15	15
	Mean	93.47	101.67	107.70	102.86	111.71
	SD	8.527	9.724	12.044	18.310	10.887

Absolute body weight gain (g) - Individual data

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No	Animal No	Recovery Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
Control	A1474022	0.0	1.3	4.2	13.4	14.5	20.8	25.8	16.1
	A1474024	0.0	4.5	10.9	14.3	15.4	23.7	27.4	17.4
	A1474026	0.0	0.9	1.3	9.3	13.5	23.2	24.1	15.4
	A1474028	0.0	4.9	8.7	17.3	23.7	32.2	31.6	18.6
	A1474030	0.0	0.2	9.8	14.4	24.1	24.4	35.3	21.4
	(n)	5	5	5	5	5	5	5	5
	Mean	0.00	2.36	6.98	13.74	18.24	24.86	28.84	17.78
	SD	0.000	2.177	4.070	2.883	5.212	4.321	4.559	2.367

Absolute body weight gain (g) - Individual data

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No	Animal No	Recovery Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
2	A1474052	0.0	0.2	13.4	13.7	26.0	32.5	32.9	17.7
	A1474054	0.0	9.5	20.9	24.1	39.3	44.6	40.6	27.7
	A1474056	0.0	2.2	2.1	10.0	14.8	15.0	20.9	5.4
	A1474058	0.0	1.2	-2.9	4.1	13.0	22.4	23.0	2.9
	A1474060	0.0	2.8	7.9	10.1	17.0	23.5	36.0	10.9
	(n)	5	5	5	5	5	5	5	5
	Mean	0.00	3.18	8.28	12.40	22.92	27.60	30.68	12.92
	SD	0.000	3.669	9.338	7.391	10.876	11.354	8.460	10.029

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Males

Group No	Animal No	Recovery Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
3	A1474082	0.0	0.2	8.2	11.2	14.7	17.0	22.0	4.0
	A1474084	0.0	2.9	8.5	11.8	18.6	24.1	26.5	14.1
	A1474086	0.0	9.3	11.8	12.0	24.3	17.4	22.3	4.4
	A1474088	0.0	2.7	14.3	7.0	19.5	20.4	34.8	7.7
	A1474090	0.0	7.7	11.3	17.5	26.9	26.3	34.8	18.8
	(n)	5	5	5	5	5	5	5	5
	Mean	0.00	4.56	10.82	11.90	20.80	21.04	28.08	9.80
	SD	0.000	3.793	2.527	3.738	4.827	4.093	6.387	6.456

Absolute body weight gain (g) - Individual data

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FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No	Animal No	Recovery Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
4	A1474112	0.0	5.5	11.4	23.6	29.8	31.9	38.6	20.2
	A1474114	0.0	7.0	13.6	20.0	33.3	29.9	36.2	24.9
	A1474116	0.0	1.0	4.3	11.5	20.7	20.9	30.2	13.2
	A1474118	0.0	6.3	7.7	18.3	22.7	20.4	32.5	13.7
	A1474120	0.0	6.7	11.9	18.2	22.6	24.0	37.3	16.9
	(n)	5	5	5	5	5	5	5	5
	Mean	0.00	5.30	9.78	18.32	25.82	25.42	34.96	17.78
	SD	0.000	2.469	3.744	4.394	5.434	5.237	3.499	4.872

Absolute body weight gain (g) - Individual data

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Females

Group No	Animal No	Recovery Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
Control	A1474021	0.0	5.4	12.3	35.3	20.2	28.0	24.2	29.5
	A1474023	0.0	-0.6	-0.8	7.2	27.5	21.5	19.6	29.9
	A1474025	0.0	-10.7	-4.2	5.5	24.0	20.1	14.5	15.5
	A1474027	0.0	5.0	6.6	9.9	6.3	13.1	20.2	40.8
	A1474029	0.0	3.8	8.4	7.8	17.6	15.3	17.3	18.9
	(n)	5	5	5	5	5	5	5	5
	Mean	0.00	0.58	4.46	13.14	19.12	19.60	19.16	26.92
	SD	0.000	6.741	6.787	12.487	8.091	5.813	3.600	10.037

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Females

Group No	Animal No	Recovery Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
2	A1474051	0.0	-4.3	0.4	-1.0	13.9	2.7	7.8	36.4
	A1474053	0.0	-0.6	0.9	3.8	5.0	2.0	8.6	3.3
	A1474055	0.0	0.3	12.2	0.4	10.7	17.5	14.5	16.0
	A1474057	0.0	1.8	4.2	-2.6	-2.2	6.7	10.6	-3.8
	A1474059	0.0	0.0	-1.2	0.9	6.5	8.3	4.9	5.6
	(n)	5	5	5	5	5	5	5	5
	Mean	0.00	-0.56	3.30	0.30	6.78*D	7.44	9.28	11.50
	SD	0.000	2.270	5.349	2.383	6.123	6.216	3.565	15.624

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REDACTED AS TO TRADE NAMES

Absolute body weight gain (g) - Individual data

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Females

Group No	Animal No	Recovery Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
3	A1474081	0.0	6.3	9.9	13.2	17.7	19.5	22.9	25.1
	A1474083	0.0	-1.7	-3.1	2.5	5.6	13.2	6.1	11.4
	A1474085	0.0	-3.2	7.0	2.5	12.1	17.9	34.9	21.5
	A1474087	0.0	-0.9	9.0	9.7	9.8	20.6	14.7	20.5
	A1474089	0.0	-16.3	-10.2	-12.7	3.8	-2.6	-12.8	-12.1
	(n)	5	5	5	5	5	5	5	5
	Mean	0.00	-3.16	2.52	3.24	9.80	13.72	13.16	13.28
	SD	0.000	8.207	8.802	9.945	5.508	9.550	17.984	15.059

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No	Animal No	Recovery Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
4	A1474111	0.0	0.4	5.2	8.4	12.5	8.9	15.2	12.8
	A1474113	0.0	-2.9	3.4	5.8	7.0	7.7	24.7	18.3
	A1474115	0.0	8.1	8.6	13.8	12.0	22.6	19.9	23.2
	A1474117	0.0	-6.1	4.5	6.1	12.3	13.7	12.7	23.2
	A1474119	0.0	1.3	2.4	13.8	17.8	6.4	10.4	8.6
	(n)	5	5	5	5	5	5	5	5
	Mean	0.00	0.16	4.82	9.58	12.32	11.86	16.58	17.22
	SD	0.000	5.314	2.367	3.981	3.823	6.607	5.747	6.452

Food consumption per animal/day (g) - Individual data

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Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No	Animal No	Allocation Day: 8	Dosing Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50
Control	A1474002	21.7	23.9	26.1	26.5	25.5	26.2	25.3	24.1
	A1474004	21.7	23.9	26.1	26.5	25.5	26.2	25.3	24.1
	A1474006	21.7	23.9	26.1	26.5	25.5	26.2	25.3	24.1
	A1474008	21.7	23.9	26.1	26.5	25.5	26.2	25.3	24.1
	A1474010	21.7	23.9	26.1	26.5	25.5	26.2	25.3	24.1
	A1474012	17.2	22.0	25.0	24.2	22.9	23.3	22.5	21.7
	A1474014	17.2	22.0	25.0	24.2	22.9	23.3	22.5	21.7
	A1474016	17.2	22.0	25.0	24.2	22.9	23.3	22.5	21.7
	A1474018	17.2	22.0	25.0	24.2	22.9	23.3	22.5	21.7
	A1474020	17.2	22.0	25.0	24.2	22.9	23.3	22.5	21.7
	A1474022	20.2	22.7	24.6	24.1	23.8	23.8	22.0	22.0
	A1474024	20.2	22.7	24.6	24.1	23.8	23.8	22.0	22.0
	A1474026	20.2	22.7	24.6	24.1	23.8	23.8	22.0	22.0
	A1474028	20.2	22.7	24.6	24.1	23.8	23.8	22.0	22.0
	A1474030	20.2	22.7	24.6	24.1	23.8	23.8	22.0	22.0
	(n)	3	3	3	3	3	3	3	3
	Mean	19.57	22.85	25.21	24.94	24.06	24.42	23.27	22.60
	SD	1.903	0.782	0.664	1.129	1.060	1.264	1.481	1.094

Food consumption per animal/day (g) - Individual data

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Pristima® Version 6.3.2 Build 22

Study: A1474
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Males

Group No	Animal No	Dosing Day: 57	Day: 64	Day: 71	Day: 78	Day: 85	Day: 92
Control	A1474002	24.6	23.8	24.3	24.9	22.8	20.5
	A1474004	24.6	23.8	24.3	24.9	22.8	20.5
	A1474006	24.6	23.8	24.3	24.9	22.8	20.5
	A1474008	24.6	23.8	24.3	24.9	22.8	20.5
	A1474010	24.6	23.8	24.3	24.9	22.8	20.5
	A1474012	22.1	21.0	21.5	22.8	20.9	18.6
	A1474014	22.1	21.0	21.5	22.8	20.9	18.6
	A1474016	22.1	21.0	21.5	22.8	20.9	18.6
	A1474018	22.1	21.0	21.5	22.8	20.9	18.6
	A1474020	22.1	21.0	21.5	22.8	20.9	18.6
	A1474022	22.2	21.5	21.7	22.0	20.4	21.3
	A1474024	22.2	21.5	21.7	22.0	20.4	21.3
	A1474026	22.2	21.5	21.7	22.0	20.4	21.3
	A1474028	22.2	21.5	21.7	22.0	20.4	21.3
	A1474030	22.2	21.5	21.7	22.0	20.4	21.3
	(n)	3	3	3	3	3	3
	Mean	22.95	22.10	22.52	23.26	21.40	20.14
	SD	1.187	1.217	1.301	1.209	1.047	1.126

Food consumption per animal/day (g) - Individual data

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No	Animal No	Allocation Day: 8	Dosing Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50
2	A1474032	20.8	22.5	24.9	24.8	24.6	24.5	23.8	22.5
	A1474034	20.8	22.5	24.9	24.8	24.6	24.5	23.8	22.5
	A1474036	20.8	22.5	24.9	24.8	24.6	24.5	23.8	22.5
	A1474038	20.8	22.5	24.9	24.8	24.6	24.5	23.8	22.5
	A1474040	20.8	22.5	24.9	24.8	24.6	24.5	23.8	22.5
	A1474042	20.9	22.7	25.6	25.9	24.8	24.6	23.8	23.2
	A1474044	20.9	22.7	25.6	25.9	24.8	24.6	23.8	23.2
	A1474046	20.9	22.7	25.6	25.9	24.8	24.6	23.8	23.2
	A1474048	20.9	22.7	25.6	25.9	24.8	24.6	23.8	23.2
	A1474050	20.9	22.7	25.6	25.9	24.8	24.6	23.8	23.2
	A1474052	21.7	23.6	25.0	25.1	24.5	24.0	23.6	22.8
	A1474054	21.7	23.6	25.0	25.1	24.5	24.0	23.6	22.8
	A1474056	21.7	23.6	25.0	25.1	24.5	24.0	23.6	22.8
	A1474058	21.7	23.6	25.0	25.1	24.5	24.0	23.6	22.8
	A1474060	21.7	23.6	25.0	25.1	24.5	24.0	23.6	22.8
	(n)	3	3	3	3	3	3	3	3
	Mean	21.13	22.93	25.17	25.26	24.65	24.37	23.73	22.86
	SD	0.398	0.491	0.292	0.490	0.114	0.240	0.065	0.287

Food consumption per animal/day (g) - Individual data

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No	Animal No	Dosing Day: 57	Day: 64	Day: 71	Day: 78	Day: 85	Day: 92
2	A1474032	23.3	21.6	22.5	23.5	22.2	19.9
	A1474034	23.3	21.6	22.5	23.5	22.2	19.9
	A1474036	23.3	21.6	22.5	23.5	22.2	19.9
	A1474038	23.3	21.6	22.5	23.5	22.2	19.9
	A1474040	23.3	21.6	22.5	23.5	22.2	19.9
	A1474042	23.6	21.9	22.8	23.3	22.2	19.3
	A1474044	23.6	21.9	22.8	23.3	22.2	19.3
	A1474046	23.6	21.9	22.8	23.3	22.2	19.3
	A1474048	23.6	21.9	22.8	23.3	22.2	19.3
	A1474050	23.6	21.9	22.8	23.3	22.2	19.3
	A1474052	23.2	21.6	22.7	23.9	22.2	22.6
	A1474054	23.2	21.6	22.7	23.9	22.2	22.6
	A1474056	23.2	21.6	22.7	23.9	22.2	22.6
	A1474058	23.2	21.6	22.7	23.9	22.2	22.6
	A1474060	23.2	21.6	22.7	23.9	22.2	22.6
	(n)	3	3	3	3	3	3
	Mean	23.38	21.71	22.68	23.54	22.18	20.60
	SD	0.191	0.142	0.103	0.229	0.024	1.435

Food consumption per animal/day (g) - Individual data

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No	Animal No	Allocation Day: 8	Dosing Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50
3	A1474062	20.9	23.6	25.6	25.9	24.5	25.1	23.9	23.7
	A1474064	20.9	23.6	25.6	25.9	24.5	25.1	23.9	23.7
	A1474066	20.9	23.6	25.6	25.9	24.5	25.1	23.9	23.7
	A1474068	20.9	23.6	25.6	25.9	24.5	25.1	23.9	23.7
	A1474070	20.9	23.6	25.6	25.9	24.5	25.1	23.9	23.7
	A1474072	21.5	22.9	25.7	25.2	24.5	25.3	23.9	23.7
	A1474074	21.5	22.9	25.7	25.2	24.5	25.3	23.9	23.7
	A1474076	21.5	22.9	25.7	25.2	24.5	25.3	23.9	23.7
	A1474078	21.5	22.9	25.7	25.2	24.5	25.3	23.9	23.7
	A1474080	21.5	22.9	25.7	25.2	24.5	25.3	23.9	23.7
	A1474082	21.1	23.1	25.3	24.3	23.7	24.3	23.3	22.5
	A1474084	21.1	23.1	25.3	24.3	23.7	24.3	23.3	22.5
	A1474086	21.1	23.1	25.3	24.3	23.7	24.3	23.3	22.5
	A1474088	21.1	23.1	25.3	24.3	23.7	24.3	23.3	22.5
	A1474090	21.1	23.1	25.3	24.3	23.7	24.3	23.3	22.5
	(n)	3	3	3	3	3	3	3	3
	Mean	21.17	23.19	25.52	25.09	24.23	24.90	23.70	23.31
	SD	0.277	0.312	0.134	0.655	0.384	0.430	0.290	0.576

REDACTED AS TO TRADE NAMES

Food consumption per animal/day (g) - Individual data

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Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No	Animal No	Dosing Day: 57	Day: 64	Day: 71	Day: 78	Day: 85	Day: 92
3	A1474062	23.6	22.8	22.8	24.0	22.6	19.8
	A1474064	23.6	22.8	22.8	24.0	22.6	19.8
	A1474066	23.6	22.8	22.8	24.0	22.6	19.8
	A1474068	23.6	22.8	22.8	24.0	22.6	19.8
	A1474070	23.6	22.8	22.8	24.0	22.6	19.8
	A1474072	23.7	22.8	23.2	24.3	21.8	19.7
	A1474074	23.7	22.8	23.2	24.3	21.8	19.7
	A1474076	23.7	22.8	23.2	24.3	21.8	19.7
	A1474078	23.7	22.8	23.2	24.3	21.8	19.7
	A1474080	23.7	22.8	23.2	24.3	21.8	19.7
	A1474082	23.4	22.3	22.7	23.7	22.4	22.6
	A1474084	23.4	22.3	22.7	23.7	22.4	22.6
	A1474086	23.4	22.3	22.7	23.7	22.4	22.6
	A1474088	23.4	22.3	22.7	23.7	22.4	22.6
	A1474090	23.4	22.3	22.7	23.7	22.4	22.6
	(n)	3	3	3	3	3	3
	Mean	23.58	22.64	22.92	24.01	22.27	20.72
	SD	0.110	0.215	0.216	0.262	0.334	1.362

REDACTED AS TO TRADE NAMES

Food consumption per animal/day (g) - Individual data

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Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No	Animal No	Allocation Day: 8	Dosing Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50
4	A1474092	21.5	23.6	25.7	25.6	24.1	25.1	23.8	23.1
	A1474094	21.5	23.6	25.7	25.6	24.1	25.1	23.8	23.1
	A1474096	21.5	23.6	25.7	25.6	24.1	25.1	23.8	23.1
	A1474098	21.5	23.6	25.7	25.6	24.1	25.1	23.8	23.1
	A1474100	21.5	23.6	25.7	25.6	24.1	25.1	23.8	23.1
	A1474102	22.0	24.3	26.2	25.7	24.7	25.1	24.1	23.4
	A1474104	22.0	24.3	26.2	25.7	24.7	25.1	24.1	23.4
	A1474106	22.0	24.3	26.2	25.7	24.7	25.1	24.1	23.4
	A1474108	22.0	24.3	26.2	25.7	24.7	25.1	24.1	23.4
	A1474110	22.0	24.3	26.2	25.7	24.7	25.1	24.1	23.4
	A1474112	22.2	25.3	26.6	26.0	25.2	25.3	23.7	23.3
	A1474114	22.2	25.3	26.6	26.0	25.2	25.3	23.7	23.3
	A1474116	22.2	25.3	26.6	26.0	25.2	25.3	23.7	23.3
	A1474118	22.2	25.3	26.6	26.0	25.2	25.3	23.7	23.3
	A1474120	22.2	25.3	26.6	26.0	25.2	25.3	23.7	23.3
	(n)	3	3	3	3	3	3	3	3
	Mean	21.91	24.41*D	26.16	25.78	24.69	25.17	23.86	23.26
	SD	0.311	0.684	0.373	0.144	0.445	0.072	0.176	0.087

Food consumption per animal/day (g) - Individual data

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Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No	Animal No	Dosing Day: 57	Day: 64	Day: 71	Day: 78	Day: 85	Day: 92
4	A1474092	23.9	21.8	20.5	24.8	23.1	19.4
	A1474094	23.9	21.8	20.5	24.8	23.1	19.4
	A1474096	23.9	21.8	20.5	24.8	23.1	19.4
	A1474098	23.9	21.8	20.5	24.8	23.1	19.4
	A1474100	23.9	21.8	20.5	24.8	23.1	19.4
	A1474102	23.3	22.6	22.7	23.6	22.3	19.8
	A1474104	23.3	22.6	22.7	23.6	22.3	19.8
	A1474106	23.3	22.6	22.7	23.6	22.3	19.8
	A1474108	23.3	22.6	22.7	23.6	22.3	19.8
	A1474110	23.3	22.6	22.7	23.6	22.3	19.8
	A1474112	23.8	23.3	24.1	24.5	23.1	23.5
	A1474114	23.8	23.3	24.1	24.5	23.1	23.5
	A1474116	23.8	23.3	24.1	24.5	23.1	23.5
	A1474118	23.8	23.3	24.1	24.5	23.1	23.5
	A1474120	23.8	23.3	24.1	24.5	23.1	23.5
	(n)	3	3	3	3	3	3
	Mean	23.65	22.60	22.41	24.26	22.83	20.89
	SD	0.282	0.624	1.464	0.514	0.377	1.831

REDACTED AS TO TRADE NAMES

Food consumption per animal/day (g) - Individual data

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No	Animal No	Allocation Day: 8	Dosing Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50
Control	A1474001	15.7	16.6	17.4	18.1	17.0	17.1	16.7	16.5
	A1474003	15.7	16.6	17.4	18.1	17.0	17.1	16.7	16.5
	A1474005	15.7	16.6	17.4	18.1	17.0	17.1	16.7	16.5
	A1474007	15.7	16.6	17.4	18.1	17.0	17.1	16.7	16.5
	A1474009	15.7	16.6	17.4	18.1	17.0	17.1	16.7	16.5
	A1474011	16.5	16.8	18.2	19.3	18.4	19.0	18.2	18.4
	A1474013	16.5	16.8	18.2	19.3	18.4	19.0	18.2	18.4
	A1474015	16.5	16.8	18.2	19.3	18.4	19.0	18.2	18.4
	A1474017	16.5	16.8	18.2	19.3	18.4	19.0	18.2	18.4
	A1474019	16.5	16.8	18.2	19.3	18.4	19.0	18.2	18.4
	A1474021	17.4	17.1	17.4	19.4	18.6	19.0	18.1	18.1
	A1474023	17.4	17.1	17.4	19.4	18.6	19.0	18.1	18.1
	A1474025	17.4	17.1	17.4	19.4	18.6	19.0	18.1	18.1
	A1474027	17.4	17.1	17.4	19.4	18.6	19.0	18.1	18.1
	A1474029	17.4	17.1	17.4	19.4	18.6	19.0	18.1	18.1
	(n)	3	3	3	3	3	3	3	3
	Mean	16.53	16.86	17.68	18.95	18.01	18.37	17.68	17.66
	SD	0.701	0.208	0.395	0.596	0.710	0.897	0.664	0.861

Food consumption per animal/day (g) - Individual data

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Females

Group No	Animal No	Dosing Day: 57	Day: 64	Day: 71	Day: 78	Day: 85	Day: 92
Control	A1474001	17.0	16.6	17.0	17.7	16.4	16.1
	A1474003	17.0	16.6	17.0	17.7	16.4	16.1
	A1474005	17.0	16.6	17.0	17.7	16.4	16.1
	A1474007	17.0	16.6	17.0	17.7	16.4	16.1
	A1474009	17.0	16.6	17.0	17.7	16.4	16.1
	A1474011	17.6	16.8	17.5	18.2	16.2	17.2
	A1474013	17.6	16.8	17.5	18.2	16.2	17.2
	A1474015	17.6	16.8	17.5	18.2	16.2	17.2
	A1474017	17.6	16.8	17.5	18.2	16.2	17.2
	A1474019	17.6	16.8	17.5	18.2	16.2	17.2
	A1474021	19.0	16.8	17.9	18.5	16.9	16.9
	A1474023	19.0	16.8	17.9	18.5	16.9	16.9
	A1474025	19.0	16.8	17.9	18.5	16.9	16.9
	A1474027	19.0	16.8	17.9	18.5	16.9	16.9
	A1474029	19.0	16.8	17.9	18.5	16.9	16.9
	(n)	3	3	3	3	3	3
	Mean	17.89	16.70	17.44	18.13	16.50	16.74
	SD	0.839	0.101	0.371	0.364	0.314	0.466

REDACTED AS TO TRADE NAMES

Food consumption per animal/day (g) - Individual data

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No	Animal No	Allocation Day: 8	Dosing Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50
2	A1474031	16.6	15.4	17.2	18.3	17.8	18.4	17.6	16.0
	A1474033	16.6	15.4	17.2	18.3	17.8	18.4	17.6	16.0
	A1474035	16.6	15.4	17.2	18.3	17.8	18.4	17.6	16.0
	A1474037	16.6	15.4	17.2	18.3	17.8	18.4	17.6	16.0
	A1474039	16.6	15.4	17.2	18.3	17.8	18.4	17.6	16.0
	A1474041	16.2	16.1	18.0	18.4	17.7	17.6	18.1	17.2
	A1474043	16.2	16.1	18.0	18.4	17.7	17.6	18.1	17.2
	A1474045	16.2	16.1	18.0	18.4	17.7	17.6	18.1	17.2
	A1474047	16.2	16.1	18.0	18.4	17.7	17.6	18.1	17.2
	A1474049	16.2	16.1	18.0	18.4	17.7	17.6	18.1	17.2
	A1474051	17.3	17.2	18.7	18.9	17.2	18.6	18.3	18.0
	A1474053	17.3	17.2	18.7	18.9	17.2	18.6	18.3	18.0
	A1474055	17.3	17.2	18.7	18.9	17.2	18.6	18.3	18.0
	A1474057	17.3	17.2	18.7	18.9	17.2	18.6	18.3	18.0
	A1474059	17.3	17.2	18.7	18.9	17.2	18.6	18.3	18.0
	(n)	3	3	3	3	3	3	3	3
	Mean	16.70	16.22	17.97	18.52	17.56	18.19	18.02	17.09
	SD	0.426	0.745	0.637	0.278	0.225	0.432	0.284	0.846

Food consumption per animal/day (g) - Individual data

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Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No	Animal No	Dosing Day: 57	Day: 64	Day: 71	Day: 78	Day: 85	Day: 92
2	A1474031	17.4	14.8	18.2	17.7	16.1	17.3
	A1474033	17.4	14.8	18.2	17.7	16.1	17.3
	A1474035	17.4	14.8	18.2	17.7	16.1	17.3
	A1474037	17.4	14.8	18.2	17.7	16.1	17.3
	A1474039	17.4	14.8	18.2	17.7	16.1	17.3
	A1474041	17.2	16.9	17.4	18.6	16.4	16.9
	A1474043	17.2	16.9	17.4	18.6	16.4	16.9
	A1474045	17.2	16.9	17.4	18.6	16.4	16.9
	A1474047	17.2	16.9	17.4	18.6	16.4	16.9
	A1474049	17.2	16.9	17.4	18.6	16.4	16.9
	A1474051	17.3	17.5	17.2	17.4	15.8	16.8
	A1474053	17.3	17.5	17.2	17.4	15.8	16.8
	A1474055	17.3	17.5	17.2	17.4	15.8	16.8
	A1474057	17.3	17.5	17.2	17.4	15.8	16.8
	A1474059	17.3	17.5	17.2	17.4	15.8	16.8
	(n)	3	3	3	3	3	3
	Mean	17.32	16.39	17.58	17.90	16.10	17.00
	SD	0.061	1.161	0.442	0.501	0.219	0.212

Food consumption per animal/day (g) - Individual data

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No	Animal No	Allocation Day: 8	Dosing Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50
3	A1474061	17.3	18.1	18.1	18.8	17.8	18.0	18.1	17.3
	A1474063	17.3	18.1	18.1	18.8	17.8	18.0	18.1	17.3
	A1474065	17.3	18.1	18.1	18.8	17.8	18.0	18.1	17.3
	A1474067	17.3	18.1	18.1	18.8	17.8	18.0	18.1	17.3
	A1474069	17.3	18.1	18.1	18.8	17.8	18.0	18.1	17.3
	A1474071	16.5	16.3	18.9	18.5	17.0	18.2	19.0	16.8
	A1474073	16.5	16.3	18.9	18.5	17.0	18.2	19.0	16.8
	A1474075	16.5	16.3	18.9	18.5	17.0	18.2	19.0	16.8
	A1474077	16.5	16.3	18.9	18.5	17.0	18.2	19.0	16.8
	A1474079	16.5	16.3	18.9	18.5	17.0	18.2	19.0	16.8
	A1474081	17.2	16.3	18.5	18.7	18.6	18.9	17.7	17.6
	A1474083	17.2	16.3	18.5	18.7	18.6	18.9	17.7	17.6
	A1474085	17.2	16.3	18.5	18.7	18.6	18.9	17.7	17.6
	A1474087	17.2	16.3	18.5	18.7	18.6	18.9	17.7	17.6
	A1474089	17.2	16.3	18.5	18.7	18.6	18.9	17.7	17.6
	(n)	3	3	3	3	3	3	3	3
	Mean	17.01	16.91	18.49	18.68	17.80	18.38	18.29	17.27
	SD	0.333	0.869	0.332	0.152	0.692	0.374	0.513	0.336

REDACTED AS TO TRADE NAMES

Food consumption per animal/day (g) - Individual data

Printed: 04 Mar 2016 10:14:44
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No	Animal No	Dosing Day: 57	Day: 64	Day: 71	Day: 78	Day: 85	Day: 92
3	A1474061	15.9	15.8	16.9	17.3	15.6	16.1
	A1474063	15.9	15.8	16.9	17.3	15.6	16.1
	A1474065	15.9	15.8	16.9	17.3	15.6	16.1
	A1474067	15.9	15.8	16.9	17.3	15.6	16.1
	A1474069	15.9	15.8	16.9	17.3	15.6	16.1
	A1474071	17.2	17.9	17.4	17.4	16.1	16.9
	A1474073	17.2	17.9	17.4	17.4	16.1	16.9
	A1474075	17.2	17.9	17.4	17.4	16.1	16.9
	A1474077	17.2	17.9	17.4	17.4	16.1	16.9
	A1474079	17.2	17.9	17.4	17.4	16.1	16.9
	A1474081	18.6	17.5	17.5	17.7	16.9	17.1
	A1474083	18.6	17.5	17.5	17.7	16.9	17.1
	A1474085	18.6	17.5	17.5	17.7	16.9	17.1
	A1474087	18.6	17.5	17.5	17.7	16.9	17.1
	A1474089	18.6	17.5	17.5	17.7	16.9	17.1
	(n)	3	3	3	3	3	3
	Mean	17.23	17.04	17.30	17.48	16.21	16.69
	SD	1.113	0.922	0.260	0.156	0.553	0.456

Food consumption per animal/day (g) - Individual data

Printed: 04 Mar 2016 10:14:44
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No	Animal No	Allocation Day: 8	Dosing Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50
4	A1474091	16.8	17.0	18.5	19.5	17.5	19.4	18.0	17.7
	A1474093	16.8	17.0	18.5	19.5	17.5	19.4	18.0	17.7
	A1474095	16.8	17.0	18.5	19.5	17.5	19.4	18.0	17.7
	A1474097	16.8	17.0	18.5	19.5	17.5	19.4	18.0	17.7
	A1474099	16.8	17.0	18.5	19.5	17.5	19.4	18.0	17.7
	A1474101	16.1	17.9	17.9	18.4	17.8	17.5	17.8	17.6
	A1474103	16.1	17.9	17.9	18.4	17.8	17.5	17.8	17.6
	A1474105	16.1	17.9	17.9	18.4	17.8	17.5	17.8	17.6
	A1474107	16.1	17.9	17.9	18.4	17.8	17.5	17.8	17.6
	A1474109	16.1	17.9	17.9	18.4	17.8	17.5	17.8	17.6
	A1474111	17.1	17.9	18.6	18.9	18.8	17.4	18.0	17.7
	A1474113	17.1	17.9	18.6	18.9	18.8	17.4	18.0	17.7
	A1474115	17.1	17.9	18.6	18.9	18.8	17.4	18.0	17.7
	A1474117	17.1	17.9	18.6	18.9	18.8	17.4	18.0	17.7
	A1474119	17.1	17.9	18.6	18.9	18.8	17.4	18.0	17.7
	(n)	3	3	3	3	3	3	3	3
	Mean	16.68	17.60	18.35	18.92	18.05	18.10	17.92	17.66
	SD	0.405	0.459	0.294	0.464	0.560	0.949	0.106	0.055

REDACTED AS TO TRADE NAMES

Food consumption per animal/day (g) - Individual data

Printed: 04 Mar 2016 10:14:44
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No	Animal No	Dosing Day: 57	Day: 64	Day: 71	Day: 78	Day: 85	Day: 92
4	A1474091	18.0	16.7	17.5	18.4	16.7	17.6
	A1474093	18.0	16.7	17.5	18.4	16.7	17.6
	A1474095	18.0	16.7	17.5	18.4	16.7	17.6
	A1474097	18.0	16.7	17.5	18.4	16.7	17.6
	A1474099	18.0	16.7	17.5	18.4	16.7	17.6
	A1474101	17.7	16.0	17.5	19.2	17.2	16.4
	A1474103	17.7	16.0	17.5	19.2	17.2	16.4
	A1474105	17.7	16.0	17.5	19.2	17.2	16.4
	A1474107	17.7	16.0	17.5	19.2	17.2	16.4
	A1474109	17.7	16.0	17.5	19.2	17.2	16.4
	A1474111	17.8	17.7	18.3	18.4	17.3	18.1
	A1474113	17.8	17.7	18.3	18.4	17.3	18.1
	A1474115	17.8	17.7	18.3	18.4	17.3	18.1
	A1474117	17.8	17.7	18.3	18.4	17.3	18.1
	A1474119	17.8	17.7	18.3	18.4	17.3	18.1
	(n)	3	3	3	3	3	3
	Mean	17.84	16.80	17.76	18.68	17.06	17.34
	SD	0.144	0.704	0.380	0.371	0.277	0.711

Food consumption per animal/day (g) - Individual data

Printed: 03 May 2016 11:32:35
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No	Animal No	Recovery Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
Control	A1474022	21.9	21.3	21.4	21.9	21.5	21.4	21.2	18.7
	A1474024	21.9	21.3	21.4	21.9	21.5	21.4	21.2	18.7
	A1474026	21.9	21.3	21.4	21.9	21.5	21.4	21.2	18.7
	A1474028	21.9	21.3	21.4	21.9	21.5	21.4	21.2	18.7
	A1474030	21.9	21.3	21.4	21.9	21.5	21.4	21.2	18.7
	(n)	1	1	1	1	1	1	1	1
	Mean	21.94	21.34	21.38	21.88	21.46	21.41	21.22	18.67
	SD	-	-	-	-	-	-	-	-

Food consumption per animal/day (g) - Individual data

Printed: 03 May 2016 11:32:35
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No	Animal No	Recovery Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
2	A1474052	21.8	22.0	22.0	22.7	22.2	22.2	21.8	19.2
	A1474054	21.8	22.0	22.0	22.7	22.2	22.2	21.8	19.2
	A1474056	21.8	22.0	22.0	22.7	22.2	22.2	21.8	19.2
	A1474058	21.8	22.0	22.0	22.7	22.2	22.2	21.8	19.2
	A1474060	21.8	22.0	22.0	22.7	22.2	22.2	21.8	19.2
	(n)	1	1	1	1	1	1	1	1
	Mean	21.81	21.99	22.02	22.67	22.20	22.16	21.81	19.21
	SD	-	-	-	-	-	-	-	-

In-Life Draft - Not to be released 2015

REDACTED AS TO TRADE NAMES

Food consumption per animal/day (g) - Individual data

Printed: 03 May 2016 11:32:35
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No	Animal No	Recovery Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
3	A1474082	22.0	22.4	22.4	22.2	22.1	22.0	21.7	19.2
	A1474084	22.0	22.4	22.4	22.2	22.1	22.0	21.7	19.2
	A1474086	22.0	22.4	22.4	22.2	22.1	22.0	21.7	19.2
	A1474088	22.0	22.4	22.4	22.2	22.1	22.0	21.7	19.2
	A1474090	22.0	22.4	22.4	22.2	22.1	22.0	21.7	19.2
	(n)	1	1	1	1	1	1	1	1
	Mean	22.00	22.39	22.40	22.24	22.12	21.96	21.67	19.21
	SD	-	-	-	-	-	-	-	-

Food consumption per animal/day (g) - Individual data

Printed: 03 May 2016 11:32:35
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Males

Group No	Animal No	Recovery Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
4	A1474112	24.1	23.4	22.8	23.5	23.6	22.8	22.9	19.8
	A1474114	24.1	23.4	22.8	23.5	23.6	22.8	22.9	19.8
	A1474116	24.1	23.4	22.8	23.5	23.6	22.8	22.9	19.8
	A1474118	24.1	23.4	22.8	23.5	23.6	22.8	22.9	19.8
	A1474120	24.1	23.4	22.8	23.5	23.6	22.8	22.9	19.8
	(n)	1	1	1	1	1	1	1	1
	Mean	24.10	23.45	22.79	23.45	23.63	22.83	22.86	19.84
	SD	-	-	-	-	-	-	-	-

Study Director: [redacted]

Food consumption per animal/day (g) - Individual data

Printed: 03 May 2016 11:32:35
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No	Animal No	Recovery Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
Control	A1474021	16.8	17.8	17.3	19.5	18.5	17.8	16.5	17.2
	A1474023	16.8	17.8	17.3	19.5	18.5	17.8	16.5	17.2
	A1474025	16.8	17.8	17.3	19.5	18.5	17.8	16.5	17.2
	A1474027	16.8	17.8	17.3	19.5	18.5	17.8	16.5	17.2
	A1474029	16.8	17.8	17.3	19.5	18.5	17.8	16.5	17.2
	(n)	1	1	1	1	1	1	1	1
	Mean	16.77	17.81	17.29	19.51	18.55	17.76	16.53	17.20
	SD	-	-	-	-	-	-	-	-

REDACTED AS TO TRADE NAMES

Food consumption per animal/day (g) - Individual data

Printed: 03 May 2016 11:32:35
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No	Animal No	Recovery Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
2	A1474051	17.5	16.8	17.5	15.9	17.1	16.7	16.8	16.2
	A1474053	17.5	16.8	17.5	15.9	17.1	16.7	16.8	16.2
	A1474055	17.5	16.8	17.5	15.9	17.1	16.7	16.8	16.2
	A1474057	17.5	16.8	17.5	15.9	17.1	16.7	16.8	16.2
	A1474059	17.5	16.8	17.5	15.9	17.1	16.7	16.8	16.2
	(n)	1	1	1	1	1	1	1	1
	Mean	17.48	16.80	17.45	15.88	17.09	16.73	16.84	16.18
	SD	-	-	-	-	-	-	-	-

Food consumption per animal/day (g) - Individual data

Printed: 03 May 2016 11:32:35
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No	Animal No	Recovery Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
3	A1474081	18.4	17.2	17.7	17.2	17.3	17.5	17.3	16.3
	A1474083	18.4	17.2	17.7	17.2	17.3	17.5	17.3	16.3
	A1474085	18.4	17.2	17.7	17.2	17.3	17.5	17.3	16.3
	A1474087	18.4	17.2	17.7	17.2	17.3	17.5	17.3	16.3
	A1474089	18.4	17.2	17.7	17.2	17.3	17.5	17.3	16.3
	(n)	1	1	1	1	1	1	1	1
	Mean	18.40	17.21	17.71	17.21	17.31	17.49	17.33	16.25
	SD	-	-	-	-	-	-	-	-

REDACTED AS TO TRADE NAMES

Food consumption per animal/day (g) - Individual data

Printed: 03 May 2016 11:32:35
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Females

Group No	Animal No	Recovery Day: 8	Day: 15	Day: 22	Day: 29	Day: 36	Day: 43	Day: 50	Day: 57
4	A1474111	17.9	18.1	17.8	18.2	17.6	17.7	17.8	17.4
	A1474113	17.9	18.1	17.8	18.2	17.6	17.7	17.8	17.4
	A1474115	17.9	18.1	17.8	18.2	17.6	17.7	17.8	17.4
	A1474117	17.9	18.1	17.8	18.2	17.6	17.7	17.8	17.4
	A1474119	17.9	18.1	17.8	18.2	17.6	17.7	17.8	17.4
	(n)	1	1	1	1	1	1	1	1
	Mean	17.88	18.11	17.80	18.22	17.65	17.71	17.80	17.40
	SD	-	-	-	-	-	-	-	-

REDACTED AS TO TRADE NAMES

Ophthalmoscopy - Individual data

Printed: 19 May 2016 14:01:41
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Study Phase: Quarantine **Day of Phase:** 15 **Session:** 1

Pretest No	Cage No	Sex	Group	Observation/ Comments
00030	3	M	-	No abnormalities detected

Not to be used for GLP Purposes

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Study Phase: Allocation **Day of Phase:** 4 **Session:** 1

Animal No	Cage No	Sex	Group	Observation/ Comments
A1474002	1	M	1	No abnormalities detected
A1474004	1	M	1	No abnormalities detected
A1474006	1	M	1	No abnormalities detected
A1474008	1	M	1	No abnormalities detected
A1474010	1	M	1	No abnormalities detected
A1474012	2	M	1	No abnormalities detected
A1474014	2	M	1	No abnormalities detected
A1474016	2	M	1	No abnormalities detected
A1474018	2	M	1	No abnormalities detected
A1474022	3	M	1	No abnormalities detected
A1474024	3	M	1	No abnormalities detected
A1474026	3	M	1	No abnormalities detected
A1474028	3	M	1	No abnormalities detected
A1474030	3	M	1	No abnormalities detected
A1474032	4	M	2	No abnormalities detected
A1474034	4	M	2	No abnormalities detected
A1474036	4	M	2	No abnormalities detected
A1474038	4	M	2	No abnormalities detected
A1474040	4	M	2	No abnormalities detected
A1474042	5	M	2	No abnormalities detected

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Study Phase: Allocation **Day of Phase:** 4 **Session:** 1

Animal No	Cage No	Sex	Group	Observation/ Comments
A1474044	5	M	2	No abnormalities detected
A1474046	5	M	2	No abnormalities detected
A1474048	5	M	2	No abnormalities detected
A1474050	5	M	2	No abnormalities detected
A1474052	6	M	2	No abnormalities detected
A1474054	6	M	2	No abnormalities detected
A1474056	6	M	2	No abnormalities detected
A1474058	6	M	2	No abnormalities detected
A1474060	6	M	2	No abnormalities detected
A1474062	7	M	3	No abnormalities detected
A1474064	7	M	3	No abnormalities detected
A1474066	7	M	3	No abnormalities detected
A1474068	7	M	3	No abnormalities detected
A1474070	7	M	3	No abnormalities detected
A1474072	8	M	3	No abnormalities detected
A1474074	8	M	3	No abnormalities detected
A1474076	8	M	3	No abnormalities detected
A1474078	8	M	3	No abnormalities detected
A1474080	8	M	3	No abnormalities detected

REDACTED AS TO TRADE NAMES

Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Study Phase: Allocation **Day of Phase:** 4 **Session:** 1

Animal No	Cage No	Sex	Group	Observation/ Comments
A1474082	9	M	3	No abnormalities detected
A1474084	9	M	3	No abnormalities detected
A1474086	9	M	3	No abnormalities detected
A1474088	9	M	3	No abnormalities detected
A1474090	9	M	3	No abnormalities detected
A1474092	10	M	4	No abnormalities detected
A1474094	10	M	4	No abnormalities detected
A1474096	10	M	4	No abnormalities detected
A1474098	10	M	4	No abnormalities detected
A1474100	10	M	4	No abnormalities detected
A1474102	11	M	4	No abnormalities detected
A1474104	11	M	4	No abnormalities detected
A1474106	11	M	4	No abnormalities detected
A1474108	11	M	4	No abnormalities detected
A1474110	11	M	4	No abnormalities detected
A1474112	12	M	4	No abnormalities detected
A1474114	12	M	4	No abnormalities detected
A1474116	12	M	4	No abnormalities detected
A1474118	12	M	4	No abnormalities detected
A1474120	12	M	4	No abnormalities detected

Day 1 - 14th December 2015

REDACTED AS TO TRADE NAMES

Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Study Phase: Allocation **Day of Phase:** 4 **Session:** 1

Animal No	Cage No	Sex	Group	Observation/ Comments

DRAFT - NOT APPROVED - 2016

REDACTED AS TO TRADE NAMES

Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Study Phase: Dosing **Day of Phase:** 87 **Session:** 1

Animal No	Cage No	Sex	Group	Observation/ Comments
A1474002	1	M	1	No abnormalities detected
A1474004	1	M	1	No abnormalities detected
A1474006	1	M	1	No abnormalities detected
A1474008	1	M	1	No abnormalities detected
A1474010	1	M	1	No abnormalities detected
A1474012	2	M	1	No abnormalities detected
A1474014	2	M	1	No abnormalities detected
A1474016	2	M	1	No abnormalities detected
A1474018	2	M	1	No abnormalities detected
A1474020	2	M	1	No abnormalities detected
A1474022	3	M	1	No abnormalities detected
A1474024	3	M	1	No abnormalities detected
A1474026	3	M	1	No abnormalities detected
A1474028	3	M	1	No abnormalities detected
A1474030	3	M	1	No abnormalities detected
A1474092	10	M	4	No abnormalities detected
A1474094	10	M	4	No abnormalities detected
A1474096	10	M	4	No abnormalities detected
A1474098	10	M	4	No abnormalities detected
A1474100	10	M	4	No abnormalities detected

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Study Phase: Dosing **Day of Phase:** 87 **Session:** 1

Animal No	Cage No	Sex	Group	Observation/ Comments
A1474102	11	M	4	No abnormalities detected
A1474104	11	M	4	No abnormalities detected
A1474106	11	M	4	No abnormalities detected
A1474108	11	M	4	No abnormalities detected
A1474110	11	M	4	No abnormalities detected
A1474112	12	M	4	No abnormalities detected
A1474114	12	M	4	No abnormalities detected
A1474116	12	M	4	No abnormalities detected
A1474118	12	M	4	No abnormalities detected
A1474120	12	M	4	No abnormalities detected

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Study Phase: Allocation **Day of Phase:** 4 **Session:** 1

Animal No	Cage No	Sex	Group	Observation/ Comments
A1474002	1	M	1	No abnormalities detected
A1474004	1	M	1	No abnormalities detected
A1474006	1	M	1	No abnormalities detected
A1474008	1	M	1	No abnormalities detected
A1474010	1	M	1	No abnormalities detected
A1474012	2	M	1	No abnormalities detected
A1474014	2	M	1	No abnormalities detected
A1474016	2	M	1	No abnormalities detected
A1474018	2	M	1	No abnormalities detected
A1474022	3	M	1	No abnormalities detected
A1474024	3	M	1	No abnormalities detected
A1474026	3	M	1	No abnormalities detected
A1474028	3	M	1	No abnormalities detected
A1474030	3	M	1	No abnormalities detected
A1474032	4	M	2	No abnormalities detected
A1474034	4	M	2	No abnormalities detected
A1474036	4	M	2	No abnormalities detected
A1474038	4	M	2	No abnormalities detected
A1474040	4	M	2	No abnormalities detected
A1474042	5	M	2	No abnormalities detected

Study Day 4 - 14th October 2015

REDACTED AS TO TRADE NAMES

Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Study Phase: Allocation **Day of Phase:** 4 **Session:** 1

Animal No	Cage No	Sex	Group	Observation/ Comments
A1474044	5	M	2	No abnormalities detected
A1474046	5	M	2	No abnormalities detected
A1474048	5	M	2	No abnormalities detected
A1474050	5	M	2	No abnormalities detected
A1474052	6	M	2	No abnormalities detected
A1474054	6	M	2	No abnormalities detected
A1474056	6	M	2	No abnormalities detected
A1474058	6	M	2	No abnormalities detected
A1474060	6	M	2	No abnormalities detected
A1474062	7	M	3	No abnormalities detected
A1474064	7	M	3	No abnormalities detected
A1474066	7	M	3	No abnormalities detected
A1474068	7	M	3	No abnormalities detected
A1474070	7	M	3	No abnormalities detected
A1474072	8	M	3	No abnormalities detected
A1474074	8	M	3	No abnormalities detected
A1474076	8	M	3	No abnormalities detected
A1474078	8	M	3	No abnormalities detected
A1474080	8	M	3	No abnormalities detected

REDACTED AS TO TRADE NAMES

Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Study Phase: Allocation **Day of Phase:** 4 **Session:** 1

Animal No	Cage No	Sex	Group	Observation/ Comments
A1474082	9	M	3	No abnormalities detected
A1474084	9	M	3	No abnormalities detected
A1474086	9	M	3	No abnormalities detected
A1474088	9	M	3	No abnormalities detected
A1474090	9	M	3	No abnormalities detected
A1474092	10	M	4	No abnormalities detected
A1474094	10	M	4	No abnormalities detected
A1474096	10	M	4	No abnormalities detected
A1474098	10	M	4	No abnormalities detected
A1474100	10	M	4	No abnormalities detected
A1474102	11	M	4	No abnormalities detected
A1474104	11	M	4	No abnormalities detected
A1474106	11	M	4	No abnormalities detected
A1474108	11	M	4	No abnormalities detected
A1474110	11	M	4	No abnormalities detected
A1474112	12	M	4	No abnormalities detected
A1474114	12	M	4	No abnormalities detected
A1474116	12	M	4	No abnormalities detected
A1474118	12	M	4	No abnormalities detected
A1474120	12	M	4	No abnormalities detected

REDACTED AS TO TRADE NAMES

Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Study Phase: Allocation **Day of Phase:** 4 **Session:** 1

Animal No	Cage No	Sex	Group	Observation/ Comments
A1474001	13	F	1	No abnormalities detected
A1474003	13	F	1	No abnormalities detected
A1474005	13	F	1	No abnormalities detected
A1474007	13	F	1	No abnormalities detected
A1474009	13	F	1	No abnormalities detected
A1474011	14	F	1	No abnormalities detected
A1474013	14	F	1	No abnormalities detected
A1474015	14	F	1	No abnormalities detected
A1474017	14	F	1	No abnormalities detected
A1474019	14	F	1	No abnormalities detected
A1474021	15	F	1	No abnormalities detected
A1474023	15	F	1	No abnormalities detected
A1474025	15	F	1	No abnormalities detected
A1474027	15	F	1	No abnormalities detected
A1474029	15	F	1	No abnormalities detected
A1474031	16	F	2	No abnormalities detected
A1474033	16	F	2	No abnormalities detected
A1474035	16	F	2	No abnormalities detected
A1474037	16	F	2	No abnormalities detected

REDACTED AS TO TRADE NAMES

Ophthalmoscopy - Individual data

Printed: 19 May 2016 13:57:12
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Study Phase: Allocation **Day of Phase:** 4 **Session:** 1

Animal No	Cage No	Sex	Group	Observation/ Comments
A1474039	16	F	2	No abnormalities detected
A1474041	17	F	2	No abnormalities detected
A1474043	17	F	2	No abnormalities detected
A1474045	17	F	2	No abnormalities detected
A1474047	17	F	2	No abnormalities detected
A1474049	17	F	2	No abnormalities detected
A1474051	18	F	2	No abnormalities detected
A1474053	18	F	2	No abnormalities detected
A1474055	18	F	2	No abnormalities detected
A1474057	18	F	2	No abnormalities detected
A1474059	18	F	2	No abnormalities detected
A1474061	19	F	3	No abnormalities detected
A1474063	19	F	3	No abnormalities detected
A1474065	19	F	3	No abnormalities detected
A1474067	19	F	3	No abnormalities detected
A1474069	19	F	3	No abnormalities detected
A1474071	20	F	3	No abnormalities detected
A1474073	20	F	3	No abnormalities detected
A1474075	20	F	3	No abnormalities detected
A1474077	20	F	3	No abnormalities detected

DRAFT - Not Approved 2016

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Study Phase: Allocation **Day of Phase:** 4 **Session:** 1

Animal No	Cage No	Sex	Group	Observation/ Comments
A1474079	20	F	3	No abnormalities detected
A1474081	21	F	3	No abnormalities detected
A1474083	21	F	3	No abnormalities detected
A1474085	21	F	3	No abnormalities detected
A1474087	21	F	3	No abnormalities detected
A1474089	21	F	3	No abnormalities detected
A1474091	22	F	4	No abnormalities detected
A1474093	22	F	4	No abnormalities detected
A1474095	22	F	4	No abnormalities detected
A1474097	22	F	4	No abnormalities detected
A1474099	22	F	4	No abnormalities detected
A1474101	23	F	4	No abnormalities detected
A1474103	23	F	4	No abnormalities detected
A1474105	23	F	4	No abnormalities detected
A1474107	23	F	4	No abnormalities detected
A1474109	23	F	4	No abnormalities detected
A1474111	24	F	4	No abnormalities detected
A1474113	24	F	4	No abnormalities detected
A1474115	24	F	4	No abnormalities detected

REDACTED AS TO TRADE NAMES

Ophthalmoscopy - Individual data

Printed: 19 May 2016 13:57:12
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Study Phase: Allocation **Day of Phase:** 4 **Session:** 1

Animal No	Cage No	Sex	Group	Observation/ Comments
A1474117	24	F	4	No abnormalities detected
A1474119	24	F	4	No abnormalities detected

Study Report - Study Document 2016

REDACTED AS TO TRADE NAMES

Ophthalmoscopy - Individual data

Printed: 19 May 2016 13:58:53
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Study Phase: Dosing **Day of Phase:** 87 **Session:** 1

Animal No	Cage No	Sex	Group	Observation/ Comments
A1474002	1	M	1	No abnormalities detected
A1474004	1	M	1	No abnormalities detected
A1474006	1	M	1	No abnormalities detected
A1474008	1	M	1	No abnormalities detected
A1474010	1	M	1	No abnormalities detected
A1474012	2	M	1	No abnormalities detected
A1474014	2	M	1	No abnormalities detected
A1474016	2	M	1	No abnormalities detected
A1474018	2	M	1	No abnormalities detected
A1474020	2	M	1	No abnormalities detected
A1474022	3	M	1	No abnormalities detected
A1474024	3	M	1	No abnormalities detected
A1474026	3	M	1	No abnormalities detected
A1474028	3	M	1	No abnormalities detected
A1474030	3	M	1	No abnormalities detected
A1474092	10	M	4	No abnormalities detected
A1474094	10	M	4	No abnormalities detected
A1474096	10	M	4	No abnormalities detected
A1474098	10	M	4	No abnormalities detected
A1474100	10	M	4	No abnormalities detected

REDACTED AS TO TRADE NAMES

Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Study Phase: Dosing **Day of Phase:** 87 **Session:** 1

Animal No	Cage No	Sex	Group	Observation/ Comments
A1474102	11	M	4	No abnormalities detected
A1474104	11	M	4	No abnormalities detected
A1474106	11	M	4	No abnormalities detected
A1474108	11	M	4	No abnormalities detected
A1474110	11	M	4	No abnormalities detected
A1474112	12	M	4	No abnormalities detected
A1474114	12	M	4	No abnormalities detected
A1474116	12	M	4	No abnormalities detected
A1474118	12	M	4	No abnormalities detected
A1474120	12	M	4	No abnormalities detected

Study A1474 - Wistar Rat - Week 13 Recovery 2016

REDACTED AS TO TRADE NAMES

Ophthalmoscopy - Individual data

Printed: 19 May 2016 13:59:59

Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Study Phase: Dosing **Day of Phase:** 87 **Session:** 1

Animal No	Cage No	Sex	Group	Observation/ Comments
A1474001	13	F	1	No abnormalities detected
A1474003	13	F	1	No abnormalities detected
A1474005	13	F	1	No abnormalities detected
A1474007	13	F	1	No abnormalities detected
A1474009	13	F	1	No abnormalities detected
A1474011	14	F	1	No abnormalities detected
A1474013	14	F	1	No abnormalities detected
A1474015	14	F	1	No abnormalities detected
A1474017	14	F	1	No abnormalities detected
A1474019	14	F	1	No abnormalities detected
A1474021	15	F	1	No abnormalities detected
A1474023	15	F	1	No abnormalities detected
A1474025	15	F	1	No abnormalities detected
A1474027	15	F	1	No abnormalities detected
A1474029	15	F	1	No abnormalities detected
A1474091	22	F	4	No abnormalities detected
A1474093	22	F	4	No abnormalities detected
A1474095	22	F	4	No abnormalities detected
A1474097	22	F	4	No abnormalities detected
A1474099	22	F	4	No abnormalities detected

Ophthalmoscopy - Individual data

Printed: 19 May 2016 13:59:59
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Study Phase: Dosing **Day of Phase:** 87 **Session:** 1

Animal No	Cage No	Sex	Group	Observation/ Comments
A1474101	23	F	4	No abnormalities detected
A1474103	23	F	4	No abnormalities detected
A1474105	23	F	4	No abnormalities detected
A1474107	23	F	4	No abnormalities detected
A1474109	23	F	4	No abnormalities detected
A1474111	24	F	4	No abnormalities detected
A1474113	24	F	4	No abnormalities detected
A1474115	24	F	4	No abnormalities detected
A1474117	24	F	4	No abnormalities detected
A1474119	24	F	4	No abnormalities detected

DRAFT - NAM December 2016

REDACTED AS TO TRADE NAMES

Haematology Complete - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Males

Group	Animal No	RBC (x10^6/µL)	HGB (g/dL)	HCT (%)	MCV (fL)	MCH (pg)	MCHC (g/dL)	RET (x10^9/L)	RETR (%)	WBC (x10^3/µL)
Control	A1474002	8.40	14.7	44.3	52.8	17.5	33.2	138.5	1.65	13.25
	A1474004	9.53	16.5	53.5	56.2	17.3	30.9	144.4	1.52	6.57
	A1474006	8.31	14.1	43.9	52.9	17.0	32.1	158.6	1.91	7.38
	A1474008	8.75	14.6	46.2	52.8	16.7	31.6	164.0	1.87	9.36
	A1474010	8.70	14.9	46.1	53.0	17.1	32.3	162.9	1.87	7.25
	A1474012	9.36	15.5	48.6	52.0	16.6	31.9	160.0	1.71	5.65
	A1474014	9.06	15.3	47.7	52.6	16.9	32.2	184.4	2.03	6.68
	A1474016	9.02	14.9	46.9	52.0	16.5	31.8	122.3	1.36	6.06
	A1474018	9.08	15.0	46.7	51.4	16.5	32.1	147.8	1.63	5.82
	A1474020	8.83	14.6	47.0	53.2	16.6	31.1	151.2	1.71	6.41
	(n)	10	10	10	10	10	10	10	10	10
	Mean	8.904	15.01	47.09	52.89	16.87	31.92	153.41	1.726	7.443
	SD	0.3868	0.652	2.660	1.290	0.350	0.646	16.802	0.1999	2.3000

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Males

Group	Animal No	NEU (x10^3/µL)	LYM (x10^3/µL)	MON (x10^3/µL)	EOS (x10^3/µL)	BAS (x10^3/µL)	LUC (x10^3/µL)	NEUR (%)	LYMR (%)	MONR (%)
Control	A1474002	1.23	11.21	0.38	0.19	0.11	0.13	9.3	84.6	2.9
	A1474004	0.53	5.72	0.13	0.08	0.06	0.05	8.0	87.1	2.0
	A1474006	0.61	6.48	0.11	0.10	0.04	0.04	8.3	87.8	1.4
	A1474008	0.93	8.01	0.19	0.13	0.06	0.04	10.0	85.5	2.1
	A1474010	0.59	6.31	0.18	0.09	0.05	0.04	8.1	87.1	2.4
	A1474012	0.48	4.86	0.11	0.12	0.03	0.04	8.5	86.0	2.0
	A1474014	1.64	4.60	0.23	0.14	0.04	0.03	24.5	68.8	3.4
	A1474016	0.82	4.82	0.18	0.16	0.03	0.06	13.5	79.6	3.0
	A1474018	0.58	4.95	0.11	0.13	0.03	0.02	10.0	85.1	1.8
	A1474020	0.74	5.32	0.14	0.14	0.03	0.03	11.6	83.0	2.2
	(n)	10	10	10	10	10	10	10	10	10
	Mean	0.815	6.228	0.176	0.128	0.048	0.048	11.18	83.46	2.32
	SD	0.3671	2.0354	0.0825	0.0329	0.0249	0.0308	4.993	5.676	0.611

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Haematology Complete - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Males

Group	Animal No	EOSR (%)	BASR (%)	LUCR (%)	PLT (x10^3/µL)
Control	A1474002	1.4	0.8	1.0	939
	A1474004	1.2	1.0	0.7	812
	A1474006	1.4	0.5	0.6	736
	A1474008	1.4	0.6	0.4	765
	A1474010	1.2	0.7	0.5	926
	A1474012	2.2	0.6	0.7	791
	A1474014	2.2	0.6	0.5	849
	A1474016	2.6	0.4	0.9	720
	A1474018	2.2	0.5	0.3	767
	A1474020	2.2	0.5	0.5	627
	(n)	10	10	10	10
	Mean	1.80	0.62	0.61	793.2
	SD	0.525	0.175	0.218	94.34

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Males

Group	Animal No	RBC (x10^6/µL)	HGB (g/dL)	HCT (%)	MCV (fL)	MCH (pg)	MCHC (g/dL)	RET (x10^9/L)	RETR (%)	WBC (x10^3/µL)
2	A1474032	8.33	14.1	43.1	51.7	16.9	32.7	134.3	1.61	5.62
	A1474034	8.84	14.7	44.7	50.5	16.6	32.9	126.7	1.43	5.31
	A1474036	8.87	14.9	45.2	50.9	16.8	33.0	136.3	1.54	5.54
	A1474038	8.25	14.4	43.4	52.7	17.4	33.1	141.5	1.72	4.93
	A1474040	8.37	14.5	43.1	51.5	17.3	33.6	117.9	1.41	4.93
	A1474042	8.54	14.4	42.8	50.1	16.8	33.6	123.2	1.44	5.07
	A1474044	8.73	14.4	46.5	53.3	16.5	31.0	174.5	2.00	8.06
	A1474046	8.40	14.6	44.2	52.6	17.4	33.0	156.2	1.86	5.35
	A1474048	8.10	14.1	42.5	52.4	17.4	33.1	135.2	1.67	8.18
	A1474050	8.42	14.0	42.8	50.9	16.6	32.6	141.1	1.68	5.77
	(n)	10	10	10	10	10	10	10	10	10
	Mean	8.485*D	14.41*D	43.83+D	51.66	16.97	32.86+D	138.69	1.636	5.876
	SD	0.2559	0.285	1.293	1.063	0.368	0.731	16.519	0.1928	1.2158

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Males

Group	Animal No	NEU (x10^3/µL)	LYM (x10^3/µL)	MON (x10^3/µL)	EOS (x10^3/µL)	BAS (x10^3/µL)	LUC (x10^3/µL)	NEUR (%)	LYMR (%)	MONR (%)
2	A1474032	0.77	4.48	0.20	0.11	0.03	0.02	13.8	79.6	3.6
	A1474034	1.16	3.84	0.15	0.09	0.03	0.03	21.8	72.4	2.9
	A1474036	0.89	4.27	0.17	0.14	0.03	0.03	16.1	77.2	3.1
	A1474038	0.50	4.15	0.11	0.12	0.02	0.02	10.2	84.3	2.3
	A1474040	0.64	3.94	0.18	0.12	0.03	0.03	13.0	79.8	3.6
	A1474042	0.69	4.08	0.13	0.15	0.01	0.02	13.5	80.4	2.6
	A1474044	0.86	6.87	0.11	0.12	0.04	0.06	10.6	85.2	1.4
	A1474046	0.61	4.31	0.27	0.10	0.02	0.04	11.4	80.5	5.1
	A1474048	0.77	6.95	0.26	0.09	0.04	0.07	9.4	84.9	3.2
	A1474050	1.17	4.24	0.17	0.11	0.03	0.05	20.2	73.5	2.9
	(n)	10	10	10	10	10	10	10	10	10
	Mean	0.806	4.713	0.175	0.115	0.028	0.037	14.00	79.78	3.07
	SD	0.2220	1.1724	0.0558	0.0196	0.0092	0.0177	4.202	4.441	0.964

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Haematology Complete - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Males

Group	Animal No	EOSR (%)	BASR (%)	LUCR (%)	PLT (x10^3/µL)
2	A1474032	2.0	0.6	0.4	786
	A1474034	1.8	0.6	0.5	802
	A1474036	2.6	0.5	0.5	820
	A1474038	2.5	0.3	0.5	803
	A1474040	2.4	0.5	0.6	873
	A1474042	2.9	0.2	0.4	834
	A1474044	1.5	0.5	0.8	862
	A1474046	1.9	0.4	0.7	823
	A1474048	1.2	0.5	0.9	786
	A1474050	1.9	0.5	0.9	834
	(n)	10	10	10	10
	Mean	2.07	0.46	0.62	822.3
	SD	0.525	0.126	0.193	29.53

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Haematology Complete - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Males

Group	Animal No	RBC (x10^6/µL)	HGB (g/dL)	HCT (%)	MCV (fL)	MCH (pg)	MCHC (g/dL)	RET (x10^9/L)	RETR (%)	WBC (x10^3/µL)
3	A1474062	8.84	14.7	45.6	51.6	16.6	32.2	163.6	1.85	5.66
	A1474064	8.38	14.4	44.0	52.5	17.2	32.8	128.8	1.54	5.81
	A1474066	8.74	14.3	43.4	49.7	16.4	33.0	128.0	1.47	5.99
	A1474068	8.74	15.1	46.1	52.8	17.3	32.7	109.8	1.26	5.65
	A1474070	8.52	14.8	46.1	54.2	17.4	32.2	157.9	1.85	5.56
	A1474072	8.65	15.1	46.3	53.5	17.4	32.5	160.4	1.85	11.99
	A1474074	8.81	14.4	45.4	51.5	16.3	31.7	173.1	1.96	8.04
	A1474076	9.54	15.7	49.5	51.9	16.4	31.6	123.8	1.30	10.30
	A1474078	8.73	14.9	47.0	53.8	17.1	31.7	146.3	1.68	12.78
	A1474080	8.48	14.4	44.5	52.5	17.0	32.4	155.9	1.84	6.02
	(n)	10	10	10	10	10	10	10	10	10
	Mean	8.743	14.78	45.79	52.40	16.91	32.28	144.76	1.660	7.780
	SD	0.3177	0.439	1.714	1.316	0.441	0.492	20.814	0.2519	2.8535

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Males

Group	Animal No	NEU (x10^3/µL)	LYM (x10^3/µL)	MON (x10^3/µL)	EOS (x10^3/µL)	BAS (x10^3/µL)	LUC (x10^3/µL)	NEUR (%)	LYMR (%)	MONR (%)
3	A1474062	1.03	4.21	0.24	0.09	0.02	0.06	18.2	74.4	4.3
	A1474064	0.58	4.92	0.17	0.08	0.03	0.03	10.0	84.6	2.9
	A1474066	1.02	4.62	0.19	0.10	0.04	0.03	17.1	77.1	3.1
	A1474068	0.75	4.70	0.10	0.05	0.01	0.04	13.3	83.2	1.7
	A1474070	0.58	4.74	0.11	0.08	0.02	0.03	10.4	85.3	2.0
	A1474072	0.91	10.61	0.19	0.08	0.12	0.08	7.6	88.4	1.6
	A1474074	1.85	5.68	0.27	0.11	0.05	0.07	23.0	70.7	3.4
	A1474076	1.30	8.39	0.30	0.17	0.07	0.07	12.6	81.5	2.9
	A1474078	1.44	10.51	0.46	0.11	0.11	0.15	11.3	82.2	3.6
	A1474080	0.57	5.11	0.18	0.07	0.02	0.07	9.5	84.9	3.0
	(n)	10	10	10	10	10	10	10	10	10
	Mean	1.003	6.349	0.221	0.094*D	0.049	0.063	13.30	81.23	2.85
	SD	0.4237	2.5063	0.1050	0.0324	0.0390	0.0362	4.752	5.500	0.861

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Males

Group	Animal No	EOSR (%)	BASR (%)	LUCR (%)	PLT (x10^3/µL)
3	A1474062	1.5	0.4	1.1	923
	A1474064	1.4	0.4	0.6	795
	A1474066	1.6	0.6	0.5	1030
	A1474068	0.8	0.3	0.7	861
	A1474070	1.4	0.4	0.5	652
	A1474072	0.7	1.0	0.7	778
	A1474074	1.4	0.6	0.9	797
	A1474076	1.7	0.7	0.6	697
	A1474078	0.9	0.8	1.2	725
	A1474080	1.1	0.4	1.1	818
	(n)	10	10	10	10
	Mean	1.25*C	0.56	0.79	807.6
	SD	0.350	0.222	0.264	110.63

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Males

Group	Animal No	RBC (x10^6/µL)	HGB (g/dL)	HCT (%)	MCV (fL)	MCH (pg)	MCHC (g/dL)	RET (x10^9/L)	RETR (%)	WBC (x10^3/µL)
4	A1474092	8.01	14.8	44.1	55.1	18.5	33.6	144.3	1.80	7.98
	A1474094	7.85	13.4	40.7	51.9	17.0	32.8	117.6	1.50	6.16
	A1474096	7.64	14.0	42.4	55.6	18.3	33.0	150.6	1.97	9.34
	A1474098	7.54	13.4	40.6	53.8	17.8	33.1	136.6	1.81	6.48
	A1474100	8.36	14.8	45.4	54.4	17.7	32.5	155.1	1.86	9.91
	A1474102	8.67	14.9	46.1	53.2	17.2	32.4	162.1	1.87	11.11
	A1474104	8.15	14.6	44.3	54.4	18.0	33.0	141.9	1.74	7.19
	A1474106	8.54	14.8	45.6	53.4	17.4	32.6	155.9	1.82	7.99
	A1474108	8.32	14.1	42.7	51.3	16.9	33.0	102.3	1.23	5.52
	A1474110	8.03	14.2	43.6	54.3	17.7	32.7	160.9	2.00	9.43
	(n)	10	10	10	10	10	10	10	10	10
	Mean	8.111+D	14.30+D	43.55+D	53.74	17.65+D	32.87+D	142.73	1.760	8.111
	SD	0.3707	0.573	1.940	1.343	0.532	0.350	19.438	0.2310	1.8117

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Males

Group	Animal No	NEU (x10^3/µL)	LYM (x10^3/µL)	MON (x10^3/µL)	EOS (x10^3/µL)	BAS (x10^3/µL)	LUC (x10^3/µL)	NEUR (%)	LYMR (%)	MONR (%)
4	A1474092	0.69	6.84	0.24	0.09	0.05	0.07	8.6	85.7	3.0
	A1474094	0.51	5.30	0.13	0.08	0.03	0.11	8.2	85.9	2.2
	A1474096	0.90	7.88	0.31	0.11	0.05	0.08	9.7	84.5	3.3
	A1474098	0.60	5.63	0.12	0.06	0.02	0.04	9.3	86.8	1.8
	A1474100	0.76	8.71	0.19	0.10	0.07	0.08	7.6	87.9	2.0
	A1474102	1.08	9.54	0.22	0.12	0.08	0.08	9.7	85.9	1.9
	A1474104	0.58	6.28	0.15	0.08	0.04	0.05	8.0	87.4	2.1
	A1474106	0.82	6.81	0.21	0.06	0.05	0.04	10.3	85.2	2.6
	A1474108	0.47	4.84	0.10	0.05	0.02	0.05	8.4	87.7	1.8
	A1474110	0.74	8.23	0.19	0.10	0.05	0.11	7.9	87.3	2.0
	(n)	10	10	10	10	10	10	10	10	10
	Mean	0.715	7.006	0.186	0.085+D	0.046	0.071	8.77	86.43	2.27
	SD	0.1872	1.5519	0.0635	0.0232	0.0196	0.0260	0.917	1.152	0.523

Abbreviations/symbols used are explained in Addendum

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Males

Group	Animal No	EOSR (%)	BASR (%)	LUCR (%)	PLT (x10^3/µL)
4	A1474092	1.1	0.7	0.9	773
	A1474094	1.4	0.5	1.8	171
	A1474096	1.1	0.5	0.9	759
	A1474098	1.0	0.4	0.7	467
	A1474100	1.0	0.7	0.8	721
	A1474102	1.1	0.7	0.7	747
	A1474104	1.2	0.6	0.7	814
	A1474106	0.8	0.7	0.5	844
	A1474108	0.8	0.4	0.9	757
	A1474110	1.1	0.5	1.2	899
	(n)	10	10	10	10
	Mean	1.06+C	0.57	0.91*D	695.2
	SD	0.178	0.125	0.363	216.52

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Haematology Complete - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Females

Group	Animal No	RBC (x10^6/µL)	HGB (g/dL)	HCT (%)	MCV (fL)	MCH (pg)	MCHC (g/dL)	RET (x10^9/L)	RETR (%)	WBC (x10^3/µL)
Control	A1474001	7.50	13.9	41.9	55.9	18.5	33.1	171.7	2.29	6.50
	A1474003	7.43	13.4	39.5	53.2	18.0	33.9	150.9	2.03	4.95
	A1474005	7.91	14.3	44.3	56.0	18.0	32.2	122.8	1.55	5.83
	A1474007	7.26	13.4	40.2	55.4	18.5	33.3	195.2	2.69	5.96
	A1474009	8.05	14.8	45.5	56.6	18.4	32.5	134.1	1.67	5.92
	A1474011	7.30	13.2	40.0	54.7	18.1	33.1	93.1	1.27	3.96
	A1474013	7.47	13.7	41.6	55.7	18.4	33.0	96.8	1.29	3.46
	A1474015	7.27	12.6	38.9	53.6	17.3	32.4	125.0	1.72	4.84
	A1474017	7.70	14.0	42.5	55.2	18.2	33.0	172.0	2.23	3.61
	A1474019	7.49	14.0	41.9	55.9	18.7	33.5	156.3	2.09	4.66
	(n)	10	10	10	10	10	10	10	10	10
	Mean	7.538	13.73	41.63	55.22	18.21	33.00	141.79	1.883	4.969
	SD	0.2693	0.617	2.100	1.089	0.396	0.519	33.416	0.4609	1.0660

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Females

Group	Animal No	NEU (x10^3/µL)	LYM (x10^3/µL)	MON (x10^3/µL)	EOS (x10^3/µL)	BAS (x10^3/µL)	LUC (x10^3/µL)	NEUR (%)	LYMR (%)	MONR (%)
Control	A1474001	0.49	5.67	0.13	0.12	0.01	0.08	7.5	87.3	2.0
	A1474003	0.32	4.35	0.11	0.10	0.02	0.04	6.6	88.0	2.2
	A1474005	0.33	5.13	0.16	0.12	0.04	0.07	5.7	87.9	2.7
	A1474007	0.44	5.18	0.19	0.09	0.02	0.04	7.5	86.9	3.2
	A1474009	0.43	5.14	0.14	0.13	0.03	0.05	7.3	86.7	2.3
	A1474011	0.35	3.37	0.11	0.08	0.01	0.02	9.0	85.3	2.8
	A1474013	0.20	3.10	0.06	0.07	0.01	0.03	5.8	89.5	1.6
	A1474015	0.39	4.21	0.09	0.09	0.02	0.04	8.0	87.1	1.9
	A1474017	0.36	3.04	0.08	0.09	0.01	0.01	9.9	84.4	2.3
	A1474019	0.32	4.01	0.16	0.10	0.02	0.04	6.9	86.1	3.5
	(n)	10	10	10	10	10	10	10	10	10
	Mean	0.363	4.320	0.123	0.099	0.019	0.042	7.42	86.92	2.45
	SD	0.0808	0.9445	0.0406	0.0191	0.0099	0.0210	1.314	1.440	0.595

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Females

Group	Animal No	EOSR (%)	BASR (%)	LUCR (%)	PLT (x10^3/µL)
Control	A1474001	1.8	0.2	1.2	824
	A1474003	2.0	0.5	0.7	953
	A1474005	2.0	0.6	1.1	843
	A1474007	1.4	0.4	0.6	866
	A1474009	2.2	0.6	0.9	827
	A1474011	2.1	0.3	0.5	875
	A1474013	1.9	0.3	0.9	927
	A1474015	1.8	0.4	0.8	855
	A1474017	2.6	0.4	0.4	869
	A1474019	2.1	0.5	0.9	903
	(n)	10	10	10	10
	Mean	1.99	0.42	0.80	874.2
	SD	0.311	0.132	0.254	42.18

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Females

Group	Animal No	RBC (x10^6/µL)	HGB (g/dL)	HCT (%)	MCV (fL)	MCH (pg)	MCHC (g/dL)	RET (x10^9/L)	RETR (%)	WBC (x10^3/µL)
2	A1474033	7.69	14.5	44.4	57.7	18.8	32.5	270.6	3.52	5.31
	A1474035	7.67	13.6	40.5	52.7	17.7	33.5	105.5	1.38	3.37
	A1474039	7.28	13.5	39.7	54.5	18.6	34.1	152.4	2.09	5.35
	A1474041	7.51	14.2	41.0	54.6	18.9	34.7	194.3	2.59	4.51
	A1474043	8.02	14.1	41.7	52.0	17.6	33.9	120.2	1.50	6.52
	A1474045	7.44	13.8	40.6	54.7	18.5	33.9	168.7	2.27	4.13
	A1474047	8.10	14.9	43.7	53.9	18.4	34.1	235.9	2.91	4.90
	(n)	7	7	7	7	7	7	7	7	7
	Mean	7.673	14.09	41.66	54.30	18.36	33.81*D	178.23	2.323	4.870
	SD	0.2995	0.501	1.752	1.819	0.513	0.682	59.905	0.7607	1.0062

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Females

Group	Animal No	NEU (x10^3/µL)	LYM (x10^3/µL)	MON (x10^3/µL)	EOS (x10^3/µL)	BAS (x10^3/µL)	LUC (x10^3/µL)	NEUR (%)	LYMR (%)	MONR (%)
2	A1474033	0.39	4.55	0.18	0.09	0.05	0.04	7.4	85.7	3.3
	A1474035	0.39	2.76	0.07	0.12	0.01	0.03	11.6	81.9	2.0
	A1474039	0.67	3.95	0.31	0.26	0.04	0.12	12.6	73.8	5.9
	A1474041	0.85	3.41	0.13	0.05	0.02	0.05	18.9	75.6	3.0
	A1474043	1.02	5.04	0.25	0.10	0.03	0.08	15.6	77.4	3.9
	A1474045	0.43	3.48	0.09	0.07	0.02	0.04	10.5	84.1	2.3
	A1474047	0.48	4.06	0.21	0.06	0.03	0.06	9.8	82.9	4.2
	(n)	7	7	7	7	7	7	7	7	7
	Mean	0.604*C	3.893	0.177	0.107	0.029	0.060	12.34*C	80.20+C	3.51
	SD	0.2501	0.7600	0.0869	0.0716	0.0135	0.0311	3.841	4.575	1.316

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REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Females

Group	Animal No	EOSR (%)	BASR (%)	LUCR (%)	PLT (x10^3/µL)
2	A1474033	1.8	0.9	0.8	819
	A1474035	3.5	0.3	0.8	807
	A1474039	4.9	0.7	2.2	427
	A1474041	1.1	0.4	1.1	918
	A1474043	1.5	0.4	1.2	943
	A1474045	1.7	0.4	1.0	798
	A1474047	1.3	0.6	1.2	745
	(n)	7	7	7	7
	Mean	2.26	0.53	1.19	779.6
	SD	1.407	0.214	0.478	170.30

Not Intended for GLP Purposes (GLP)

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REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Females

Group	Animal No	RBC (x10^6/µL)	HGB (g/dL)	HCT (%)	MCV (fL)	MCH (pg)	MCHC (g/dL)	RET (x10^9/L)	RETR (%)	WBC (x10^3/µL)
3	A1474061	7.69	13.8	41.2	53.5	17.9	33.4	130.4	1.70	8.23
	A1474063	7.77	14.7	43.6	56.0	18.9	33.7	104.6	1.35	7.01
	A1474065	7.62	14.0	42.3	55.5	18.3	33.0	154.9	2.03	7.72
	A1474067	8.29	14.2	43.4	52.3	17.2	32.8	118.5	1.43	9.01
	A1474069	7.91	14.6	43.3	54.8	18.4	33.6	192.2	2.43	4.17
	A1474071	7.89	14.0	42.1	53.4	17.8	33.3	128.1	1.62	4.27
	A1474073	8.60	15.3	46.4	54.0	17.8	32.9	164.4	1.91	5.35
	A1474075	7.95	14.3	43.5	54.7	18.0	32.9	165.8	2.09	5.62
	A1474077	8.16	14.1	42.7	52.3	17.3	33.1	169.2	2.07	4.97
	A1474079	7.63	14.0	41.1	53.9	18.4	34.2	120.1	1.58	5.08
	(n)	10	10	10	10	10	10	10	10	10
	Mean	7.951+D	14.30	42.96	54.04	18.00	33.29	144.82	1.821	6.143
	SD	0.3160	0.450	1.515	1.237	0.521	0.443	28.232	0.3407	1.7199

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Females

Group	Animal No	NEU (x10^3/µL)	LYM (x10^3/µL)	MON (x10^3/µL)	EOS (x10^3/µL)	BAS (x10^3/µL)	LUC (x10^3/µL)	NEUR (%)	LYMR (%)	MONR (%)
3	A1474061	0.68	7.17	0.19	0.07	0.04	0.07	8.3	87.2	2.3
	A1474063	0.64	6.02	0.16	0.12	0.03	0.05	9.1	85.9	2.3
	A1474065	1.07	6.04	0.29	0.13	0.04	0.16	13.8	78.2	3.8
	A1474067	0.63	7.92	0.20	0.09	0.06	0.12	7.0	87.8	2.3
	A1474069	0.30	3.63	0.10	0.05	0.01	0.06	7.3	87.2	2.5
	A1474071	0.65	3.20	0.27	0.07	0.01	0.06	15.3	74.9	6.2
	A1474073	0.35	4.66	0.19	0.06	0.03	0.06	6.5	87.1	3.6
	A1474075	0.44	4.77	0.22	0.09	0.02	0.07	7.9	84.9	3.9
	A1474077	0.68	4.05	0.11	0.05	0.02	0.06	13.8	81.4	2.2
	A1474079	0.79	4.02	0.14	0.05	0.02	0.06	15.6	79.1	2.8
	(n)	10	10	10	10	10	10	10	10	10
	Mean	0.623+C	5.148	0.187	0.078	0.028	0.077	10.46*C	83.37*C	3.19
	SD	0.2230	1.5736	0.0625	0.0290	0.0155	0.0350	3.695	4.621	1.251

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Females

Group	Animal No	EOSR (%)	BASR (%)	LUCR (%)	PLT (x10^3/µL)
3	A1474061	0.9	0.5	0.9	883
	A1474063	1.7	0.5	0.6	850
	A1474065	1.6	0.5	2.1	893
	A1474067	1.0	0.6	1.4	1014
	A1474069	1.1	0.4	1.5	871
	A1474071	1.7	0.3	1.5	942
	A1474073	1.1	0.6	1.0	809
	A1474075	1.7	0.4	1.3	949
	A1474077	1.0	0.5	1.1	873
	A1474079	0.9	0.4	1.1	849
	(n)	10	10	10	10
	Mean	1.27#C	0.47	1.25	893.8
	SD	0.356	0.095	0.412	59.56

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Haematology Complete - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Females

Group	Animal No	RBC (x10^6/µL)	HGB (g/dL)	HCT (%)	MCV (fL)	MCH (pg)	MCHC (g/dL)	RET (x10^9/L)	RETR (%)	WBC (x10^3/µL)
4	A1474091	7.29	13.3	39.8	54.6	18.3	33.5	117.2	1.61	5.87
	A1474093	7.46	14.0	42.3	56.7	18.7	33.0	124.2	1.67	6.91
	A1474095	7.41	13.4	38.9	52.5	18.1	34.5	114.6	1.54	4.23
	A1474097	7.27	13.7	39.9	54.9	18.8	34.3	107.3	1.48	5.60
	A1474103	7.92	14.3	42.8	54.1	18.1	33.4	82.6	1.04	6.74
	A1474105	7.91	14.6	43.3	54.7	18.5	33.8	144.4	1.82	3.80
	A1474107	7.69	14.3	41.7	54.2	18.6	34.4	152.1	1.98	5.51
	A1474109	7.94	14.5	43.3	54.5	18.3	33.5	151.9	1.91	5.08
	(n)	8	8	8	8	8	8	8	8	8
	Mean	7.611	14.01	41.50	54.53	18.43	33.80*D	124.29	1.631	5.468
	SD	0.2883	0.497	1.735	1.152	0.266	0.545	24.234	0.2971	1.0918

Abbreviations/symbols used are explained in Addendum

Haematology Complete - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Females

Group	Animal No	NEU (x10^3/µL)	LYM (x10^3/µL)	MON (x10^3/µL)	EOS (x10^3/µL)	BAS (x10^3/µL)	LUC (x10^3/µL)	NEUR (%)	LYMR (%)	MONR (%)
4	A1474091	0.37	5.19	0.14	0.10	0.02	0.05	6.4	88.4	2.3
	A1474093	0.33	6.22	0.20	0.07	0.03	0.06	4.8	90.0	2.9
	A1474095	0.27	3.79	0.08	0.06	0.01	0.03	6.3	89.5	2.0
	A1474097	0.78	4.48	0.17	0.17	0.00	-	14.0	80.0	3.0
	A1474103	0.30	6.03	0.15	0.12	0.03	0.11	4.4	89.5	2.2
	A1474105	0.28	3.22	0.13	0.08	0.01	0.07	7.3	84.8	3.4
	A1474107	0.41	4.83	0.12	0.09	0.02	0.04	7.5	87.7	2.1
	A1474109	0.27	4.38	0.24	0.10	0.02	0.07	5.4	86.2	4.7
	(n)	8	8	8	8	8	7	8	8	8
	Mean	0.376	4.768	0.154	0.099	0.018	0.061	7.01	87.01	2.83
	SD	0.1707	1.0330	0.0496	0.0344	0.0104	0.0261	3.032	3.347	0.907

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Haematology Complete - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Females

Group	Animal No	EOSR (%)	BASR (%)	LUCR (%)	PLT (x10^3/µL)
4	A1474091	1.7	0.4	0.8	860
	A1474093	1.0	0.5	0.8	793
	A1474095	1.4	0.3	0.6	878
	A1474097	3.0	0.0	-	820
	A1474103	1.8	0.5	1.7	877
	A1474105	2.2	0.4	1.8	796
	A1474107	1.6	0.4	0.7	905
	A1474109	2.0	0.3	1.4	828
	(n)	8	8	7	8
	Mean	1.84	0.35	1.11	844.6
	SD	0.595	0.160	0.505	41.33

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Coagulation - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Males

Group	Animal No	PT (sec)
Control	A1474002	24.5
	A1474004	23.6
	A1474006	25.8
	A1474008	24.7
	A1474010	23.9
	A1474012	25.5
	A1474014	23.0
	A1474016	23.6
	A1474018	24.3
	A1474020	24.9
	(n)	10
	Mean	24.38
	SD	0.883

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Coagulation - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Males

Group	Animal No	PT (sec)
2	A1474032	24.3
	A1474034	24.7
	A1474036	25.3
	A1474038	25.6
	A1474040	24.8
	A1474042	25.3
	A1474044	23.3
	A1474046	23.1
	A1474048	22.1
	(n)	9
	Mean	24.28
	SD	1.192

FDA - DRAFT - FOR DISCUSSION ONLY

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Coagulation - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Males

Group	Animal No	PT (sec)
3	A1474062	24.2
	A1474064	22.1
	A1474066	22.6
	A1474068	22.5
	A1474070	22.3
	A1474072	23.7
	A1474074	23.9
	A1474076	24.1
	A1474078	23.2
	A1474080	23.6
	(n)	10
	Mean	23.22*C
	SD	0.787

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Coagulation - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Males

Group	Animal No	PT (sec)
4	A1474094	20.3
	A1474096	25.6
	A1474098	23.2
	A1474100	26.0
	A1474102	19.3
	A1474104	21.0
	A1474106	21.8
	A1474108	24.7
	A1474110	22.6
	(n)	9
	Mean	22.72
	SD	2.360

Abbreviations/symbols used are explained in Addendum

GLP - DRAFT - NOT Reviewed - 2016

REDACTED AS TO TRADE NAMES

Coagulation - Individual data

Printed: 26 Jan 2016 13:05:17
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Females

Group	Animal No	PT (sec)
Control	A1474001	23.0
	A1474003	24.2
	A1474005	25.0
	A1474007	24.4
	A1474009	24.4
	A1474011	24.2
	A1474013	24.7
	A1474015	24.8
	A1474017	23.8
	A1474019	23.0
	(n)	10
	Mean	24.15
	SD	0.695

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Coagulation - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Females

Group	Animal No	PT (sec)
2	A1474033	23.9
	A1474035	23.9
	A1474037	23.0
	A1474039	23.4
	A1474041	23.9
	A1474043	24.6
	A1474045	26.0
	A1474047	22.7
	(n)	8
	Mean	23.93
	SD	1.028

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Females

Group	Animal No	PT (sec)
3	A1474061	23.1
	A1474063	24.7
	A1474065	23.1
	A1474067	24.4
	A1474069	24.3
	A1474071	24.3
	A1474073	23.8
	A1474075	23.4
	A1474077	25.3
	A1474079	23.9
	(n)	10
	Mean	24.03
	SD	0.710

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Coagulation - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Females

Group	Animal No	PT (sec)
4	A1474091	23.7
	A1474093	21.8
	A1474095	23.9
	A1474097	21.9
	A1474099	23.0
	A1474101	18.9
	A1474103	22.0
	A1474105	22.2
	A1474107	23.0
	A1474109	21.9
	(n)	10
	Mean	22.23+D
	SD	1.402

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Blood cells morphology - Individual data

Printed: 26 Jan 2016 13:14:48

Pristima® Version 6.3.2 Build 22

Study: A1474

Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Observation	Days Seen
A1474097	F	4	Atipical mononuclear leucocytes, Slight	D93

D = Dosing

REDACTED AS TO TRADE NAMES

Clinical Chemistry Complete - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Males

Group	Animal No	ALP (U/L)	ALT (U/L)	AST (U/L)	GGT (U/L)	TBIL (mg/dL)	CHOL (mg/dL)	TRIG (mg/dL)	GLU (mg/dL)	UREA (mg/dL)
Control	A1474002	131.4	43.6	64.1	-1.4e	0.02	60.7	65.8	207.0	40.9
	A1474004	147.6	245.3	253.5	-1.9e	-0.02e	72.3	44.3	223.5	52.2
	A1474006	142.7	75.1	116.3	-2.7e	0.02	61.4	47.8	129.6	44.1
	A1474008	206.5	66.7	117.2	-2.9e	-0.02e	60.1	54.5	229.2	39.9
	A1474010	161.8	43.1	77.0	-0.7e	0.03	68.3	63.1	142.3	42.5
	A1474012	160.6	34.9	63.3	0.0	0.03	82.9	152.0	154.3	42.7
	A1474014	135.1	43.7	74.3	-0.5e	0.05	64.8	71.9	109.5	37.8
	A1474016	199.4	51.7	73.2	-2.0e	0.02	64.8	38.9	190.6	49.1
	A1474018	146.4	51.9	85.5	-1.3e	0.01	64.9	63.7	95.5	39.3
	A1474020	201.2	50.4	83.5	-1.6e	0.03	48.9	46.8	208.3	35.7
	(n)	10	10	10	1@	8@	10	10	10	10
	Mean	163.27	70.64	100.79	0.00	0.024	64.91	64.88	168.98	42.42
	SD	28.645	62.498	56.905	-	0.0074	8.815	32.437	48.846	5.034

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Males

Group	Animal No	CREA (mg/dL)	Cl (mmol/L)	Ca (mmol/L)	Na (mmol/L)	K (mmol/L)	IP (mg/dL)	PROT (g/dL)	ALB (g/dL)	GLO (g/dL)
Control	A1474002	0.42	104.3	2.47	143.9	3.76	6.83	6.2	3.7	2.5
	A1474004	0.54	105.0	2.68	141.7	9.22	9.72	6.8	4.0	2.8
	A1474006	0.43	104.8	2.43	143.5	3.81	7.61	5.8	3.3	2.5
	A1474008	0.41	104.8	2.34	141.9	4.54	6.65	5.8	3.4	2.4
	A1474010	0.35	105.0	2.49	139.0	3.84	5.18	6.7	3.9	2.8
	A1474012	0.38	102.8	2.41	144.2	3.83	4.22	6.2	3.7	2.5
	A1474014	0.33	115.9	2.48	144.8	3.77	5.07	6.6	3.9	2.7
	A1474016	0.30	104.5	2.41	140.8	3.65	4.36	6.1	3.7	2.4
	A1474018	0.35	104.5	2.47	144.4	3.79	6.02	6.2	3.8	2.4
	A1474020	0.36	111.4	2.37	139.7	3.71	6.42	5.9	3.5	2.4
	(n)	10	10	10	10	10	10	10	10	10
	Mean	0.387	106.30	2.455	142.39	4.392	6.208	6.23	3.69	2.54
	SD	0.0677	4.066	0.0931	2.071	1.7145	1.6560	0.362	0.228	0.165

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Males

Group	Animal No	A/G
Control	A1474002	1.5
	A1474004	1.4
	A1474006	1.3
	A1474008	1.4
	A1474010	1.4
	A1474012	1.5
	A1474014	1.4
	A1474016	1.5
	A1474018	1.6
	A1474020	1.5
	(n)	10
	Mean	1.45
	SD	0.085

DRAFT - Initial Data Entered 2016

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Males

Group	Animal No	ALP (U/L)	ALT (U/L)	AST (U/L)	GGT (U/L)	TBIL (mg/dL)	CHOL (mg/dL)	TRIG (mg/dL)	GLU (mg/dL)	UREA (mg/dL)
2	A1474032	193.4	191.4	162.1	-0.7e	0.00	48.9	50.1	122.4	32.0
	A1474034	144.4	70.4	85.6	-1.1e	0.01	49.9	29.4	101.9	31.0
	A1474036	163.3	41.0	66.4	-1.3e	0.02	52.5	65.5	113.9	31.6
	A1474038	122.0	42.0	65.1	-2.6e	-0.01e	60.5	37.6	103.3	34.4
	A1474040	181.3	48.3	67.9	-1.7e	0.01	52.5	57.0	129.0	35.4
	A1474042	134.9	49.3	60.9	-1.7e	0.02	50.5	43.7	96.8	38.5
	A1474044	132.7	50.1	60.8	-1.8e	0.02	49.7	44.5	96.9	37.6
	A1474046	160.0	41.7	66.5	-2.3e	-0.02e	55.1	44.1	146.8	37.0
	A1474048	157.1	72.8	86.6	-2.5e	-0.04e	49.5	46.9	120.6	34.8
	A1474050	175.1	62.1	76.0	-0.9e	0.01	49.9	28.0	151.5	32.9
	(n)	10	10	10	0@	7@	10	10	10	10
	Mean	156.42	66.91	79.79	-	0.013	51.90+D	44.68	118.31*C	34.52+C
	SD	22.976	45.257	30.368	-	0.0076	3.567	11.464	19.677	2.630

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Males

Group	Animal No	CREA (mg/dL)	Cl (mmol/L)	Ca (mmol/L)	Na (mmol/L)	K (mmol/L)	IP (mg/dL)	PROT (g/dL)	ALB (g/dL)	GLO (g/dL)
2	A1474032	0.32	104.9	2.47	147.1	3.91	5.45	6.1	3.7	2.4
	A1474034	0.26	96.1	2.47	139.9	3.38	4.86	6.5	3.8	2.7
	A1474036	0.26	101.4	2.42	146.3	3.33	5.47	6.1	3.6	2.5
	A1474038	0.27	110.8	2.40	141.4	3.37	5.38	6.1	3.7	2.4
	A1474040	0.29	96.9	2.42	145.6	2.94	4.86	5.9	3.5	2.4
	A1474042	0.24	110.8	2.47	140.2	3.81	5.29	6.2	3.8	2.4
	A1474044	0.26	100.0	2.48	145.0	3.55	5.18	6.2	3.7	2.5
	A1474046	0.32	108.0	2.46	142.6	3.98	6.18	6.2	3.6	2.6
	A1474048	0.31	103.8	2.43	143.8	3.51	6.92	6.0	3.6	2.4
	A1474050	0.29	115.8	2.41	146.8	3.73	6.44	6.0	3.6	2.4
	(n)	10	10	10	10	10	10	10	10	10
	Mean	0.282+D	104.85	2.443	143.87	3.551	5.603	6.13	3.66	2.47
	SD	0.0282	6.472	0.0298	2.711	0.3159	0.6864	0.164	0.097	0.106

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Males

Group	Animal No	A/G
2	A1474032	1.5
	A1474034	1.4
	A1474036	1.4
	A1474038	1.5
	A1474040	1.5
	A1474042	1.6
	A1474044	1.5
	A1474046	1.4
	A1474048	1.5
	A1474050	1.5
	(n)	10
	Mean	1.48
	SD	0.063

FDA - CDER/CBER/OTR Electronic Records Archive

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Males

Group	Animal No	ALP (U/L)	ALT (U/L)	AST (U/L)	GGT (U/L)	TBIL (mg/dL)	CHOL (mg/dL)	TRIG (mg/dL)	GLU (mg/dL)	UREA (mg/dL)
3	A1474062	157.5	59.1	69.3	-1.9e	-0.03e	54.3	25.5	86.5	42.0
	A1474064	148.5	54.9	64.1	-0.9e	0.01	42.2	39.2	123.6	39.0
	A1474066	182.4	73.9	96.6	-1.1e	0.01	41.2	20.1	87.7	34.4
	A1474068	146.5	67.2	96.6	-3.4e	-0.04e	49.8	26.1	114.6	34.4
	A1474070	150.8	48.5	72.3	-2.5e	0.00	46.7	38.4	117.1	52.5
	A1474072	167.4	52.4	72.0	-0.9e	0.01	41.3	39.0	179.3	49.2
	A1474074	177.3	67.1	89.5	-3.0e	-0.02e	47.9	31.2	164.1	36.3
	A1474076	161.5	53.7	68.8	-1.0e	0.00	56.1	37.6	105.5	42.5
	A1474078	167.6	56.4	80.2	0.0	0.00	47.3	15.6	195.0	55.8
	A1474080	169.8	66.8	84.0	1.1	0.06	53.5	27.8	145.0	49.7
	(n)	10	10	10	2@	7@	10	10	10	10
	Mean	162.93	60.00	79.34	0.55	0.013	48.03+D	30.05+C	131.84	43.58
	SD	12.163	8.241	11.875	0.778	0.0214	5.434	8.440	37.618	7.775

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Males

Group	Animal No	CREA (mg/dL)	Cl (mmol/L)	Ca (mmol/L)	Na (mmol/L)	K (mmol/L)	IP (mg/dL)	PROT (g/dL)	ALB (g/dL)	GLO (g/dL)
3	A1474062	0.29	104.0	2.50	142.8	3.90	5.33	6.2	3.7	2.5
	A1474064	0.27	108.9	2.40	143.9	3.51	5.63	6.0	3.6	2.4
	A1474066	0.26	104.6	2.50	144.2	3.70	5.81	6.4	3.8	2.6
	A1474068	0.29	100.0	2.49	142.7	3.94	5.61	6.1	3.6	2.5
	A1474070	0.41	104.1	2.44	143.9	3.65	6.87	5.9	3.5	2.4
	A1474072	0.30	100.9	2.46	142.8	3.83	6.39	5.7	3.3	2.4
	A1474074	0.33	109.8	2.52	144.2	3.80	6.54	6.1	3.5	2.6
	A1474076	0.27	104.6	2.49	145.1	4.48	5.50	6.4	3.8	2.6
	A1474078	0.43	108.6	2.54	144.6	3.92	7.87	5.9	3.4	2.5
	A1474080	0.43	99.8	2.49	142.7	3.54	6.24	6.1	3.5	2.6
	(n)	10	10	10	10	10	10	10	10	10
	Mean	0.328	104.53	2.483	143.69	3.827	6.179	6.08	3.57	2.51
	SD	0.0688	3.651	0.0403	0.880	0.2757	0.7788	0.220	0.164	0.088

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Males

Group	Animal No	A/G
3	A1474062	1.5
	A1474064	1.5
	A1474066	1.5
	A1474068	1.4
	A1474070	1.5
	A1474072	1.4
	A1474074	1.3
	A1474076	1.5
	A1474078	1.4
	A1474080	1.3
	(n)	10
	Mean	1.43
	SD	0.082

GLP - DRAFT - Data Unverified

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Males

Group	Animal No	ALP (U/L)	ALT (U/L)	AST (U/L)	GGT (U/L)	TBIL (mg/dL)	CHOL (mg/dL)	TRIG (mg/dL)	GLU (mg/dL)	UREA (mg/dL)
4	A1474092	321.4	82.5	79.0	-0.3e	-0.01e	47.3	37.3	227.4	41.4
	A1474094	305.8	83.6	84.2	-2.2e	-0.03e	62.4	43.4	226.9	41.0
	A1474096	277.8	59.9	65.6	-1.4e	-0.02e	43.1	36.0	210.1	49.8
	A1474098	283.3	192.5	148.5	-1.1e	-0.01e	53.4	25.8	221.3	54.3
	A1474100	232.1	80.2	85.0	0.8	-0.02e	53.4	50.2	253.7	55.6
	A1474102	167.7	97.0	106.9	-0.2e	-0.02e	64.3	19.0	139.9	65.9
	A1474104	187.4	109.8	80.2	0.3	-0.01e	67.3	26.8	106.7	54.7
	A1474106	196.4	185.7	97.7	0.9	0.00	64.9	21.8	111.8	52.6
	A1474108	210.9	40.2	65.8	0.4	0.01	49.6	25.2	143.6	51.5
	A1474110	139.4	67.9	65.6	-0.7e	-0.01e	57.7	19.5	152.7	59.3
	(n)	10	10	10	4@	2@	10	10	10	10
	Mean	232.22*C	99.93	87.85	0.60	0.005	56.34*D	30.50*C	179.41	52.61+C
	SD	61.984	50.758	25.327	0.294	0.0071	8.267	10.666	53.943	7.507

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Males

Group	Animal No	CREA (mg/dL)	Cl (mmol/L)	Ca (mmol/L)	Na (mmol/L)	K (mmol/L)	IP (mg/dL)	PROT (g/dL)	ALB (g/dL)	GLO (g/dL)
4	A1474092	0.29	107.3	2.62	144.4	3.63	6.87	6.0	3.5	2.5
	A1474094	0.29	92.0	2.54	143.2	3.90	6.37	6.0	3.5	2.5
	A1474096	0.36	102.9	2.51	142.9	4.11	5.80	5.9	3.5	2.4
	A1474098	0.42	107.6	2.48	143.8	4.32	6.89	5.8	3.4	2.4
	A1474100	0.33	103.2	2.46	143.2	4.19	6.74	6.1	3.6	2.5
	A1474102	0.46	110.1	2.60	143.7	3.74	7.26	5.9	3.3	2.6
	A1474104	0.29	105.9	2.55	145.1	3.74	6.74	6.3	3.8	2.5
	A1474106	0.39	105.5	2.58	145.2	3.80	6.26	6.6	3.9	2.7
	A1474108	0.30	101.1	2.48	144.6	3.55	5.90	5.9	3.7	2.2
	A1474110	0.34	111.5	2.56	146.1	3.86	5.83	6.1	3.6	2.5
	(n)	10	10	10	10	10	10	10	10	10
	Mean	0.347	104.71	2.538*C	144.22	3.884	6.466	6.06	3.58	2.48
	SD	0.0600	5.501	0.0543	1.039	0.2495	0.5103	0.237	0.181	0.132

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Males

Group	Animal No	A/G
4	A1474092	1.4
	A1474094	1.4
	A1474096	1.5
	A1474098	1.4
	A1474100	1.4
	A1474102	1.3
	A1474104	1.5
	A1474106	1.4
	A1474108	1.7
	A1474110	1.4
	(n)	10
	Mean	1.44
	SD	0.107

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Females

Group	Animal No	ALP (U/L)	ALT (U/L)	AST (U/L)	GGT (U/L)	TBIL (mg/dL)	CHOL (mg/dL)	TRIG (mg/dL)	GLU (mg/dL)	UREA (mg/dL)
Control	A1474001	107.9	44.6	82.0	1.8	0.18	103.6	37.0	128.2	39.3
	A1474003	97.5	36.0	74.5	0.2	0.09	68.8	47.8	133.2	30.4
	A1474005	81.0	45.0	69.6	0.9	0.09	68.1	35.1	107.1	44.6
	A1474007	139.9	45.2	75.8	0.1	0.09	70.3	27.0	126.3	38.4
	A1474009	91.3	49.0	65.8	1.2	0.06	86.4	62.8	115.7	48.1
	A1474011	131.0	34.9	64.4	0.8	0.08	82.4	35.0	99.2	35.8
	A1474013	87.6	28.5	55.5	0.8	0.07	81.9	44.4	117.7	36.6
	A1474015	149.2	34.4	81.6	0.6	0.04	65.2	26.9	108.4	43.2
	A1474017	120.6	43.3	84.5	1.6	0.08	86.4	48.5	105.3	46.6
	A1474019	114.5	45.7	72.1	0.8	0.04	103.3	62.9	92.3	49.9
	(n)	10	10	10	10	10	10	10	10	10
	Mean	112.05	40.66	72.58	0.88	0.082	81.64	42.74	113.34	41.29
	SD	23.131	6.657	9.067	0.541	0.0394	13.922	12.997	13.243	6.203

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Females

Group	Animal No	CREA (mg/dL)	Cl (mmol/L)	Ca (mmol/L)	Na (mmol/L)	K (mmol/L)	IP (mg/dL)	PROT (g/dL)	ALB (g/dL)	GLO (g/dL)
Control	A1474001	0.47	108.5	2.46	143.1	3.18	5.43	6.1	3.8	2.3
	A1474003	0.40	105.3	2.53	142.1	3.11	4.67	6.2	3.7	2.5
	A1474005	0.50	108.5	2.47	141.3	3.07	5.21	5.8	3.5	2.3
	A1474007	0.46	103.8	2.42	142.3	2.97	6.67	5.5	3.4	2.1
	A1474009	0.41	111.1	2.44	146.9	3.21	4.83	5.8	3.5	2.3
	A1474011	0.40	113.2	2.30	142.7	3.81	5.14	5.7	3.4	2.3
	A1474013	0.40	105.5	2.39	144.4	3.10	5.61	5.8	3.7	2.1
	A1474015	0.48	108.0	2.31	140.3	3.35	6.06	5.7	3.5	2.2
	A1474017	0.46	107.2	2.36	144.6	3.33	4.89	5.7	3.5	2.2
	A1474019	0.45	96.8	2.42	145.8	4.61	8.85	5.8	3.5	2.3
	(n)	10	10	10	10	10	10	10	10	10
	Mean	0.443	106.79	2.410	143.35	3.374	5.736	5.81	3.55	2.26
	SD	0.0374	4.469	0.0720	2.053	0.4928	1.2512	0.202	0.135	0.117

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Females

Group	Animal No	A/G
Control	A1474001	1.7
	A1474003	1.5
	A1474005	1.5
	A1474007	1.6
	A1474009	1.5
	A1474011	1.5
	A1474013	1.8
	A1474015	1.6
	A1474017	1.6
	A1474019	1.5
	(n)	10
	Mean	1.58
	SD	0.103

SD - DRAFT - NOT DESIGNATED

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Females

Group	Animal No	ALP (U/L)	ALT (U/L)	AST (U/L)	GGT (U/L)	TBIL (mg/dL)	CHOL (mg/dL)	TRIG (mg/dL)	GLU (mg/dL)	UREA (mg/dL)
2	A1474031	108.4	56.6	171.9	-0.2e	0.02	78.4	36.0	85.3	40.3
	A1474033	153.2	145.3	209.0	-0.1e	0.07	60.4	34.2	74.9	43.0
	A1474035	144.0	34.0	75.0	0.8	0.06	58.7	30.7	92.5	32.7
	A1474037	129.0	40.6	101.8	0.8	0.03	81.4	46.0	93.8	36.7
	A1474039	112.5	35.1	64.0	1.0	0.07	67.6	65.0	101.5	40.4
	A1474041	106.4	54.6	72.2	1.1	0.26	88.5	49.8	108.1	34.2
	A1474043	96.4	39.2	70.0	1.1	0.07	72.7	44.0	108.5	37.2
	A1474045	115.9	44.5	69.3	0.2	0.11	54.0	52.1	107.8	40.8
	A1474047	110.0	31.8	67.2	0.3	0.10	70.8	46.4	107.5	44.3
	A1474049	123.7	49.6	103.4	0.5	0.11	87.4	41.5	113.5	40.7
	(n)	10	10	10	8@	10	10	10	10	10
	Mean	119.95	53.13	100.38	0.73	0.090	71.99	44.57	99.34	39.03
	SD	17.709	33.489	50.195	0.354	0.0670	11.998	9.944	12.364	3.729

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Females

Group	Animal No	CREA (mg/dL)	Cl (mmol/L)	Ca (mmol/L)	Na (mmol/L)	K (mmol/L)	IP (mg/dL)	PROT (g/dL)	ALB (g/dL)	GLO (g/dL)
2	A1474031	0.39	105.8	2.41	142.3	6.83	9.08	5.8	3.6	2.2
	A1474033	0.49	110.8	2.52	139.5	9.74	10.40	6.2	3.6	2.6
	A1474035	0.41	104.3	2.38	137.4	3.99	4.70	6.4	3.9	2.5
	A1474037	0.42	110.4	2.39	142.7	4.33	5.16	6.0	3.7	2.3
	A1474039	0.36	106.3	2.42	144.3	3.03	4.76	5.7	3.6	2.1
	A1474041	0.33	104.6	2.44	141.6	3.42	5.45	5.8	3.5	2.3
	A1474043	0.32	105.3	2.52	142.3	3.26	5.01	6.0	3.8	2.2
	A1474045	0.37	104.2	2.40	140.2	3.30	4.93	5.9	3.6	2.3
	A1474047	0.34	113.0	2.46	144.9	3.55	5.42	6.0	3.7	2.3
	A1474049	0.36	114.4	2.43	140.6	3.50	5.30	5.8	3.6	2.2
	(n)	10	10	10	10	10	10	10	10	10
	Mean	0.379*D	107.91	2.437	141.58	4.495	6.021	5.96	3.66	2.30
	SD	0.0509	3.861	0.0497	2.245	2.1443	2.0008	0.212	0.117	0.149

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REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Females

Group	Animal No	A/G
2	A1474031	1.6
	A1474033	1.4
	A1474035	1.6
	A1474037	1.6
	A1474039	1.7
	A1474041	1.5
	A1474043	1.7
	A1474045	1.6
	A1474047	1.6
	A1474049	1.6
	(n)	10
	Mean	1.59
	SD	0.088

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Females

Group	Animal No	ALP (U/L)	ALT (U/L)	AST (U/L)	GGT (U/L)	TBIL (mg/dL)	CHOL (mg/dL)	TRIG (mg/dL)	GLU (mg/dL)	UREA (mg/dL)
3	A1474061	109.1	48.4	89.9	0.5	0.11	54.7	23.2	80.7	39.0
	A1474063	88.3	40.4	75.4	0.1	0.04	76.6	43.0	78.9	35.9
	A1474065	92.4	35.2	65.6	-0.3e	0.08	63.4	36.5	99.6	46.0
	A1474067	86.4	46.4	62.5	0.9	0.06	77.8	40.8	110.4	47.6
	A1474069	115.2	52.0	61.0	0.4	0.05	73.1	41.9	130.6	42.4
	A1474071	89.4	35.1	63.4	0.2	0.07	74.0	40.7	106.0	39.1
	A1474073	95.8	32.1	60.3	1.1	0.08	71.0	43.2	110.7	39.5
	A1474075	97.0	46.1	68.8	-0.6e	0.05	89.7	38.3	116.7	44.8
	A1474077	91.3	40.2	71.3	0.7	0.05	73.6	33.0	110.0	39.2
	A1474079	113.0	33.0	70.6	0.2	0.06	72.5	38.0	116.0	42.8
	(n)	10	10	10	8@	10	10	10	10	10
	Mean	97.79	40.89	68.88	0.51	0.065	72.64	37.86	105.96	41.63
	SD	10.689	7.020	8.884	0.360	0.0207	9.106	6.042	15.960	3.702

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Females

Group	Animal No	CREA (mg/dL)	Cl (mmol/L)	Ca (mmol/L)	Na (mmol/L)	K (mmol/L)	IP (mg/dL)	PROT (g/dL)	ALB (g/dL)	GLO (g/dL)
3	A1474061	0.39	110.4	2.57	143.2	3.74	6.70	6.2	3.8	2.4
	A1474063	0.34	105.6	2.49	143.0	3.61	5.90	5.9	3.7	2.2
	A1474065	0.43	101.5	2.54	142.5	3.20	6.42	6.1	3.7	2.4
	A1474067	0.42	102.9	2.53	144.1	3.26	5.81	6.2	3.8	2.4
	A1474069	0.31	115.7	2.51	143.8	3.53	5.14	6.3	3.8	2.5
	A1474071	0.32	107.2	2.50	143.9	3.42	4.90	6.1	3.7	2.4
	A1474073	0.35	109.2	2.51	145.4	2.99	5.34	6.1	3.7	2.4
	A1474075	0.34	97.4	2.55	142.5	3.15	5.79	6.2	3.7	2.5
	A1474077	0.39	108.9	2.53	144.8	3.59	4.73	6.4	4.0	2.4
	A1474079	0.32	111.7	2.49	142.7	3.22	5.02	6.0	3.8	2.2
	(n)	10	10	10	10	10	10	10	10	10
	Mean	0.361+D	107.05	2.522+C	143.59	3.371	5.575	6.15+D	3.77+D	2.38
	SD	0.0433	5.364	0.0266	0.989	0.2420	0.6590	0.143	0.095	0.103

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Females

Group	Animal No	A/G
3	A1474061	1.6
	A1474063	1.7
	A1474065	1.5
	A1474067	1.6
	A1474069	1.5
	A1474071	1.5
	A1474073	1.5
	A1474075	1.5
	A1474077	1.7
	A1474079	1.7
	(n)	10
	Mean	1.58
	SD	0.092

GLP - DRAFT - 14th December 2015

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Females

Group	Animal No	ALP (U/L)	ALT (U/L)	AST (U/L)	GGT (U/L)	TBIL (mg/dL)	CHOL (mg/dL)	TRIG (mg/dL)	GLU (mg/dL)	UREA (mg/dL)
4	A1474091	79.5	41.3	57.3	0.6	0.04	79.7	58.7	158.7	29.3
	A1474093	103.4	49.0	64.6	1.1	0.02	94.7	52.8	132.5	43.1
	A1474095	89.4	29.3	59.8	0.6	0.01	72.0	47.3	159.6	37.3
	A1474097	88.0	27.6	53.3	1.3	0.04	67.9	82.0	128.5	40.2
	A1474099	83.9	36.5	61.8	0.9	0.03	79.0	47.6	128.3	53.0
	A1474101	86.1	29.3	55.1	0.0	0.03	60.9	40.6	108.9	52.6
	A1474103	109.4	30.0	49.5	0.9	0.04	72.8	66.4	126.0	39.7
	A1474105	70.1	35.2	63.0	0.8	0.05	67.3	45.5	106.7	43.8
	A1474107	130.6	29.3	57.3	-0.1e	0.03	67.8	55.5	139.3	37.6
	A1474109	101.0	37.2	61.6	0.3	0.03	75.5	48.7	146.6	38.2
	(n)	10	10	10	9@	10	10	10	10	10
	Mean	94.14	34.47	58.33+C	0.72	0.032+C	73.76	54.51*D	133.51*D	41.48
	SD	17.375	6.809	4.736	0.399	0.0114	9.341	12.141	18.117	7.156

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Females

Group	Animal No	CREA (mg/dL)	Cl (mmol/L)	Ca (mmol/L)	Na (mmol/L)	K (mmol/L)	IP (mg/dL)	PROT (g/dL)	ALB (g/dL)	GLO (g/dL)
4	A1474091	0.31	105.1	2.60	141.8	3.27	5.22	6.4	4.0	2.4
	A1474093	0.35	104.9	2.57	143.6	3.45	6.09	5.8	3.4	2.4
	A1474095	0.33	111.4	2.46	142.6	3.36	5.39	6.2	3.7	2.5
	A1474097	0.33	104.6	2.44	143.4	3.37	6.26	6.0	3.7	2.3
	A1474099	0.51	111.2	2.46	143.4	3.77	6.35	5.8	3.7	2.1
	A1474101	0.33	106.4	2.42	143.2	3.06	5.64	5.8	3.5	2.3
	A1474103	0.34	113.8	2.54	148.3	3.42	5.77	6.5	4.0	2.5
	A1474105	0.31	107.3	2.52	142.3	3.70	5.43	6.2	3.9	2.3
	A1474107	0.34	102.6	2.47	143.1	3.32	5.59	5.9	3.7	2.2
	A1474109	0.32	97.2	2.38	140.8	3.89	6.06	6.1	3.7	2.4
	(n)	10	10	10	10	10	10	10	10	10
	Mean	0.347+D	106.45	2.486*C	143.25	3.461	5.780	6.07*D	3.73*D	2.34
	SD	0.0587	4.829	0.0695	1.976	0.2526	0.3907	0.254	0.195	0.126

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Dosing Day 92

Females

Group	Animal No	A/G
4	A1474091	1.7
	A1474093	1.4
	A1474095	1.5
	A1474097	1.6
	A1474099	1.8
	A1474101	1.5
	A1474103	1.6
	A1474105	1.7
	A1474107	1.7
	A1474109	1.5
	(n)	10
	Mean	1.60
	SD	0.125

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Clinical Chemistry Complete - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 57

Males

Group	Animal No	ALP (U/L)	ALT (U/L)	AST (U/L)	GGT (U/L)	TBIL (mg/dL)	CHOL (mg/dL)	TRIG (mg/dL)	GLU (mg/dL)	UREA (mg/dL)
Control	A1474022	196.3	42.9	55.9	-0.5e	0.02	85.3	99.1	189.6	42.5
	A1474024	249.1	52.9	77.2	-0.3e	0.03	68.8	61.4	164.0	58.6
	A1474026	155.0	45.7	62.0	0.5	0.01	91.4	90.0	213.8	40.6
	A1474028	126.1	29.7	63.2	-2.4e	0.01	75.2	79.3	111.8	39.5
	A1474030	226.3	36.1	61.7	-1.6e	0.04	80.7	81.0	115.2	35.7
	(n)	5	5	5	1@	5	5	5	5	5
	Mean	190.56	41.46	64.00	0.50	0.022	80.28	82.16	158.88	43.38
	SD	50.391	8.916	7.902	-	0.0130	8.755	14.044	45.029	8.863

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 57

Males

Group	Animal No	CREA (mg/dL)	Cl (mmol/L)	Ca (mmol/L)	Na (mmol/L)	K (mmol/L)	IP (mg/dL)	PROT (g/dL)	ALB (g/dL)	GLO (g/dL)
Control	A1474022	0.52	100.5	2.38	141.9	4.23	3.88	6.1	3.6	2.5
	A1474024	0.54	101.4	2.35	142.5	3.66	5.79	6.1	3.6	2.5
	A1474026	0.47	101.7	2.48	140.4	3.88	4.97	6.6	3.8	2.8
	A1474028	0.43	101.0	2.38	142.5	4.32	3.81	6.4	3.8	2.6
	A1474030	0.41	104.4	2.38	141.0	4.46	3.94	6.3	3.8	2.5
	(n)	5	5	5	5	5	5	5	5	5
	Mean	0.474	101.80	2.394	141.66	4.110	4.478	6.30	3.72	2.58
	SD	0.0559	1.522	0.0498	0.934	0.3303	0.8742	0.212	0.110	0.130

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 57

Males

Group	Animal No	A/G
Control	A1474022	1.4
	A1474024	1.4
	A1474026	1.4
	A1474028	1.5
	A1474030	1.5
	(n)	5
	Mean	1.44
	SD	0.055

DRAFT - Not Designated Data

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 57

Males

Group	Animal No	ALP (U/L)	ALT (U/L)	AST (U/L)	GGT (U/L)	TBIL (mg/dL)	CHOL (mg/dL)	TRIG (mg/dL)	GLU (mg/dL)	UREA (mg/dL)
2	A1474052	134.6	50.0	78.7	-2.2e	0.01	65.8	56.5	106.8	33.0
	A1474054	178.2	47.9	66.4	-1.1e	0.00	74.0	79.4	154.8	35.0
	A1474056	168.0	62.3	76.4	-0.2e	0.04	47.0	49.8	131.3	39.1
	A1474058	182.9	41.3	63.1	-1.2e	0.00	58.9	60.7	160.7	41.0
	A1474060	170.6	46.6	65.6	-0.8e	0.02	76.0	55.5	115.3	34.2
	(n)	5	5	5	0@	5	5	5	5	5
	Mean	166.86	49.62	70.04	-	0.014	64.34	60.38*D	133.78	36.46
	SD	18.986	7.782	7.010	-	0.0167	11.850	11.321	23.675	3.420

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 57

Males

Group	Animal No	CREA (mg/dL)	Cl (mmol/L)	Ca (mmol/L)	Na (mmol/L)	K (mmol/L)	IP (mg/dL)	PROT (g/dL)	ALB (g/dL)	GLO (g/dL)
2	A1474052	0.38	109.0	2.48	140.8	3.98	4.51	6.2	3.7	2.5
	A1474054	0.36	100.6	2.48	140.1	3.82	4.86	6.1	3.6	2.5
	A1474056	0.40	100.1	2.42	141.8	3.26	4.57	6.0	3.5	2.5
	A1474058	0.40	107.4	2.41	141.4	3.41	5.07	6.2	3.8	2.4
	A1474060	0.39	109.8	2.48	138.9	4.19	4.61	6.5	3.7	2.8
	(n)	5	5	5	5	5	5	5	5	5
	Mean	0.386*D	105.38	2.454	140.60	3.732	4.724	6.20	3.66	2.54
	SD	0.0167	4.676	0.0358	1.147	0.3891	0.2349	0.187	0.114	0.152

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Clinical Chemistry Complete - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 57

Males

Group	Animal No	A/G
2	A1474052	1.5
	A1474054	1.4
	A1474056	1.4
	A1474058	1.6
	A1474060	1.3
	(n)	5
	Mean	1.44
	SD	0.114

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Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 57

Males

Group	Animal No	ALP (U/L)	ALT (U/L)	AST (U/L)	GGT (U/L)	TBIL (mg/dL)	CHOL (mg/dL)	TRIG (mg/dL)	GLU (mg/dL)	UREA (mg/dL)
3	A1474082	125.7	56.2	66.8	0.1	0.05	82.9	56.2	86.1	45.7
	A1474084	168.0	51.8	60.7	0.5	0.02	75.2	55.9	95.6	55.9
	A1474086	165.1	85.0	97.9	0.1	0.04	73.7	46.5	93.4	43.0
	A1474088	147.9	61.5	79.2	0.4	0.02	53.7	64.0	120.5	45.8
	A1474090	198.8	112.6	112.8	0.2	0.03	70.1	68.2	167.2	45.2
	(n)	5	5	5	5	5	5	5	5	5
	Mean	161.10	73.42	83.48	0.26	0.032	71.12	58.16*D	112.56	47.12
	SD	26.983	25.373	21.697	0.182	0.0130	10.800	8.364	33.179	5.038

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 57

Males

Group	Animal No	CREA (mg/dL)	Cl (mmol/L)	Ca (mmol/L)	Na (mmol/L)	K (mmol/L)	IP (mg/dL)	PROT (g/dL)	ALB (g/dL)	GLO (g/dL)
3	A1474082	0.36	103.2	2.46	142.6	4.09	4.97	5.8	3.4	2.4
	A1474084	0.34	103.6	2.42	142.5	3.94	4.81	5.8	3.4	2.4
	A1474086	0.31	105.6	2.40	141.7	3.70	5.20	6.0	3.5	2.5
	A1474088	0.43	101.9	2.42	141.1	3.54	5.12	6.2	3.6	2.6
	A1474090	0.45	104.1	2.52	138.6	3.73	5.48	6.2	3.5	2.7
	(n)	5	5	5	5	5	5	5	5	5
	Mean	0.378+D	103.68	2.444	141.30	3.800	5.116	6.00*D	3.48+D	2.52
	SD	0.0597	1.348	0.0477	1.629	0.2158	0.2522	0.200	0.084	0.130

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 57

Males

Group	Animal No	A/G
3	A1474082	1.4
	A1474084	1.4
	A1474086	1.4
	A1474088	1.4
	A1474090	1.3
	(n)	5
	Mean	1.38
	SD	0.045

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Abbreviations/symbols used are explained in Addendum

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 57

Males

Group	Animal No	ALP (U/L)	ALT (U/L)	AST (U/L)	GGT (U/L)	TBIL (mg/dL)	CHOL (mg/dL)	TRIG (mg/dL)	GLU (mg/dL)	UREA (mg/dL)
4	A1474112	193.9	76.4	84.3	-0.1e	0.00	70.2	28.2	141.0	48.5
	A1474114	123.9	45.3	63.5	0.2	0.01	68.6	27.5	114.5	45.7
	A1474116	226.1	309.7	129.3	0.5	0.01	76.0	25.9	162.1	43.4
	A1474118	188.6	58.4	62.6	0.1	0.00	69.5	27.8	164.9	42.4
	A1474120	205.7	46.7	66.3	0.6	0.04	76.4	59.5	161.5	39.1
	(n)	5	5	5	4@	5	5	5	5	5
	Mean	187.64	107.30	81.20	0.35	0.012	72.14	33.78+D	148.80	43.82
	SD	38.433	113.829	28.304	0.238	0.0164	3.752	14.404	21.417	3.532

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 57

Males

Group	Animal No	CREA (mg/dL)	Cl (mmol/L)	Ca (mmol/L)	Na (mmol/L)	K (mmol/L)	IP (mg/dL)	PROT (g/dL)	ALB (g/dL)	GLO (g/dL)
4	A1474112	0.42	98.3	2.57	141.1	3.83	5.38	6.3	3.8	2.5
	A1474114	0.38	113.4	2.58	143.5	4.04	5.83	6.3	3.8	2.5
	A1474116	0.36	95.6	2.54	139.9	3.58	5.52	6.5	3.8	2.7
	A1474118	0.36	105.4	2.47	144.5	3.56	5.34	6.3	3.7	2.6
	A1474120	0.41	106.3	2.48	138.2	3.71	5.21	6.3	3.6	2.7
	(n)	5	5	5	5	5	5	5	5	5
	Mean	0.386*D	103.80	2.528+D	141.44	3.744	5.456	6.34	3.74	2.60
	SD	0.0279	7.044	0.0507	2.578	0.1981	0.2365	0.089	0.089	0.100

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 57

Males

Group	Animal No	A/G
4	A1474112	1.5
	A1474114	1.5
	A1474116	1.4
	A1474118	1.4
	A1474120	1.3
	(n)	5
	Mean	1.42
	SD	0.084

GLP - DRAFT - Valid for review only

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 57

Females

Group	Animal No	ALP (U/L)	ALT (U/L)	AST (U/L)	GGT (U/L)	TBIL (mg/dL)	CHOL (mg/dL)	TRIG (mg/dL)	GLU (mg/dL)	UREA (mg/dL)
Control	A1474021	83.7	43.8	58.5	-1.3e	0.04	102.2	123.3	76.6	36.7
	A1474023	101.0	40.8	67.7	-1.1e	0.06	77.7	51.1	80.3	39.8
	A1474025	103.5	43.4	71.3	-0.8e	0.01	101.2	50.4	93.0	34.7
	A1474027	109.0	43.6	73.0	1.8	0.07	81.2	68.0	62.3	39.6
	A1474029	123.7	49.2	59.3	-1.4e	0.05	111.0	71.5	92.5	38.1
	(n)	5	5	5	1@	5	5	5	5	5
	Mean	104.18	44.16	65.96	1.80	0.046	94.66	72.86	80.94	37.78
	SD	14.442	3.071	6.729	-	0.0230	14.452	29.781	12.706	2.130

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 57

Females

Group	Animal No	CREA (mg/dL)	Cl (mmol/L)	Ca (mmol/L)	Na (mmol/L)	K (mmol/L)	IP (mg/dL)	PROT (g/dL)	ALB (g/dL)	GLO (g/dL)
Control	A1474021	0.50	106.6	2.45	142.5	3.15	4.87	6.6	3.9	2.7
	A1474023	0.55	110.7	2.31	143.0	3.31	5.44	5.9	3.6	2.3
	A1474025	0.46	110.3	2.35	141.1	3.81	4.14	6.1	3.6	2.5
	A1474027	0.53	107.1	2.29	140.1	3.56	3.51	6.1	3.6	2.5
	A1474029	0.53	108.8	2.35	139.0	3.98	3.36	6.8	4.0	2.8
	(n)	5	5	5	5	5	5	5	5	5
	Mean	0.514	108.70	2.350	141.14	3.562	4.264	6.30	3.74	2.56
	SD	0.0351	1.840	0.0616	1.656	0.3426	0.8876	0.381	0.195	0.195

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 57

Females

Group	Animal No	A/G
Control	A1474021	1.4
	A1474023	1.6
	A1474025	1.4
	A1474027	1.4
	A1474029	1.4
	(n)	5
	Mean	1.44
	SD	0.089

NC - DRAFT - [illegible]

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 57

Females

Group	Animal No	ALP (U/L)	ALT (U/L)	AST (U/L)	GGT (U/L)	TBIL (mg/dL)	CHOL (mg/dL)	TRIG (mg/dL)	GLU (mg/dL)	UREA (mg/dL)
2	A1474051	133.1	47.2	70.5	-0.2e	0.11	90.4	30.1	114.2	30.1
	A1474053	85.6	41.1	67.8	0.0	0.12	71.0	49.5	85.9	36.9
	A1474055	100.0	36.4	64.0	-1.7e	0.13	78.9	48.5	96.5	33.3
	A1474057	85.9	31.4	66.2	0.3	0.13	71.6	65.8	101.6	35.1
	A1474059	74.0	37.2	55.7	-1.4e	0.11	104.9	55.8	99.5	37.4
	(n)	5	5	5	2@	5	5	5	5	5
	Mean	95.72	38.66	64.84	0.15	0.120	83.36	49.94	99.54	34.56
	SD	22.837	5.891	5.632	0.212	0.0100	14.357	13.055	10.179	2.971

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 57

Females

Group	Animal No	CREA (mg/dL)	Cl (mmol/L)	Ca (mmol/L)	Na (mmol/L)	K (mmol/L)	IP (mg/dL)	PROT (g/dL)	ALB (g/dL)	GLO (g/dL)
2	A1474051	0.38	100.5	2.51	141.7	3.40	4.62	6.6	3.9	2.7
	A1474053	0.46	101.4	2.37	138.5	3.42	4.18	6.0	3.7	2.3
	A1474055	0.47	100.1	2.49	141.9	3.56	3.70	6.3	3.9	2.4
	A1474057	0.48	105.3	2.39	138.4	3.18	3.96	6.2	3.9	2.3
	A1474059	0.46	97.1	2.33	136.0	3.19	3.65	6.3	3.8	2.5
	(n)	5	5	5	5	5	5	5	5	5
	Mean	0.450*D	100.88+D	2.418	139.30	3.350	4.022	6.28	3.84	2.44
	SD	0.0400	2.952	0.0782	2.493	0.1628	0.3964	0.217	0.089	0.167

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 57

Females

Group	Animal No	A/G
2	A1474051	1.4
	A1474053	1.6
	A1474055	1.6
	A1474057	1.7
	A1474059	1.5
	(n)	5
	Mean	1.56
	SD	0.114

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 57

Females

Group	Animal No	ALP (U/L)	ALT (U/L)	AST (U/L)	GGT (U/L)	TBIL (mg/dL)	CHOL (mg/dL)	TRIG (mg/dL)	GLU (mg/dL)	UREA (mg/dL)
3	A1474081	95.5	50.4	85.6	-0.2e	0.07	99.8	60.2	101.6	47.7
	A1474083	92.1	39.0	60.7	-0.6e	0.09	89.7	70.3	77.2	41.7
	A1474085	83.1	41.7	85.1	-0.8e	0.04	70.5	68.6	118.9	38.6
	A1474087	73.0	32.1	62.7	-1.3e	0.10	63.1	42.5	118.1	45.8
	A1474089	97.3	30.3	60.0	-0.4e	0.07	71.6	38.3	123.5	44.7
	(n)	5	5	5	0@	5	5	5	5	5
	Mean	88.20	38.70	70.82	-	0.074	78.94	55.98	107.86*D	43.70
	SD	10.104	8.064	13.302	-	0.0230	15.223	14.802	19.043	3.585

Not Drug-Induced Data

Abbreviations/symbols used are explained in Addendum

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 57

Females

Group	Animal No	CREA (mg/dL)	Cl (mmol/L)	Ca (mmol/L)	Na (mmol/L)	K (mmol/L)	IP (mg/dL)	PROT (g/dL)	ALB (g/dL)	GLO (g/dL)
3	A1474081	0.59	101.3	2.49	140.4	3.23	5.02	7.0	4.3	2.7
	A1474083	0.47	104.3	2.47	142.2	2.92	5.35	6.2	3.6	2.6
	A1474085	0.50	110.7	2.44	139.2	2.68	5.17	5.9	3.6	2.3
	A1474087	0.54	102.7	2.43	142.9	2.86	4.64	5.9	3.6	2.3
	A1474089	0.55	99.5	2.36	140.9	3.39	3.56	6.1	3.6	2.5
	(n)	5	5	5	5	5	5	5	5	5
	Mean	0.530	103.70	2.438	141.12	3.016	4.748	6.22	3.74	2.48
	SD	0.0464	4.294	0.0497	1.465	0.2881	0.7137	0.455	0.313	0.179

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 57

Females

Group	Animal No	A/G
3	A1474081	1.6
	A1474083	1.4
	A1474085	1.6
	A1474087	1.6
	A1474089	1.4
	(n)	5
	Mean	1.52
	SD	0.110

Study - Unaudited - Not Guaranteed 2016

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Clinical Chemistry Complete - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 57

Females

Group	Animal No	ALP (U/L)	ALT (U/L)	AST (U/L)	GGT (U/L)	TBIL (mg/dL)	CHOL (mg/dL)	TRIG (mg/dL)	GLU (mg/dL)	UREA (mg/dL)
4	A1474111	91.4	34.9	67.2	0.4	0.06	88.1	53.6	121.0	39.6
	A1474113	68.6	33.1	53.2	-1.8e	0.00	79.9	50.9	130.4	35.0
	A1474115	107.4	38.9	65.6	-0.7e	0.03	106.0	63.0	116.2	49.2
	A1474117	64.4	25.3	64.4	0.1	0.03	71.7	45.2	118.7	33.3
	A1474119	161.5	50.7	69.7	-0.6e	0.03	107.7	71.1	117.7	48.0
	(n)	5	5	5	2@	5	5	5	5	5
	Mean	98.66	36.58	64.02	0.25	0.030	90.68	56.76	120.80+D	41.02
	SD	39.228	9.313	6.366	0.212	0.0212	15.870	10.278	5.643	7.306

Abbreviations/symbols used are explained in Addendum

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 57

Females

Group	Animal No	CREA (mg/dL)	Cl (mmol/L)	Ca (mmol/L)	Na (mmol/L)	K (mmol/L)	IP (mg/dL)	PROT (g/dL)	ALB (g/dL)	GLO (g/dL)
4	A1474111	0.48	103.9	2.45	141.5	3.10	5.74	6.1	3.8	2.3
	A1474113	0.41	103.0	2.39	139.4	3.30	4.43	6.0	3.6	2.4
	A1474115	0.49	104.8	2.48	139.6	3.07	4.76	6.1	3.7	2.4
	A1474117	0.44	111.5	2.34	141.0	3.13	3.39	6.2	3.7	2.5
	A1474119	0.47	104.7	2.40	140.5	3.23	4.90	6.4	3.8	2.6
	(n)	5	5	5	5	5	5	5	5	5
	Mean	0.458	105.58	2.412	140.40	3.166	4.644	6.16	3.72	2.44
	SD	0.0327	3.388	0.0545	0.897	0.0961	0.8513	0.152	0.084	0.114

Abbreviations/symbols used are explained in Addendum

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Recovery Day 57

Females

Group	Animal No	A/G
4	A1474111	1.7
	A1474113	1.5
	A1474115	1.5
	A1474117	1.5
	A1474119	1.5
	(n)	5
	Mean	1.54
	SD	0.089

Abbreviations/symbols used are explained in Addendum

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

Males

Group No	Animal No	TBW (g)	Adrenal glands (g)	Brain (g)	Epididymides (g)	Heart (g)	Kidneys (g)
Control	A1474002	457.2	0.050	2.06	1.322	1.52	2.39
	A1474004	467.7	0.040	1.96	1.352	1.50	3.01
	A1474006	467.4	0.057	1.96	1.656	1.57	2.75
	A1474008	463.9	0.047	1.94	1.254	1.65	2.82
	A1474010	458.2	0.061	2.01	1.516	1.47	2.88
	A1474012	420.0	0.048	1.91	1.301	1.18	2.40
	A1474014	438.8	0.046	2.04	1.670	1.56	2.63
	A1474016	379.7	0.053	1.85	1.240	1.30	2.32
	A1474018	464.5	0.047	1.94	1.356	1.36	2.67
	A1474020	392.2	0.047	1.89	1.189	1.47	2.21
	(n)	10	10	10	10	10	10
	Mean	440.96	0.0496	1.956	1.3856	1.458	2.608
	SD	32.710	0.00600	0.0659	0.17042	0.1405	0.2661

RTC Study No.: A1474

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

		Males				
Group No	Animal No	TBW (g)	Liver (g)	Spleen (g)	Thymus (g)	Testes (g)
Control	A1474002	457.2	11.40	0.790	0.350	3.748
	A1474004	467.7	13.38	0.701	0.417	3.919
	A1474006	467.4	11.86	0.983	0.489	3.848
	A1474008	463.9	11.92	0.821	0.413	3.536
	A1474010	458.2	11.63	0.842	0.355	3.897
	A1474012	420.0	11.07	0.727	0.464	3.689
	A1474014	438.8	11.83	0.882	0.305	3.941
	A1474016	379.7	9.16	0.724	0.320	3.610
	A1474018	464.5	11.49	1.052	0.298	3.788
	A1474020	392.2	9.27	0.644	0.280	3.390
	(n)	10	10	10	10	10
	Mean	440.96	11.301	0.8166	0.3691	3.7366
	SD	32.710	1.2567	0.12846	0.07279	0.18093

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

Males

Group No	Animal No	TBW (g)	Adrenal glands (g)	Brain (g)	Epididymides (g)	Heart (g)	Kidneys (g)
2	A1474032	421.5	0.045	1.93	1.625	1.50	2.54
	A1474034	431.7	0.039	1.98	1.336	1.30	2.40
	A1474036	457.0	0.040	1.89	1.243	1.44	2.64
	A1474038	427.2	0.044	1.9-	1.578	1.54	2.29
	A1474040	415.8	0.048	1.94	1.329	1.33	2.45
	A1474042	435.0	0.045	1.94	1.431	1.48	2.46
	A1474044	439.2	0.057	1.90	1.752	1.43	2.73
	A1474046	461.6	0.049	1.90	1.241	1.24	2.55
	A1474048	403.5	0.053	2.04	1.649	1.50	2.61
	A1474050	458.7	0.045	1.86	1.271	1.32	2.29
	(n)	10	10	10	10	10	10
	Mean	435.12	0.0465	1.932	1.4455	1.408	2.496
	SD	19.395	0.00550	0.0507	0.18979	0.1026	0.1456

RTC Study No.: A1474

APPENDIX 16 - Absolute organ weights (g) - Individual data

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

Males

Group No	Animal No	TBW (g)	Liver (g)	Spleen (g)	Thymus (g)	Testes (g)
2	A1474032	421.5	10.40	0.880	0.378	4.076
	A1474034	431.7	12.01	0.758	0.284	3.884
	A1474036	457.0	11.23	0.723	0.365	3.720
	A1474038	427.2	12.25	0.944	0.394	3.434
	A1474040	415.8	10.69	0.766	0.283	4.032
	A1474042	435.0	11.35	0.846	0.461	3.980
	A1474044	439.2	11.98	0.772	0.395	3.698
	A1474046	461.6	11.87	0.856	0.322	3.724
	A1474048	403.5	12.91	0.805	0.483	4.448
	A1474050	458.7	10.73	0.682	0.379	3.494
	(n)	10	10	10	10	10
	Mean	435.12	11.542	0.8032	0.3744	3.8490
	SD	19.395	0.7969	0.07879	0.06625	0.30102

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

Males

Group No	Animal No	TBW (g)	Adrenal glands (g)	Brain (g)	Epididymides (g)	Heart (g)	Kidneys (g)
3	A1474062	413.8	0.038	1.92	1.004	1.29	2.27
	A1474064	446.1	0.037	1.94	1.374	1.37	2.34
	A1474066	461.6	0.046	2.12	1.341	1.41	2.81
	A1474068	436.2	0.048	1.93	1.333	1.48	2.77
	A1474070	439.0	0.060	1.81	1.496	1.59	2.74
	A1474072	446.9	0.040	1.84	1.311	1.33	2.54
	A1474074	456.0	0.055	1.94	1.473	1.64	2.76
	A1474076	441.7	0.064	1.86	1.911	1.53	2.83
	A1474078	439.8	0.052	1.97	1.438	1.49	2.61
	A1474080	386.2	0.038	1.98	1.276	1.28	2.30
	(n)	10	10	10	10	10	10
	Mean	436.73	0.0478	1.931	1.3957	1.441	2.597
	SD	21.857	0.00974	0.0869	0.22747	0.1250	0.2214

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

Males

Group No	Animal No	TBW (g)	Liver (g)	Spleen (g)	Thymus (g)	Testes (g)
3	A1474062	413.8	13.61	0.727	0.268	2.361
	A1474064	446.1	12.19	0.802	0.371	3.839
	A1474066	461.6	13.53	0.713	0.423	3.727
	A1474068	436.2	13.14	0.757	0.399	3.889
	A1474070	439.0	13.43	0.837	0.359	3.816
	A1474072	446.9	13.41	0.819	0.309	4.030
	A1474074	456.0	13.56	0.794	0.259	4.128
	A1474076	441.7	14.45	0.784	0.338	4.036
	A1474078	439.8	13.23	0.738	0.510	4.138
	A1474080	386.2	11.19	0.587	0.302	3.693
	(n)	10	10	10	10	10
	Mean	436.73	13.174+C	0.7558	0.3538	3.7657
	SD	21.857	0.8897	0.07184	0.07662	0.51810

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

		Males					
Group No	Animal No	TBW (g)	Adrenal glands (g)	Brain (g)	Epididymides (g)	Heart (g)	Kidneys (g)
4	A1474092	450.4	0.053	2.00	1.607	1.44	2.86
	A1474094	440.6	0.048	1.94	1.411	1.47	3.03
	A1474096	431.6	0.039	1.86	1.404	1.31	2.65
	A1474098	455.2	0.044	2.06	1.344	1.24	2.62
	A1474100	491.8	0.043	1.97	1.439	1.69	2.97
	A1474102	438.7	0.064	1.92	1.308	1.31	2.69
	A1474104	413.1	0.051	1.90	1.346	1.48	2.62
	A1474106	448.5	0.045	1.89	1.411	1.37	2.79
	A1474108	455.6	0.035	1.91	1.579	1.48	2.59
	A1474110	400.2	0.042	1.92	1.361	1.37	2.50
	(n)	10	10	10	10	10	10
	Mean	442.57	0.0464	1.937	1.4210	1.416	2.732
	SD	25.061	0.00817	0.0587	0.09905	0.1267	0.1741

Study Director Signature Date

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

			Males			
Group No	Animal No	TBW (g)	Liver (g)	Spleen (g)	Thymus (g)	Testes (g)
4	A1474092	450.4	22.49	0.912	0.357	3.968
	A1474094	440.6	21.93	0.790	0.384	3.814
	A1474096	431.6	21.34	0.830	0.262	3.874
	A1474098	455.2	21.44	0.745	0.306	3.835
	A1474100	491.8	23.36	0.810	0.385	3.688
	A1474102	438.7	17.09	0.839	0.436	3.714
	A1474104	413.1	18.98	0.769	0.305	3.958
	A1474106	448.5	20.41	0.752	0.316	4.015
	A1474108	455.6	17.66	0.732	0.409	3.633
	A1474110	400.2	17.11	0.711	0.399	3.998
	(n)	10	10	10	10	10
	Mean	442.57	20.181#C	0.7890	0.3559	3.8497
	SD	25.061	2.3157	0.06036	0.05600	0.13689

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

		Females					
Group No	Animal No	TBW (g)	Adrenal glands (g)	Brain (g)	Heart (g)	Kidneys (g)	Liver (g)
Control	A1474001	266.6	0.055	1.78	0.86	1.37	6.11
	A1474003	289.5	0.060	1.67	1.06	1.61	6.56
	A1474005	264.8	0.067	1.67	1.08	1.46	6.20
	A1474007	242.6	0.062	1.8[illegible]	0.97	1.44	5.98
	A1474009	262.0	0.061	1.78	0.89	1.52	6.63
	A1474011	271.5	0.052	1.77	0.89	1.55	6.94
	A1474013	261.5	0.064	1.75	0.99	1.54	6.27
	A1474015	281.9	0.066	1.89	1.14	1.68	6.54
	A1474017	294.2	0.069	1.71	1.06	1.67	6.63
	A1474019	276.9	0.052	1.75	0.85	1.64	7.43
	(n)	10	10	10	10	10	10
	Mean	271.15	0.0608	1.761	0.979	1.548	6.529
	SD	15.165	0.00609	0.0692	0.1033	0.1036	0.4288

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Absolute organ weight (g) - Individual data

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

		Females				
Group No	Animal No	TBW (g)	Ovaries (g)	Spleen (g)	Thymus (g)	Uterus (g)
Control	A1474001	266.6	0.098	0.632	0.228	0.618
	A1474003	289.5	0.122	0.626	0.290	1.245
	A1474005	264.8	0.114	0.660	0.265	0.646
	A1474007	242.6	0.111	0.539	0.208	0.364
	A1474009	262.0	0.129	0.650	0.240	0.455
	A1474011	271.5	0.112	0.612	0.226	0.537
	A1474013	261.5	0.102	0.563	0.257	0.636
	A1474015	281.9	0.129	0.728	0.283	0.858
	A1474017	294.2	0.106	0.649	0.316	0.886
	A1474019	276.9	0.115	0.661	0.239	0.459
	(n)	10	10	10	10	10
	Mean	271.15	0.1138	0.6340	0.2552	0.6704
	SD	15.165	0.01050	0.04937	0.03349	0.26228

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Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

Group No	Animal No	TBW (g)	Adrenal glands (g)	Brain (g)	Heart (g)	Kidneys (g)	Liver (g)
			Females				
2	A1474031	267.1	0.054	1.81	0.96	1.81	7.32
	A1474033	276.9	0.063	1.96	0.86	1.64	6.62
	A1474035	277.0	0.062	1.87	1.07	1.66	6.50
	A1474037	295.1	0.068	1.83	1.08	1.72	6.70
	A1474039	264.9	0.052	1.74	0.85	1.42	6.33
	A1474041	268.7	0.075	1.78	1.17	1.72	7.45
	A1474043	273.4	0.058	1.79	0.86	1.65	5.97
	A1474045	263.2	0.057	1.65	0.94	1.39	5.83
	A1474047	249.3	0.055	1.64	1.00	1.49	5.96
	A1474049	264.4	0.061	1.68	0.96	1.41	6.19
	(n)	10	10	10	10	10	10
	Mean	270.00	0.0605	1.777	0.975	1.591	6.487
	SD	11.927	0.00698	0.1024	0.1067	0.1507	0.5552

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APPENDIX 16 - Absolute organ weights (g) - Individual data

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

		Females				
Group No	Animal No	TBW (g)	Ovaries (g)	Spleen (g)	Thymus (g)	Uterus (g)
2	A1474031	267.1	0.101	0.521	0.219	0.883
	A1474033	276.9	0.099	0.687	0.318	0.805
	A1474035	277.0	0.102	0.607	0.287	0.592
	A1474037	295.1	0.143	0.665	0.338	0.581
	A1474039	264.9	0.097	0.682	0.220	0.474
	A1474041	268.7	0.156	0.750	0.298	0.912
	A1474043	273.4	0.096	0.649	0.303	0.447
	A1474045	263.2	0.118	0.582	0.226	0.683
	A1474047	249.3	0.104	0.686	0.277	0.837
	A1474049	264.4	0.111	0.628	0.208	1.238
	(n)	10	10	10	10	10
	Mean	270.00	0.1127	0.6457	0.2694	0.7452
	SD	11.927	0.02072	0.06440	0.04716	0.24001

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

		Females					
Group No	Animal No	TBW (g)	Adrenal glands (g)	Brain (g)	Heart (g)	Kidneys (g)	Liver (g)
3	A1474061	263.9	0.053	1.92	0.94	1.65	6.70
	A1474063	272.5	0.048	1.63	0.82	1.41	6.50
	A1474065	288.7	0.052	1.71	1.07	1.57	7.22
	A1474067	258.6	0.049	1.72	0.92	1.52	6.55
	A1474069	262.0	0.067	1.78	0.88	1.54	6.33
	A1474071	242.3	0.063	1.79	0.91	1.55	6.08
	A1474073	260.2	0.058	1.68	0.83	1.49	6.10
	A1474075	275.2	0.056	1.78	1.03	1.65	7.04
	A1474077	280.8	0.054	1.82	1.18	1.47	6.71
	A1474079	270.4	0.053	1.74	0.88	1.61	6.10
	(n)	10	10	10	10	10	10
	Mean	267.46	0.0553	1.757	0.946	1.546	6.533
	SD	13.037	0.00596	0.0807	0.1141	0.0778	0.3960

RTC Study No.: A1474

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

		Females				
Group No	Animal No	TBW (g)	Ovaries (g)	Spleen (g)	Thymus (g)	Uterus (g)
3	A1474061	263.9	0.133	0.669	0.273	0.668
	A1474063	272.5	0.119	0.466	0.278	0.502
	A1474065	288.7	0.128	0.701	0.294	0.613
	A1474067	258.6	0.118	0.631	0.238	0.426
	A1474069	262.0	0.125	0.575	0.305	1.218
	A1474071	242.3	0.087	0.591	0.276	0.858
	A1474073	260.2	0.110	0.633	0.279	0.859
	A1474075	275.2	0.111	0.585	0.275	0.511
	A1474077	280.8	0.133	0.595	0.286	1.358
	A1474079	270.4	0.115	0.589	0.208	0.398
	(n)	10	10	10	10	10
	Mean	267.46	0.1179	0.6035	0.2712	0.7411
	SD	13.037	0.01367	0.06318	0.02814	0.33073

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Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

Females

Group No	Animal No	TBW (g)	Adrenal glands (g)	Brain (g)	Heart (g)	Kidneys (g)	Liver (g)
4	A1474091	261.4	0.057	1.88	0.97	1.58	9.02
	A1474093	246.8	0.058	1.76	0.89	1.57	8.63
	A1474095	290.9	0.079	1.80	1.01	1.88	8.23
	A1474097	283.5	0.058	1.71	0.93	1.81	7.79
	A1474099	260.7	0.067	1.81	1.00	1.64	8.44
	A1474101	265.0	0.076	1.77	1.09	1.71	7.94
	A1474103	262.4	0.060	1.74	0.95	1.59	8.86
	A1474105	275.1	0.053	1.82	0.84	1.51	7.79
	A1474107	270.7	0.064	1.76	1.00	1.70	8.03
	A1474109	270.5	0.041	1.74	0.96	1.56	8.52
	(n)	10	10	10	10	10	10
	Mean	268.70	0.0613	1.779	0.964	1.655	8.325+D
	SD	12.518	0.01102	0.0493	0.0690	0.1188	0.4385

RTC Study No.: A1474

REDACTED AS TO TRADE NAMES

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Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

		Females				
Group No	Animal No	TBW (g)	Ovaries (g)	Spleen (g)	Thymus (g)	Uterus (g)
4	A1474091	261.4	0.111	0.582	0.183	0.649
	A1474093	246.8	0.104	0.566	0.237	0.480
	A1474095	290.9	0.136	0.762	0.260	2.108
	A1474097	283.5	0.104	0.618	0.199	0.580
	A1474099	260.7	0.088	0.563	0.267	0.869
	A1474101	265.0	0.141	0.630	0.253	0.992
	A1474103	262.4	0.113	0.665	0.234	1.024
	A1474105	275.1	0.112	0.577	0.241	0.833
	A1474107	270.7	0.135	0.632	0.338	1.466
	A1474109	270.5	0.093	0.556	0.224	0.418
	(n)	10	10	10	10	10
	Mean	268.70	0.1137	0.6151	0.2436	0.9419
	SD	12.518	0.01821	0.06303	0.04217	0.51267

REDACTED AS TO TRADE NAMES

Absolute organ weight (g) - Individual data

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Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

Males

Group No	Animal No	TBW (g)	Adrenal glands (g)	Brain (g)	Epididymides (g)	Heart (g)	Kidneys (g)
Control	A1474022	476.3	0.044	1.98	1.208	1.62	2.74
	A1474024	431.3	0.033	1.90	1.357	1.33	2.73
	A1474026	468.0	0.050	1.92	1.399	1.59	3.13
	A1474028	471.4	0.042	1.98	1.266	1.56	3.23
	A1474030	446.8	0.042	1.90	1.439	1.43	2.55
	(n)	5	5	5	5	5	5
	Mean	458.76	0.0422	1.936	1.3338	1.506	2.876
	SD	19.039	0.00610	0.0410	0.09523	0.1222	0.2898

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REDACTED AS TO TRADE NAMES

Absolute organ weight (g) - Individual data

Printed: 06 Mar 2016 09:38:35
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

				Males		
Group No	Animal No	TBW (g)	Liver (g)	Spleen (g)	Thymus (g)	Testes (g)
Control	A1474022	476.3	11.05	0.667	0.263	3.823
	A1474024	431.3	9.70	0.707	0.183	3.732
	A1474026	468.0	12.63	0.902	0.283	4.159
	A1474028	471.4	11.69	0.823	0.301	4.063
	A1474030	446.8	9.85	0.824	0.296	4.172
	(n)	5	5	5	5	5
	Mean	458.76	10.984	0.7846	0.2652	3.9898
	SD	19.039	1.2396	0.09574	0.04824	0.20091

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Printed: 06 Mar 2016 09:38:35
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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

Males

Group No	Animal No	TBW (g)	Adrenal glands (g)	Brain (g)	Epididymides (g)	Heart (g)	Kidneys (g)
2	A1474052	494.0	0.050	1.95	1.427	1.44	2.69
	A1474054	497.8	0.044	1.87	1.336	1.45	2.95
	A1474056	473.0	0.046	2.04	1.414	1.54	2.60
	A1474058	459.1	0.042	1.92	1.779	1.45	2.54
	A1474060	465.8	0.053	1.98	1.446	1.43	2.66
	(n)	5	5	5	5	5	5
	Mean	477.94	0.0470	1.952	1.4804	1.462	2.688
	SD	17.169	0.00447	0.0638	0.17209	0.0444	0.1574

Non-GLP Investigative Study

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Printed: 06 Mar 2016 09:38:35
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

Males

Group No	Animal No	TBW (g)	Liver (g)	Spleen (g)	Thymus (g)	Testes (g)
2	A1474052	494.0	11.53	0.909	0.247	3.696
	A1474054	497.8	12.56	0.826	0.263	3.751
	A1474056	473.0	10.74	0.863	0.243	3.967
	A1474058	459.1	11.51	0.793	0.314	4.522
	A1474060	465.8	11.10	0.800	0.238	4.059
	(n)	5	5	5	5	5
	Mean	477.94	11.488	0.8382	0.2610	3.9990
	SD	17.169	0.6822	0.04816	0.03107	0.32843

RTC Study No.: A1474

APPENDIX 16 - Absolute organ weights (g) - Individual data

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Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

Males

Group No	Animal No	TBW (g)	Adrenal glands (g)	Brain (g)	Epididymides (g)	Heart (g)	Kidneys (g)
3	A1474082	449.4	0.052	1.89	1.324	1.57	2.60
	A1474084	429.9	0.060	2.06	1.422	1.44	2.71
	A1474086	460.2	0.041	1.95	1.389	1.58	2.93
	A1474088	499.3	0.045	1.99	1.425	1.56	2.99
	A1474090	488.0	0.054	2.02	1.125	1.59	3.15
	(n)	5	5	5	5	5	5
	Mean	465.36	0.0504	1.982	1.3370	1.548	2.876
	SD	28.299	0.00750	0.0653	0.12529	0.0614	0.2206

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Absolute organ weight (g) - Individual data

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

			Males			
Group No	Animal No	TBW (g)	Liver (g)	Spleen (g)	Thymus (g)	Testes (g)
3	A1474082	449.4	10.89	0.708	0.264	4.138
	A1474084	429.9	11.02	0.692	0.318	3.823
	A1474086	460.2	12.23	0.896	0.262	4.046
	A1474088	499.3	13.43	0.836	0.286	3.707
	A1474090	488.0	11.90	0.866	0.280	1.544
	(n)	5	5	5	5	5
	Mean	465.36	11.894	0.8036	0.2820	3.4516
	SD	28.299	1.0301	0.09588	0.02258	1.08011

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

Males

Group No	Animal No	TBW (g)	Adrenal glands (g)	Brain (g)	Epididymides (g)	Heart (g)	Kidneys (g)
4	A1474112	495.3	0.047	1.99	1.441	1.44	3.19
	A1474114	482.5	0.054	1.97	1.525	1.59	3.22
	A1474116	477.4	0.046	1.84	1.291	1.42	2.54
	A1474118	429.6	0.040	1.91	1.452	1.47	2.89
	A1474120	471.4	0.058	1.90	1.403	1.61	2.89
	(n)	5	5	5	5	5	5
	Mean	471.24	0.0490	1.922	1.4224	1.506	2.946
	SD	24.887	0.00707	0.0597	0.08572	0.0879	0.2765

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Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

Males

Group No	Animal No	TBW (g)	Liver (g)	Spleen (g)	Thymus (g)	Testes (g)
4	A1474112	495.3	16.40	0.844	0.292	4.884
	A1474114	482.5	15.37	0.874	0.250	4.233
	A1474116	477.4	14.84	0.580	0.291	3.822
	A1474118	429.6	15.48	0.8[illegible]7	0.322	4.290
	A1474120	471.4	12.77	0.770	0.306	4.171
	(n)	5	5	5	5	5
	Mean	471.24	14.972+D	0.7850	0.2922	4.2800
	SD	24.887	1.3529	0.12128	0.02674	0.38366

RTC Study No.: A1474

APPENDIX 16 - Absolute organ weights (g) - Individual data

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Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

Females

Group No	Animal No	TBW (g)	Adrenal glands (g)	Brain (g)	Heart (g)	Kidneys (g)	Liver (g)
Control	A1474021	319.0	0.053	1.82	1.08	2.07	6.98
	A1474023	296.0	0.039	1.78	0.99	1.50	5.90
	A1474025	281.7	0.045	1.67	0.88	1.40	5.49
	A1474027	292.8	0.054	1.74	0.91	1.46	6.52
	A1474029	287.5	0.059	1.70	0.99	1.56	7.51
	(n)	5	5	5	5	5	5
	Mean	295.40	0.0500	1.742	0.970	1.598	6.480
	SD	14.267	0.00794	0.0602	0.0784	0.2702	0.8107

Non-GLP - Study Not Performed Under GLP

REDACTED AS TO TRADE NAMES

Printed: 06 Mar 2016 09:38:35
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

			Females			
Group No	Animal No	TBW (g)	Ovaries (g)	Spleen (g)	Thymus (g)	Uterus (g)
Control	A1474021	319.0	0.122	0.708	0.239	0.592
	A1474023	296.0	0.120	0.655	0.243	0.492
	A1474025	281.7	0.089	0.543	0.270	0.541
	A1474027	292.8	0.095	0.574	0.204	0.431
	A1474029	287.5	0.102	0.592	0.210	0.683
	(n)	5	5	5	5	5
	Mean	295.40	0.1056	0.6144	0.2332	0.5478
	SD	14.267	0.01481	0.06641	0.02681	0.09622

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Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

Group No	Animal No	TBW (g)	Adrenal glands (g)	Brain (g)	Heart (g)	Kidneys (g)	Liver (g)
			Females				
2	A1474051	272.9	0.060	1.82	0.87	1.64	6.16
	A1474053	282.6	0.067	1.84	1.00	1.58	5.63
	A1474055	309.9	0.056	1.83	0.94	1.76	6.50
	A1474057	294.7	0.053	1.76	0.96	1.59	6.36
	A1474059	252.1	0.058	1.82	0.98	1.70	6.01
	(n)	5	5	5	5	5	5
	Mean	282.44	0.0588	1.814	0.950	1.654	6.132
	SD	21.886	0.00526	0.0313	0.0500	0.0760	0.3373

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Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

			Females			
Group No	Animal No	TBW (g)	Ovaries (g)	Spleen (g)	Thymus (g)	Uterus (g)
2	A1474051	272.9	0.095	0.521	0.181	1.253
	A1474053	282.6	0.114	0.596	0.192	0.578
	A1474055	309.9	0.105	0.703	0.180	1.113
	A1474057	294.7	0.106	0.706	0.262	1.098
	A1474059	252.1	0.082	0.572	0.170	0.583
	(n)	5	5	5	5	5
	Mean	282.44	0.1004	0.6196	0.1970	0.9250
	SD	21.886	0.01230	0.08211	0.03716	0.32025

Non-GLP Unaudited Preliminary Data

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Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

		Females					
Group No	Animal No	TBW (g)	Adrenal glands (g)	Brain (g)	Heart (g)	Kidneys (g)	Liver (g)
3	A1474081	287.5	0.061	1.69	0.91	1.69	6.76
	A1474083	288.7	0.060	1.78	1.04	1.70	6.81
	A1474085	290.1	0.055	1.81	0.87	1.71	6.97
	A1474087	282.8	0.060	1.80	1.02	1.68	6.48
	A1474089	266.1	0.054	1.81	1.05	1.60	5.78
	(n)	5	5	5	5	5	5
	Mean	283.04	0.0580	1.778	0.978	1.677	6.560
	SD	9.859	0.00324	0.0505	0.0823	0.0447	0.4705

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Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

		Females				
Group No	Animal No	TBW (g)	Ovaries (g)	Spleen (g)	Thymus (g)	Uterus (g)
3	A1474081	287.5	0.093	0.526	0.279	0.694
	A1474083	288.7	0.116	0.714	0.228	0.803
	A1474085	290.1	0.117	0.623	0.200	0.735
	A1474087	282.8	0.165	0.669	0.161	0.856
	A1474089	266.1	0.106	0.579	0.214	0.712
	(n)	5	5	5	5	5
	Mean	283.04	0.1194	0.6222	0.2164	0.7600*C
	SD	9.859	0.02726	0.07372	0.04300	0.06773

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Printed: 06 Mar 2016 09:38:35
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

		Females					
Group No	Animal No	TBW (g)	Adrenal glands (g)	Brain (g)	Heart (g)	Kidneys (g)	Liver (g)
4	A1474111	270.6	0.059	1.82	0.94	1.53	7.50
	A1474113	289.3	0.058	1.81	0.99	1.59	8.46
	A1474115	277.6	0.050	1.80	0.98	1.56	8.00
	A1474117	277.3	0.050	1.78	0.93	1.47	7.70
	A1474119	276.3	0.056	1.88	0.93	1.71	7.62
	(n)	5	5	5	5	5	5
	Mean	278.22	0.0546	1.817	0.953	1.572	7.854+D
	SD	6.814	0.00434	0.0372	0.0298	0.0882	0.3861

Non-GLP - Unaudited - Investigational Use Only

Absolute organ weight (g) - Individual data

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Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

		Females				
Group No	Animal No	TBW (g)	Ovaries (g)	Spleen (g)	Thymus (g)	Uterus (g)
4	A1474111	270.6	0.138	0.666	0.237	0.622
	A1474113	289.3	0.107	0.633	0.161	0.503
	A1474115	277.6	0.119	0.664	0.173	0.469
	A1474117	277.3	0.120	0.565	0.220	0.880
	A1474119	276.3	0.134	0.590	0.151	0.483
	(n)	5	5	5	5	5
	Mean	278.22	0.1236	0.6236	0.1884	0.5914
	SD	6.814	0.01250	0.04495	0.03791	0.17232

REDACTED AS TO TRADE NAMES

Organ weight to terminal body weight (%) - Individual data

Printed: 01 Feb 2016 11:52:32
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

			Males				
Group No	Animal No	TBW (g)	Adrenal glands	Brain	Epididymides	Heart	Kidneys
Control	A1474002	457.2	0.011	0.451	0.289	0.332	0.523
	A1474004	467.7	0.009	0.419	0.289	0.321	0.644
	A1474006	467.4	0.012	0.419	0.354	0.336	0.588
	A1474008	463.9	0.010	0.418	0.270	0.356	0.608
	A1474010	458.2	0.013	0.439	0.331	0.321	0.629
	A1474012	420.0	0.011	0.455	0.310	0.281	0.571
	A1474014	438.8	0.010	0.465	0.381	0.356	0.599
	A1474016	379.7	0.014	0.487	0.327	0.342	0.611
	A1474018	464.5	0.010	0.418	0.292	0.293	0.575
	A1474020	392.2	0.012	0.482	0.303	0.375	0.563
	(n)	10	10	10	10	10	10
	Mean	440.96	0.0113	0.4452	0.3146	0.3312	0.5911
	SD	32.710	0.00162	0.02688	0.03377	0.02879	0.03496

Organ weight to terminal body weight (%) - Individual data

Printed: 01 Feb 2016 11:52:32
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

			Males			
Group No	Animal No	TBW (g)	Liver	Spleen	Thymus	Testes
Control	A1474002	457.2	2.493	0.173	0.077	0.820
	A1474004	467.7	2.861	0.159	0.089	0.838
	A1474006	467.4	2.537	0.210	0.105	0.823
	A1474008	463.9	2.570	0.177	0.089	0.762
	A1474010	458.2	2.538	0.184	0.077	0.851
	A1474012	420.0	2.636	0.173	0.110	0.878
	A1474014	438.8	2.696	0.201	0.070	0.898
	A1474016	379.7	2.412	0.191	0.084	0.951
	A1474018	464.5	2.474	0.226	0.064	0.816
	A1474020	392.2	2.364	0.164	0.071	0.864
	(n)	10	10	10	10	10
	Mean	440.96	2.5581	0.1849	0.0837	0.8501
	SD	32.710	0.14453	0.02278	0.01505	0.05179

REDACTED AS TO TRADE NAMES

Organ weight to terminal body weight (%) - Individual data

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Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

			Males				
Group No	Animal No	TBW (g)	Adrenal glands	Brain	Epididymides	Heart	Kidneys
2	A1474032	421.5	0.011	0.458	0.386	0.356	0.603
	A1474034	431.7	0.009	0.459	0.309	0.301	0.556
	A1474036	457.0	0.009	0.414	0.272	0.315	0.578
	A1474038	427.2	0.010	0.454	0.369	0.360	0.536
	A1474040	415.8	0.012	0.467	0.320	0.320	0.589
	A1474042	435.0	0.010	0.446	0.329	0.340	0.566
	A1474044	439.2	0.013	0.433	0.399	0.326	0.622
	A1474046	461.6	0.011	0.412	0.269	0.269	0.552
	A1474048	403.5	0.013	0.506	0.409	0.372	0.647
	A1474050	458.7	0.010	0.405	0.277	0.288	0.499
	(n)	10	10	10	10	10	10
	Mean	435.12	0.0107	0.4452	0.3338	0.3246	0.5747
	SD	19.395	0.00147	0.03053	0.05360	0.03314	0.04285

REDACTED AS TO TRADE NAMES

Organ weight to terminal body weight (%) - Individual data

Printed: 01 Feb 2016 11:52:32
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

			Males			
Group No	Animal No	TBW (g)	Liver	Spleen	Thymus	Testes
2	A1474032	421.5	2.467	0.209	0.090	0.967
	A1474034	431.7	2.782	0.176	0.066	0.900
	A1474036	457.0	2.457	0.158	0.080	0.814
	A1474038	427.2	2.868	0.221	0.092	0.804
	A1474040	415.8	2.571	0.184	0.068	0.970
	A1474042	435.0	2.609	0.194	0.106	0.915
	A1474044	439.2	2.728	0.176	0.090	0.842
	A1474046	461.6	2.571	0.185	0.070	0.807
	A1474048	403.5	3.200	0.200	0.120	1.102
	A1474050	458.7	2.339	0.149	0.083	0.762
	(n)	10	10	10	10	10
	Mean	435.12	2.6592	0.1852	0.0864	0.8882
	SD	19.395	0.24788	0.02204	0.01714	0.10379

REDACTED AS TO TRADE NAMES

Organ weight to terminal body weight (%) - Individual data

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Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

			Males				
Group No	Animal No	TBW (g)	Adrenal glands	Brain	Epididymides	Heart	Kidneys
3	A1474062	413.8	0.009	0.464	0.243	0.312	0.549
	A1474064	446.1	0.008	0.435	0.308	0.307	0.525
	A1474066	461.6	0.010	0.459	0.291	0.305	0.609
	A1474068	436.2	0.011	0.442	0.306	0.339	0.635
	A1474070	439.0	0.014	0.412	0.341	0.362	0.624
	A1474072	446.9	0.009	0.412	0.293	0.298	0.568
	A1474074	456.0	0.012	0.425	0.323	0.360	0.605
	A1474076	441.7	0.014	0.421	0.433	0.346	0.641
	A1474078	439.8	0.012	0.448	0.327	0.339	0.593
	A1474080	386.2	0.010	0.513	0.330	0.331	0.596
	(n)	10	10	10	10	10	10
	Mean	436.73	0.0109	0.4432	0.3194	0.3300	0.5944
	SD	21.857	0.00206	0.03048	0.04853	0.02323	0.03751

REDACTED AS TO TRADE NAMES

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

			Males			
Group No	Animal No	TBW (g)	Liver	Spleen	Thymus	Testes
3	A1474062	413.8	3.289	0.176	0.065	0.571
	A1474064	446.1	2.733	0.189	0.083	0.861
	A1474066	461.6	2.931	0.154	0.092	0.807
	A1474068	436.2	3.012	0.174	0.091	0.892
	A1474070	439.0	3.059	0.191	0.082	0.869
	A1474072	446.9	3.001	0.183	0.069	0.902
	A1474074	456.0	2.974	0.174	0.057	0.905
	A1474076	441.7	3.271	0.177	0.077	0.914
	A1474078	439.8	3.008	0.168	0.116	0.941
	A1474080	386.2	2.897	0.152	0.078	0.956
	(n)	10	10	10	10	10
	Mean	436.73	3.0176#C	0.1729	0.0809	0.8617
	SD	21.857	0.16510	0.01204	0.01656	0.11059

REDACTED AS TO TRADE NAMES

Organ weight to terminal body weight (%) - Individual data

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

			Males				
Group No	Animal No	TBW (g)	Adrenal glands	Brain	Epididymides	Heart	Kidneys
4	A1474092	450.4	0.012	0.444	0.357	0.320	0.635
	A1474094	440.6	0.011	0.440	0.320	0.334	0.688
	A1474096	431.6	0.009	0.431	0.325	0.304	0.614
	A1474098	455.2	0.010	0.453	0.295	0.272	0.576
	A1474100	491.8	0.009	0.401	0.293	0.344	0.604
	A1474102	438.7	0.015	0.438	0.298	0.299	0.613
	A1474104	413.1	0.012	0.460	0.326	0.358	0.634
	A1474106	448.5	0.010	0.421	0.315	0.305	0.622
	A1474108	455.6	0.008	0.419	0.347	0.325	0.568
	A1474110	400.2	0.010	0.480	0.340	0.342	0.625
	(n)	10	10	10	10	10	10
	Mean	442.57	0.0105	0.4386	0.3215	0.3202	0.6179
	SD	25.061	0.00200	0.02249	0.02204	0.02568	0.03327

REDACTED AS TO TRADE NAMES

Organ weight to terminal body weight (%) - Individual data

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Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

			Males			
Group No	Animal No	TBW (g)	Liver	Spleen	Thymus	Testes
4	A1474092	450.4	4.993	0.202	0.079	0.881
	A1474094	440.6	4.977	0.179	0.087	0.866
	A1474096	431.6	4.944	0.192	0.061	0.898
	A1474098	455.2	4.710	0.164	0.067	0.842
	A1474100	491.8	4.750	0.165	0.078	0.750
	A1474102	438.7	3.896	0.191	0.099	0.847
	A1474104	413.1	4.595	0.186	0.074	0.958
	A1474106	448.5	4.551	0.168	0.070	0.895
	A1474108	455.6	3.876	0.161	0.090	0.797
	A1474110	400.2	4.275	0.178	0.100	0.999
	(n)	10	10	10	10	10
	Mean	442.57	4.5567#C	0.1786	0.0806	0.8733
	SD	25.061	0.41626	0.01428	0.01323	0.07214

REDACTED AS TO TRADE NAMES

Organ weight to terminal body weight (%) - Individual data

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

			Females				
Group No	Animal No	TBW (g)	Adrenal glands	Brain	Heart	Kidneys	Liver
Control	A1474001	266.6	0.021	0.668	0.323	0.514	2.292
	A1474003	289.5	0.021	0.577	0.366	0.556	2.266
	A1474005	264.8	0.025	0.631	0.408	0.551	2.341
	A1474007	242.6	0.026	0.758	0.400	0.594	2.465
	A1474009	262.0	0.023	0.679	0.340	0.580	2.531
	A1474011	271.5	0.019	0.652	0.328	0.571	2.556
	A1474013	261.5	0.024	0.669	0.379	0.589	2.398
	A1474015	281.9	0.023	0.670	0.404	0.596	2.320
	A1474017	294.2	0.023	0.581	0.360	0.568	2.254
	A1474019	276.9	0.019	0.632	0.307	0.592	2.683
	(n)	10	10	10	10	10	10
	Mean	271.15	0.0225	0.6518	0.3614	0.5711	2.4105
	SD	15.165	0.00248	0.05215	0.03632	0.02554	0.14366

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

			Females			
Group No	Animal No	TBW (g)	Ovaries	Spleen	Thymus	Uterus
Control	A1474001	266.6	0.037	0.237	0.086	0.232
	A1474003	289.5	0.042	0.215	0.100	0.430
	A1474005	264.8	0.043	0.249	0.100	0.244
	A1474007	242.6	0.046	0.230	0.086	0.150
	A1474009	262.0	0.049	0.248	0.092	0.174
	A1474011	271.5	0.041	0.225	0.083	0.198
	A1474013	261.5	0.039	0.215	0.098	0.243
	A1474015	281.9	0.046	0.258	0.100	0.304
	A1474017	294.2	0.036	0.221	0.107	0.301
	A1474019	276.9	0.042	0.239	0.086	0.166
	(n)	10	10	10	10	10
	Mean	271.15	0.0421	0.2339	0.0939	0.2442
	SD	15.165	0.00414	0.01484	0.00840	0.08413

REDACTED AS TO TRADE NAMES

Organ weight to terminal body weight (%) - Individual data

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

			Females				
Group No	Animal No	TBW (g)	Adrenal glands	Brain	Heart	Kidneys	Liver
2	A1474031	267.1	0.020	0.678	0.359	0.678	2.741
	A1474033	276.9	0.023	0.703	0.311	0.592	2.391
	A1474035	277.0	0.022	0.675	0.386	0.599	2.347
	A1474037	295.1	0.023	0.627	0.366	0.583	2.270
	A1474039	264.9	0.020	0.657	0.321	0.536	2.390
	A1474041	268.7	0.028	0.662	0.435	0.640	2.773
	A1474043	273.4	0.021	0.655	0.315	0.604	2.184
	A1474045	263.2	0.022	0.627	0.357	0.528	2.215
	A1474047	249.3	0.022	0.658	0.401	0.598	2.391
	A1474049	264.4	0.023	0.635	0.363	0.533	2.341
	(n)	10	10	10	10	10	10
	Mean	270.00	0.0224	0.6582	0.3614	0.5891	2.4041
	SD	11.927	0.00226	0.02503	0.03964	0.04776	0.19974

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

			Females			
Group No	Animal No	TBW (g)	Ovaries	Spleen	Thymus	Uterus
2	A1474031	267.1	0.038	0.195	0.082	0.331
	A1474033	276.9	0.036	0.243	0.115	0.291
	A1474035	277.0	0.037	0.219	0.104	0.214
	A1474037	295.1	0.048	0.225	0.115	0.197
	A1474039	264.9	0.037	0.257	0.083	0.179
	A1474041	268.7	0.058	0.279	0.111	0.339
	A1474043	273.4	0.035	0.237	0.111	0.163
	A1474045	263.2	0.045	0.221	0.086	0.259
	A1474047	249.3	0.042	0.275	0.111	0.336
	A1474049	264.4	0.042	0.238	0.079	0.468
	(n)	10	10	10	10	10
	Mean	270.00	0.0417	0.2395	0.0995	0.2777
	SD	11.927	0.00720	0.02619	0.01516	0.09440

Organ weight to terminal body weight (%) - Individual data

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

			Females				
Group No	Animal No	TBW (g)	Adrenal glands	Brain	Heart	Kidneys	Liver
3	A1474061	263.9	0.020	0.728	0.356	0.625	2.539
	A1474063	272.5	0.018	0.693	0.301	0.517	2.385
	A1474065	288.7	0.018	0.592	0.371	0.544	2.501
	A1474067	258.6	0.019	0.665	0.356	0.588	2.533
	A1474069	262.0	0.026	0.679	0.336	0.588	2.416
	A1474071	242.3	0.026	0.739	0.376	0.640	2.509
	A1474073	260.2	0.022	0.646	0.319	0.573	2.344
	A1474075	275.2	0.020	0.647	0.374	0.600	2.558
	A1474077	280.8	0.019	0.648	0.420	0.524	2.390
	A1474079	270.4	0.020	0.643	0.325	0.595	2.256
	(n)	10	10	10	10	10	10
	Mean	267.46	0.0208	0.6585	0.3534	0.5793	2.4431
	SD	13.037	0.00294	0.04754	0.03453	0.04058	0.09994

Organ weight to terminal body weight (%) - Individual data

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

			Females			
Group No	Animal No	TBW (g)	Ovaries	Spleen	Thymus	Uterus
3	A1474061	263.9	0.050	0.254	0.103	0.253
	A1474063	272.5	0.044	0.171	0.102	0.184
	A1474065	288.7	0.044	0.243	0.102	0.212
	A1474067	258.6	0.046	0.244	0.092	0.165
	A1474069	262.0	0.048	0.219	0.116	0.465
	A1474071	242.3	0.036	0.244	0.114	0.354
	A1474073	260.2	0.042	0.243	0.107	0.330
	A1474075	275.2	0.040	0.213	0.100	0.186
	A1474077	280.8	0.047	0.212	0.102	0.484
	A1474079	270.4	0.043	0.218	0.077	0.147
	(n)	10	10	10	10	10
	Mean	267.46	0.0440	0.2260	0.1016	0.2780
	SD	13.037	0.00412	0.02471	0.01110	0.12378

REDACTED AS TO TRADE NAMES

Organ weight to terminal body weight (%) - Individual data

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Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

			Females				
Group No	Animal No	TBW (g)	Adrenal glands	Brain	Heart	Kidneys	Liver
4	A1474091	261.4	0.022	0.719	0.371	0.604	3.451
	A1474093	246.8	0.024	0.713	0.361	0.636	3.497
	A1474095	290.9	0.027	0.619	0.347	0.646	2.829
	A1474097	283.5	0.020	0.603	0.328	0.638	2.748
	A1474099	260.7	0.026	0.694	0.384	0.629	3.237
	A1474101	265.0	0.029	0.668	0.411	0.645	2.996
	A1474103	262.4	0.023	0.663	0.362	0.606	3.377
	A1474105	275.1	0.019	0.662	0.305	0.549	2.832
	A1474107	270.7	0.024	0.650	0.369	0.628	2.966
	A1474109	270.5	0.015	0.643	0.355	0.577	3.150
	(n)	10	10	10	10	10	10
	Mean	268.70	0.0228	0.6635	0.3594	0.6159	3.1082#C
	SD	12.518	0.00395	0.03766	0.02906	0.03211	0.27397

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Final sacrifice / Dosing

			Females			
Group No	Animal No	TBW (g)	Ovaries	Spleen	Thymus	Uterus
4	A1474091	261.4	0.042	0.223	0.070	0.248
	A1474093	246.8	0.042	0.229	0.096	0.194
	A1474095	290.9	0.047	0.262	0.089	0.725
	A1474097	283.5	0.037	0.218	0.070	0.205
	A1474099	260.7	0.034	0.216	0.102	0.333
	A1474101	265.0	0.053	0.238	0.095	0.374
	A1474103	262.4	0.043	0.253	0.089	0.390
	A1474105	275.1	0.041	0.210	0.088	0.303
	A1474107	270.7	0.050	0.233	0.125	0.542
	A1474109	270.5	0.034	0.206	0.083	0.155
	(n)	10	10	10	10	10
	Mean	268.70	0.0423	0.2288	0.0908	0.3469
	SD	12.518	0.00638	0.01835	0.01592	0.17498

REDACTED AS TO TRADE NAMES

Organ weight to terminal body weight (%) - Individual data

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

			Males				
Group No	Animal No	TBW (g)	Adrenal glands	Brain	Epididymides	Heart	Kidneys
Control	A1474022	476.3	0.009	0.416	0.254	0.340	0.575
	A1474024	431.3	0.008	0.441	0.315	0.308	0.633
	A1474026	468.0	0.011	0.410	0.299	0.340	0.669
	A1474028	471.4	0.009	0.420	0.269	0.331	0.685
	A1474030	446.8	0.009	0.425	0.322	0.320	0.571
	(n)	5	5	5	5	5	5
	Mean	458.76	0.0092	0.4224	0.2916	0.3278	0.6266
	SD	19.039	0.00109	0.01156	0.02952	0.01362	0.05247

REDACTED AS TO TRADE NAMES

Organ weight to terminal body weight (%) - Individual data

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

			Males			
Group No	Animal No	TBW (g)	Liver	Spleen	Thymus	Testes
Control	A1474022	476.3	2.320	0.140	0.055	0.803
	A1474024	431.3	2.249	0.164	0.042	0.865
	A1474026	468.0	2.699	0.193	0.060	0.889
	A1474028	471.4	2.480	0.175	0.064	0.862
	A1474030	446.8	2.205	0.184	0.066	0.934
	(n)	5	5	5	5	5
	Mean	458.76	2.3904	0.1711	0.0576	0.8705
	SD	19.039	0.20158	0.02046	0.00946	0.04753

REDACTED AS TO TRADE NAMES

Organ weight to terminal body weight (%) - Individual data

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Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

			Males				
Group No	Animal No	TBW (g)	Adrenal glands	Brain	Epididymides	Heart	Kidneys
2	A1474052	494.0	0.010	0.395	0.289	0.291	0.545
	A1474054	497.8	0.009	0.376	0.268	0.291	0.593
	A1474056	473.0	0.010	0.431	0.299	0.326	0.550
	A1474058	459.1	0.009	0.418	0.387	0.316	0.553
	A1474060	465.8	0.011	0.425	0.310	0.307	0.571
	(n)	5	5	5	5	5	5
	Mean	477.94	0.0098	0.4090	0.3108	0.3062	0.5622
	SD	17.169	0.00099	0.02321	0.04556	0.01506	0.01970

REDACTED AS TO TRADE NAMES

Organ weight to terminal body weight (%) - Individual data

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Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

			Males			
Group No	Animal No	TBW (g)	Liver	Spleen	Thymus	Testes
2	A1474052	494.0	2.334	0.184	0.050	0.748
	A1474054	497.8	2.523	0.166	0.053	0.754
	A1474056	473.0	2.271	0.182	0.051	0.839
	A1474058	459.1	2.507	0.173	0.068	0.985
	A1474060	465.8	2.383	0.172	0.051	0.871
	(n)	5	5	5	5	5
	Mean	477.94	2.4036	0.1754	0.0547	0.8394
	SD	17.169	0.10948	0.00765	0.00770	0.09736

Organ weight to terminal body weight (%) - Individual data

Printed: 06 Mar 2016 09:41:30
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

			Males				
Group No	Animal No	TBW (g)	Adrenal glands	Brain	Epididymides	Heart	Kidneys
3	A1474082	449.4	0.012	0.421	0.295	0.349	0.579
	A1474084	429.9	0.014	0.479	0.331	0.335	0.630
	A1474086	460.2	0.009	0.424	0.302	0.343	0.637
	A1474088	499.3	0.009	0.399	0.285	0.312	0.599
	A1474090	488.0	0.011	0.414	0.231	0.326	0.645
	(n)	5	5	5	5	5	5
	Mean	465.36	0.0109	0.4272	0.2886	0.3332	0.6180
	SD	28.299	0.00208	0.03064	0.03665	0.01460	0.02820

REDACTED AS TO TRADE NAMES

Organ weight to terminal body weight (%) - Individual data

Printed: 06 Mar 2016 09:41:30
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

			Males			
Group No	Animal No	TBW (g)	Liver	Spleen	Thymus	Testes
3	A1474082	449.4	2.423	0.158	0.059	0.921
	A1474084	429.9	2.563	0.161	0.074	0.889
	A1474086	460.2	2.658	0.195	0.057	0.879
	A1474088	499.3	2.690	0.171	0.057	0.742
	A1474090	488.0	2.439	0.177	0.057	0.316
	(n)	5	5	5	5	5
	Mean	465.36	2.5545	0.1724	0.0609	0.7496
	SD	28.299	0.12214	0.01479	0.00736	0.25166

REDACTED AS TO TRADE NAMES

Printed: 06 Mar 2016 09:41:30
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

			Males				
Group No	Animal No	TBW (g)	Adrenal glands	Brain	Epididymides	Heart	Kidneys
4	A1474112	495.3	0.009	0.402	0.291	0.291	0.644
	A1474114	482.5	0.011	0.403	0.316	0.330	0.667
	A1474116	477.4	0.010	0.385	0.270	0.297	0.532
	A1474118	429.6	0.009	0.445	0.338	0.342	0.673
	A1474120	471.4	0.012	0.403	0.298	0.342	0.613
	(n)	5	5	5	5	5	5
	Mean	471.24	0.0104	0.4086	0.3026	0.3203	0.6258
	SD	24.887	0.00131	0.02186	0.02564	0.02455	0.05747

REDACTED AS TO TRADE NAMES

Organ weight to terminal body weight (%) - Individual data

Printed: 06 Mar 2016 09:41:30
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

			Males			
Group No	Animal No	TBW (g)	Liver	Spleen	Thymus	Testes
4	A1474112	495.3	3.311	0.170	0.059	0.986
	A1474114	482.5	3.185	0.181	0.052	0.877
	A1474116	477.4	3.109	0.121	0.061	0.801
	A1474118	429.6	3.603	0.199	0.075	0.999
	A1474120	471.4	2.709	0.163	0.065	0.885
	(n)	5	5	5	5	5
	Mean	471.24	3.1835+D	0.1672	0.0623	0.9095
	SD	24.887	0.32534	0.02894	0.00851	0.08263

REDACTED AS TO TRADE NAMES

Organ weight to terminal body weight (%) - Individual data

Printed: 06 Mar 2016 09:41:30
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

Females

Group No	Animal No	TBW (g)	Adrenal glands	Brain	Heart	Kidneys	Liver
Control	A1474021	319.0	0.017	0.571	0.339	0.649	2.188
	A1474023	296.0	0.013	0.601	0.334	0.507	1.993
	A1474025	281.7	0.016	0.593	0.312	0.497	1.949
	A1474027	292.8	0.018	0.594	0.311	0.499	2.227
	A1474029	287.5	0.021	0.591	0.344	0.543	2.612
	(n)	5	5	5	5	5	5
	Mean	295.40	0.0169	0.5901	0.3281	0.5388	2.1938
	SD	14.267	0.00275	0.01157	0.01549	0.06428	0.26285

Organ weight to terminal body weight (%) - Individual data

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Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

			Females			
Group No	Animal No	TBW (g)	Ovaries	Spleen	Thymus	Uterus
Control	A1474021	319.0	0.038	0.222	0.075	0.186
	A1474023	296.0	0.041	0.221	0.082	0.166
	A1474025	281.7	0.032	0.193	0.096	0.192
	A1474027	292.8	0.032	0.196	0.070	0.147
	A1474029	287.5	0.035	0.206	0.073	0.238
	(n)	5	5	5	5	5
	Mean	295.40	0.0357	0.2076	0.0791	0.1857
	SD	14.267	0.00379	0.01369	0.01040	0.03388

REDACTED AS TO TRADE NAMES

Organ weight to terminal body weight (%) - Individual data

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Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

			Females				
Group No	Animal No	TBW (g)	Adrenal glands	Brain	Heart	Kidneys	Liver
2	A1474051	272.9	0.022	0.667	0.319	0.601	2.257
	A1474053	282.6	0.024	0.651	0.354	0.559	1.992
	A1474055	309.9	0.018	0.591	0.303	0.568	2.097
	A1474057	294.7	0.018	0.597	0.326	0.540	2.158
	A1474059	252.1	0.023	0.722	0.389	0.674	2.384
	(n)	5	5	5	5	5	5
	Mean	282.44	0.0210*D	0.6455	0.3381	0.5884	2.1778
	SD	21.886	0.00274	0.05405	0.03371	0.05294	0.15009

Organ weight to terminal body weight (%) - Individual data

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Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

			Females			
Group No	Animal No	TBW (g)	Ovaries	Spleen	Thymus	Uterus
2	A1474051	272.9	0.035	0.191	0.066	0.459
	A1474053	282.6	0.040	0.211	0.068	0.205
	A1474055	309.9	0.034	0.227	0.058	0.359
	A1474057	294.7	0.036	0.240	0.089	0.373
	A1474059	252.1	0.033	0.227	0.067	0.231
	(n)	5	5	5	5	5
	Mean	282.44	0.0355	0.2190	0.0697	0.3253*C
	SD	21.886	0.00298	0.01872	0.01144	0.10574

REDACTED AS TO TRADE NAMES

Organ weight to terminal body weight (%) - Individual data

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Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

			Females				
Group No	Animal No	TBW (g)	Adrenal glands	Brain	Heart	Kidneys	Liver
3	A1474081	287.5	0.021	0.588	0.317	0.588	2.351
	A1474083	288.7	0.021	0.617	0.360	0.589	2.359
	A1474085	290.1	0.019	0.624	0.300	0.591	2.403
	A1474087	282.8	0.021	0.636	0.361	0.594	2.291
	A1474089	266.1	0.020	0.680	0.395	0.601	2.172
	(n)	5	5	5	5	5	5
	Mean	283.04	0.0205*D	0.6289	0.3464	0.5926	2.3153
	SD	9.859	0.00094	0.03375	0.03799	0.00542	0.08929

REDACTED AS TO TRADE NAMES

Organ weight to terminal body weight (%) - Individual data

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Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

			Females			
Group No	Animal No	TBW (g)	Ovaries	Spleen	Thymus	Uterus
3	A1474081	287.5	0.032	0.183	0.097	0.241
	A1474083	288.7	0.040	0.247	0.079	0.278
	A1474085	290.1	0.040	0.215	0.069	0.253
	A1474087	282.8	0.058	0.237	0.057	0.303
	A1474089	266.1	0.040	0.218	0.080	0.268
	(n)	5	5	5	5	5
	Mean	283.04	0.0422	0.2198	0.0765	0.2686*C
	SD	9.859	0.00963	0.02463	0.01486	0.02359

REDACTED AS TO TRADE NAMES

Organ weight to terminal body weight (%) - Individual data

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Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

			Females				
Group No	Animal No	TBW (g)	Adrenal glands	Brain	Heart	Kidneys	Liver
4	A1474111	270.6	0.022	0.671	0.346	0.564	2.770
	A1474113	289.3	0.020	0.626	0.342	0.550	2.924
	A1474115	277.6	0.018	0.648	0.353	0.562	2.882
	A1474117	277.3	0.018	0.643	0.334	0.532	2.775
	A1474119	276.3	0.020	0.680	0.337	0.619	2.758
	(n)	5	5	5	5	5	5
	Mean	278.22	0.0196	0.6536+C	0.3425	0.5653	2.8219+D
	SD	6.814	0.00162	0.02203	0.00754	0.03267	0.07587

Organ weight to terminal body weight (%) - Individual data

Printed: 06 Mar 2016 09:41:30
Pristima® Version 6.3.2 Build 22

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Death Status: Recovery sacrifice / Recovery

			Females			
Group No	Animal No	TBW (g)	Ovaries	Spleen	Thymus	Uterus
4	A1474111	270.6	0.051	0.246	0.088	0.230
	A1474113	289.3	0.037	0.219	0.056	0.174
	A1474115	277.6	0.043	0.239	0.062	0.169
	A1474117	277.3	0.043	0.204	0.079	0.317
	A1474119	276.3	0.048	0.214	0.055	0.175
	(n)	5	5	5	5	5
	Mean	278.22	0.0445	0.2243	0.0679	0.2130
	SD	6.814	0.00545	0.01779	0.01479	0.06345

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474002	M	1	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Prostate gland		INFLAMMATORY CELL FOCI, Minimal, Multifocal /Comments: Interstitial
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

Adrenal glands	Aorta	Bone marrow	Brain	Bronchi
Caecum	Cervical nodes	Colon	Duodenum	Epididymides
Eyes	Femur with joint	Heart	Ileum	Jejunum
Kidneys	Larynx	Lungs	Mammary area	Mesenteric nodes
Nasopharynx	Oesophagus	Optic nerves	Pancreas	Parathyroid glands
Pituitary gland	Rectum	Salivary gland	Sciatic nerve	Seminal vesicles
Skeletal muscle	Skin	Spinal cord	Spleen	Stomach
Testes	Thymus	Thyroid gland	Trachea	Urinary bladder
GALT/PEYER'S PATCH				

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474004	M	1	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Aorta		INFLAMMATORY CELL FOCI , Minimal, Focal /Comments: Surrounding connective tissue
Kidneys		NEPHROPATHY, Minimal, Unilateral
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

Adrenal glands	Bone marrow	Brain	Bronchi	Caecum
Cervical nodes	Colon	Duodenum	Epididymides	Eyes
Femur with joint	Heart	Ileum	Jejunum	Larynx
Lungs	Mammary area	Mesenteric nodes	Nasopharynx	Oesophagus
Optic nerves	Pancreas	Parathyroid glands	Pituitary gland	Prostate gland
Rectum	Salivary gland	Sciatic nerve	Seminal vesicles	Skeletal muscle
Skin	Spinal cord	Spleen	Stomach	Testes
Thymus	Thyroid gland	Trachea	Urinary bladder	GALT/PEYER'S PATCH

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474006	M	1	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Kidneys		NEPHROPATHY, Minimal, Bilateral
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Stomach	Abnormal area(s), Single, Dark red, Depressed - 2x1mm, glandular region	Tissue is unremarkable

The following tissues were unremarkable microscopically:

Adrenal glands	Aorta	Bone marrow	Brain	Bronchi
Caecum	Cervical nodes	Colon	Duodenum	Epididymides
Eyes	Femur with joint	Heart	Ileum	Jejunum
Larynx	Lungs	Mammary area	Mesenteric nodes	Nasopharynx
Oesophagus	Optic nerves	Pancreas	Parathyroid glands	Pituitary gland
Prostate gland	Rectum	Salivary gland	Sciatic nerve	Seminal vesicles
Skeletal muscle	Skin	Spinal cord	Spleen	Testes
Thymus	Thyroid gland	Trachea	Urinary bladder	GALT/PEYER'S PATCH

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474008	M	1	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Heart		INFLAMMATORY CELL FOCI, Minimal, Focal /Comments: Myocardial
Kidneys		NEPHROPATHY, Mild, Bilateral
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

Adrenal glands	Aorta	Bone marrow	Brain	Bronchi
Caecum	Cervical nodes	Colon	Duodenum	Epididymides
Eyes	Femur with joint	Ileum	Jejunum	Larynx
Lungs	Mammary area	Mesenteric nodes	Nasopharynx	Oesophagus
Optic nerves	Pancreas	Parathyroid glands	Pituitary gland	Prostate gland
Rectum	Salivary gland	Sciatic nerve	Seminal vesicles	Skeletal muscle
Skin	Spinal cord	Spleen	Stomach	Testes
Thymus	Thyroid gland	Trachea	Urinary bladder	GALT/PEYER'S PATCH

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474010	M	1	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Heart		INFLAMMATORY CELL FOCI, Mild, Multifocal /Comments: Myocardial
Kidneys		NEPHROPATHY, Minimal, Bilateral
Liver		INFLAMMATORY CELL FOCI, Minimal, Focal
Lungs		MINERALIZATION, Minimal, Focal /Comments: Vascular
Pituitary gland		CYST/S, Minimal, Multifocal /Comments: Pars distalis
Prostate gland		INFLAMMATORY CELL FOCI, Mild, Multifocal /Comments: Interstitial
Whole animal	No abnormalities detected	

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474010	M	1	92	Dosing	Final sacrifice

The following tissues were unremarkable microscopically:

Adrenal glands	Aorta	Bone marrow	Brain	Bronchi
Caecum	Cervical nodes	Colon	Duodenum	Epididymides
Eyes	Femur with joint	Ileum	Jejunum	Larynx
Mammary area	Mesenteric nodes	Nasopharynx	Oesophagus	Optic nerves
Pancreas	Parathyroid glands	Rectum	Salivary gland	Sciatic nerve
Seminal vesicles	Skeletal muscle	Skin	Spinal cord	Spleen
Stomach	Testes	Thymus	Thyroid gland	Trachea
Urinary bladder	GALT/PEYER'S PATCH			

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474012	M	1	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Heart		INFLAMMATORY CELL FOCI, Minimal, Focal /Comments: Myocardial
Kidneys		NEPHROPATHY, Mild, Bilateral
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Lungs		MINERALIZATION, Minimal, Focal /Comments: Vascular
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

Adrenal glands	Aorta	Bone marrow	Brain	Bronchi
Caecum	Cervical nodes	Colon	Duodenum	Epididymides
Eyes	Femur with joint	Ileum	Jejunum	Larynx
Mammary area	Mesenteric nodes	Nasopharynx	Oesophagus	Optic nerves
Pancreas	Parathyroid glands	Pituitary gland	Prostate gland	Rectum
Salivary gland	Sciatic nerve	Seminal vesicles	Skeletal muscle	Skin
Spinal cord	Spleen	Stomach	Testes	Thymus
Thyroid gland	Trachea	Urinary bladder	GALT/PEYER'S PATCH	

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474014	M	1	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Heart		INFLAMMATORY CELL FOCI, Minimal, Focal /Comments: Myocardial
Kidneys		NEPHROPATHY, Minimal, Bilateral
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Parathyroid glands		Missing
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

Adrenal glands	Aorta	Bone marrow	Brain	Bronchi
Caecum	Cervical nodes	Colon	Duodenum	Epididymides
Eyes	Femur with joint	Ileum	Jejunum	Larynx
Lungs	Mammary area	Mesenteric nodes	Nasopharynx	Oesophagus
Optic nerves	Pancreas	Pituitary gland	Prostate gland	Rectum
Salivary gland	Sciatic nerve	Seminal vesicles	Skeletal muscle	Skin
Spinal cord	Spleen	Stomach	Testes	Thymus
Thyroid gland	Trachea	Urinary bladder	GALT/PEYER'S PATCH	

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474016	M	1	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Kidneys		NEPHROPATHY, Minimal, Bilateral
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Lungs		MINERALIZATION, Minimal, Focal /Comments: Vascular
Thymus	Abnormal colour, Dark	Tissue is unremarkable
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

Adrenal glands	Aorta	Bone marrow	Brain	Bronchi
Caecum	Cervical nodes	Colon	Duodenum	Epididymides
Eyes	Femur with joint	Heart	Ileum	Jejunum
Larynx	Mammary area	Mesenteric nodes	Nasopharynx	Oesophagus
Optic nerves	Pancreas	Parathyroid glands	Pituitary gland	Prostate gland
Rectum	Salivary gland	Sciatic nerve	Seminal vesicles	Skeletal muscle
Skin	Spinal cord	Spleen	Stomach	Testes
Thyroid gland	Trachea	Urinary bladder	GALT/PEYER'S PATCH	

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474018	M	1	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Heart		INFLAMMATORY CELL FOCI, Minimal, Focal /Comments: Myocardial
Kidneys		NEPHROPATHY, Minimal, Bilateral
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Lungs		MINERALIZATION, Minimal, Focal /Comments: Vascular INFLAMMATORY CELL FOCI, Minimal, Multifocal /Comments: Perivascular/interstistial
Prostate gland		INFLAMMATORY CELL FOCI, Minimal, Multifocal /Comments: Interstitial
Spleen	Abnormal shape, Swollen	Tissue is unremarkable
GALT/PEYER'S PATCH		LYMPHOID HYPERPLASIA, Mild

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474018	M	1	92	Dosing	Final sacrifice

The following tissues were unremarkable microscopically:

Adrenal glands	Aorta	Bone marrow	Brain	Bronchi
Caecum	Cervical nodes	Colon	Duodenum	Epididymides
Eyes	Femur with joint	Ileum	Jejunum	Larynx
Mammary area	Mesenteric nodes	Nasopharynx	Oesophagus	Optic nerves
Pancreas	Parathyroid glands	Pituitary gland	Rectum	Salivary gland
Sciatic nerve	Seminal vesicles	Skeletal muscle	Skin	Spinal cord
Stomach	Testes	Thymus	Thyroid gland	Trachea
Urinary bladder				

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474020	M	1	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Kidneys		NEPHROPATHY, Minimal, Bilateral
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Lungs		MINERALIZATION, Minimal, Focal INFLAMMATORY CELL FOCI, Minimal, Multifocal /Comments: Perivascular/interstistial
Optic nerves		Both Missing
GALT/PEYER'S PATCH		LYMPHOID HYPERPLASIA, Mild
Whole animal	No abnormalities detected	

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474020	M	1	92	Dosing	Final sacrifice

The following tissues were unremarkable microscopically:

Adrenal glands	Aorta	Bone marrow	Brain	Bronchi
Caecum	Cervical nodes	Colon	Duodenum	Epididymides
Eyes	Femur with joint	Heart	Ileum	Jejunum
Larynx	Mammary area	Mesenteric nodes	Nasopharynx	Oesophagus
Pancreas	Parathyroid glands	Pituitary gland	Prostate gland	Rectum
Salivary gland	Sciatic nerve	Seminal vesicles	Skeletal muscle	Skin
Spinal cord	Spleen	Stomach	Testes	Thymus
Thyroid gland	Trachea	Urinary bladder		

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474022	M	1	57	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

Liver Pituitary gland Thyroid gland

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474024	M	1	57	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		
		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Thymus		
	Abnormal size, Small	

The following tissues were unremarkable microscopically:

Pituitary gland Thyroid gland

GLP - DRAFT - Test Facility Only

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474026	M	1	57	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Kidneys		
	Pelvic dilatation, Minimal - right	
Liver		
		INFLAMMATORY CELL FOCI, Minimal, Multifocal

The following tissues were unremarkable microscopically:

Pituitary gland Thyroid gland

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474028	M	1	57	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:
Pituitary gland Thyroid gland

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474030	M	1	57	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

Pituitary gland Thyroid gland

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474032	M	2	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:
Pituitary gland Thyroid gland

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474034	M	2	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal HEPATOCYTIC VACUOLATION, Minimal, Multifocal /Comments: Fatty change like (micro and macrovescicular)
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

Pituitary gland Thyroid gland

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474036	M	2	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal HEPATOCYTIC VACUOLATION, Minimal, Multifocal /Comments: Fatty change like (micro and macrovesicular)
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

Pituitary gland Thyroid gland

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474038	M	2	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal HEPATOCYTIC VACUOLATION, Minimal, Multifocal /Comments: Fatty change like (micro and macrovescicular)
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

Pituitary gland Thyroid gland

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474040	M	2	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Cervical nodes	Abnormal colour, Single, Dark	Tissue is unremarkable
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal HEPATOCYTIC VACUOLATION, Minimal, Multifocal /Comments: Fatty change like (micro and macrovescicular)

The following tissues were unremarkable microscopically:
Pituitary gland Thyroid gland

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474042	M	2	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal HEPATOCYTIC VACUOLATION, Mild, Multifocal /Comments: Fatty change like (micro and macrovescicular)
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

Pituitary gland Thyroid gland

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474044	M	2	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal HEPATOCYTIC VACUOLATION, Minimal, Multifocal /Comments: Fatty change like (micro and macrovescicular)
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

Pituitary gland Thyroid gland

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474046	M	2	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal HEPATOCYTIC VACUOLATION, Minimal, Multifocal /Comments: Fatty change like (micro and macrovesicular)
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

Pituitary gland Thyroid gland

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474048	M	2	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal HEPATOCYTIC VACUOLATION, Minimal, Multifocal /Comments: Fatty change like (micro and macrovesicular)
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

Pituitary gland Thyroid gland

GLP - DRAFT - Not Quality Assured

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474050	M	2	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal HEPATOCYTIC VACUOLATION, Minimal, Multifocal /Comments: Fatty change like (micro and macrovescicular)
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

Pituitary gland Thyroid gland

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474052	M	2	57	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal HEPATOCYTIC VACUOLATION, Mild, Multifocal /Comments: Fatty change like (micro and macrovescicular)
Pituitary gland		CYST/S, Minimal, Focal /Comments: Pars intermedia
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

Thyroid gland

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474054	M	2	57	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal HEPATOCYTIC VACUOLATION, Minimal, Multifocal /Comments: Fatty change like (micro and macrovescicular)
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

Pituitary gland Thyroid gland

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474056	M	2	57	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Kidneys	Abnormal area(s), Single, Depressed - 3x1mm, right	
Liver		INFLAMMATORY CELL FOCI, Mild, Multifocal HEPATOCYTIC VACUOLATION, Minimal, Multifocal /Comments: Fatty change like (micro and macrovesicular)

The following tissues were unremarkable microscopically:
Pituitary gland Thyroid gland

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474058	M	2	57	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:
Pituitary gland Thyroid gland

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474060	M	2	57	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal HEPATOCYTIC VACUOLATION, Minimal, Multifocal /Comments: Fatty change like (micro and macrovesicular)
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:
Pituitary gland Thyroid gland

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474062	M	3	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal Hepatocytic hypertrophy, Minimal, Multifocal /Comments: Centrilobular, hepatocytes with cytoplasmatic eosinophilia HEPATOCYTIC VACUOLATION, Minimal, Multifocal /Comments: Fatty change like (micro and macrovescicular)
Pituitary gland		CYST/S, Minimal, Focal /Comments: Pars distalis
Stomach	Abnormal area(s), Two, Dark - up to 2x1mm, glandular region	Tissue is unremarkable
Thyroid gland		FOLLICULAR HYPERTROPHY, Minimal

The following tissues were unremarkable microscopically:

No Tissues to list

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474064	M	3	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal Hepatocytic hypertrophy, Minimal, Diffuse /Comments: Centrilobular, hepatocytes with cytoplasmatic eosinophilia HEPATOCYTIC VACUOLATION, Minimal, Multifocal /Comments: Fatty change like (micro and macrovescicular)
Thyroid gland		FOLLICULAR HYPERTROPHY, Minimal
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

Pituitary gland

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474066	M	3	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal Hepatocytic hypertrophy, Minimal, Multifocal /Comments: Centrilobular, hepatocytes with cytoplasmatic eosinophilia HEPATOCYTIC VACUOLATION, Minimal, Multifocal /Comments: Fatty change like (mainly macrovescicular)
Thyroid gland		FOLLICULAR HYPERTROPHY, Minimal
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:
Pituitary gland

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474068	M	3	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal Hepatocytic hypertrophy, Minimal, Multifocal /Comments: Centrilobular, hepatocytes with cytoplasmatic eosinophilia
Thyroid gland		FOLLICULAR HYPERTROPHY, Minimal
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

Pituitary gland

DRAFT - Not Official Until 2016

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474070	M	3	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal Hepatocytic hypertrophy, Minimal, Multifocal /Comments: Centrilobular, hepatocytes with cytoplasmatic eosinophilia HEPATOCYTIC VACUOLATION, Mild, Multifocal /Comments: Fatty change like (micro and macrovescicular)
Thyroid gland		FOLLICULAR HYPERTROPHY, Minimal
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:
Pituitary gland

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474072	M	3	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal Hepatocytic hypertrophy, Minimal, Multifocal /Comments: Centrilobular, hepatocytes with cytoplasmatic eosinophilia HEPATOCYTIC VACUOLATION, Minimal, Multifocal /Comments: Fatty change like (micro and macrovescicular)
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

Pituitary gland Thyroid gland

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474074	M	3	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal Hepatocytic hypertrophy, Minimal, Multifocal /Comments: Centrilobular, hepatocytes with cytoplasmatic eosinophilia
Thyroid gland		FOLLICULAR HYPERTROPHY, Minimal
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:
Pituitary gland

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474076	M	3	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver	Abnormal shape, Swollen	INFLAMMATORY CELL FOCI, Minimal, Multifocal /Comments: Centrilobular Hepatocytic hypertrophy, Mild, Multifocal /Comments: Centrilobular, hepatocytes with cytoplasmatic eosinophilia
Thyroid gland		FOLLICULAR HYPERTROPHY, Minimal

The following tissues were unremarkable microscopically:
Pituitary gland

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474078	M	3	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver	Abnormal shape, Swollen	INFLAMMATORY CELL FOCI, Minimal, Multifocal Hepatocytic hypertrophy, Mild, Multifocal /Comments: Centrilobular, hepatocytes with cytoplasmatic eosinophilia
Thyroid gland		FOLLICULAR HYPERTROPHY, Minimal

The following tissues were unremarkable microscopically:
Pituitary gland

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474080	M	3	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal Hepatocytic hypertrophy, Minimal, Multifocal /Comments: Centrilobular, hepatocytes with cytoplasmatic eosinophilia HEPATOCYTIC VACUOLATION, Minimal, Multifocal /Comments: Fatty change like (micro and macrovescicular)
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

Pituitary gland Thyroid gland

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474082	M	3	57	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal HEPATOCYTIC VACUOLATION, Minimal, Multifocal /Comments: Fatty change like (micro and macrovescicular)
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

Pituitary gland Thyroid gland

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474084	M	3	57	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:
Pituitary gland Thyroid gland

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474086	M	3	57	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Mild, Multifocal
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

Pituitary gland Thyroid gland

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474088	M	3	57	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Mild, Multifocal HEPATOCYTIC VACUOLATION, Mild, Multifocal /Comments: Fatty change like (micro and macrovescicular)
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

Pituitary gland Thyroid gland

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474090	M	3	57	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal HEPATOCYTIC VACUOLATION, Minimal, Multifocal /Comments: Fatty change like (micro and macrovesicular)
Testes	Abnormal size, Small - up to 16x11x10mm Abnormal consistency, Flaccid	

The following tissues were unremarkable microscopically:

Pituitary gland Thyroid gland

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474092	M	4	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Kidneys		NEPHROPATHY, Minimal, Unilateral
Liver	Abnormal shape, Swollen Abnormal size, Enlarged	INFLAMMATORY CELL FOCI, Minimal, Multifocal /Comments: Centrilobular Hepatocytic hypertrophy, Mild, Multifocal /Comments: Centrilobular, hepatocytes with cytoplasmatic eosinophilia
Lungs		INFLAMMATORY CELL FOCI, Minimal, Focal /Comments: Perivascular/Interstistial
Pituitary gland		BASOPHILIC CELL HYPERTROPHY, Mild /Comments: Pars distalis, like TSH secreting cells
Seminal vesicles		COLLOID DEPLETION, Mild, Bilateral
Thyroid gland		FOLLICULAR HYPERTROPHY, Mild

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474092	M	4	92	Dosing	Final sacrifice

The following tissues were unremarkable microscopically:

Adrenal glands	Aorta	Bone marrow	Brain	Bronchi
Caecum	Cervical nodes	Colon	Duodenum	Epididymides
Eyes	Femur with joint	Heart	Ileum	Jejunum
Larynx	Mammary area	Mesenteric nodes	Nasopharynx	Oesophagus
Optic nerves	Pancreas	Parathyroid glands	Prostate gland	Rectum
Salivary gland	Sciatic nerve	Skeletal muscle	Skin	Spinal cord
Spleen	Stomach	Testes	Thymus	Trachea
Urinary bladder	GALT/PEYER'S PATCH			

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474094	M	4	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Kidneys		NEPHROPATHY, Minimal, Bilateral
Liver	Abnormal shape, Swollen Abnormal size, Enlarged	Hepatocytic hypertrophy, Mild, Multifocal /Comments: Centrilobular/midzonal, hepatocytes with cytoplasmatic eosinophilia INFLAMMATORY CELL FOCI, Minimal, Multifocal
Lungs		MINERALIZATION, Minimal, Focal /Comments: Vascular
Pituitary gland		BASOPHILIC CELL HYPERTROPHY, Mild /Comments: Pars distalis, like TSH secreting cells
Prostate gland		INFLAMMATORY CELL FOCI, Minimal, Multifocal /Comments: Interstitial
Thyroid gland		FOLLICULAR HYPERTROPHY, Mild

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474094	M	4	92	Dosing	Final sacrifice

The following tissues were unremarkable microscopically:

Adrenal glands	Aorta	Bone marrow	Brain	Bronchi
Caecum	Cervical nodes	Colon	Duodenum	Epididymides
Eyes	Femur with joint	Heart	Ileum	Jejunum
Larynx	Mammary area	Mesenteric nodes	Nasopharynx	Oesophagus
Optic nerves	Pancreas	Parathyroid glands	Rectum	Salivary gland
Sciatic nerve	Seminal vesicles	Skeletal muscle	Skin	Spinal cord
Spleen	Stomach	Testes	Thymus	Trachea
Urinary bladder	GALT/PEYER'S PATCH			

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474096	M	4	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Heart		INFLAMMATORY CELL FOCI, Minimal, Focal /Comments: Perivascular
Kidneys		NEPHROPATHY, Mild, Bilateral
Liver	Abnormal shape, Swollen Abnormal size, Enlarged	Hepatocytic hypertrophy, Minimal, Multifocal /Comments: Centrilobular/midzonal, hepatocytes with cytoplasmatic eosinophilia INFLAMMATORY CELL FOCI, Minimal, Multifocal
Lungs		MINERALIZATION, Minimal, Focal /Comments: Vascular ALVEOLAR MACROPHAGE AGGREGATION, Minimal, Multifocal
Pituitary gland		BASOPHILIC CELL HYPERTROPHY, Mild /Comments: Pars distalis, like TSH secreting cells
Thyroid gland		FOLLICULAR HYPERTROPHY, Minimal
GALT/PEYER'S PATCH		LYMPHOID HYPERPLASIA, Minimal

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474096	M	4	92	Dosing	Final sacrifice

The following tissues were unremarkable microscopically:

Adrenal glands	Aorta	Bone marrow	Brain	Bronchi
Caecum	Cervical nodes	Colon	Duodenum	Epididymides
Eyes	Femur with joint	Ileum	Jejunum	Larynx
Mammary area	Mesenteric nodes	Nasopharynx	Oesophagus	Optic nerves
Pancreas	Parathyroid glands	Prostate gland	Rectum	Salivary gland
Sciatic nerve	Seminal vesicles	Skeletal muscle	Skin	Spinal cord
Spleen	Stomach	Testes	Thymus	Trachea
Urinary bladder				

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474098	M	4	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Adrenal glands		CORTICAL VACUOLATION, Mild, Bilateral
Kidneys		NEPHROPATHY, Minimal, Unilateral
Liver	Abnormal shape, Swollen	Hepatocytic hypertrophy, Mild, Multifocal /Comments: Centrilobular/midzonal, hepatocytes with cytoplasmatic eosinophilia INFLAMMATORY CELL FOCI, Minimal, Multifocal
Pituitary gland		BASOPHILIC CELL HYPERTROPHY, Mild /Comments: Pars distalis, like TSH secreting cells
Thyroid gland		FOLLICULAR HYPERTROPHY, Mild

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474098	M	4	92	Dosing	Final sacrifice

The following tissues were unremarkable microscopically:

Aorta	Bone marrow	Brain	Bronchi	Caecum
Cervical nodes	Colon	Duodenum	Epididymides	Eyes
Femur with joint	Heart	Ileum	Jejunum	Larynx
Lungs	Mammary area	Mesenteric nodes	Nasopharynx	Oesophagus
Optic nerves	Pancreas	Parathyroid glands	Prostate gland	Rectum
Salivary gland	Sciatic nerve	Seminal vesicles	Skeletal muscle	Skin
Spinal cord	Spleen	Stomach	Testes	Thymus
Trachea	Urinary bladder	GALT/PEYER'S PATCH		

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474100	M	4	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Kidneys		NEPHROPATHY, Minimal, Bilateral
Liver	Abnormal shape, Swollen Abnormal size, Enlarged	Hepatocytic hypertrophy, Mild, Multifocal /Comments: Panlobular, hepatocytes with cytoplasmatic eosinophilia INFLAMMATORY CELL FOCI, Minimal, Multifocal
Lungs		HAEMORRHAGE, Minimal, Multifocal /Comments: Alveolar
Pituitary gland		BASOPHILIC CELL HYPERTROPHY, Mild /Comments: Pars distalis, like TSH secreting cells
Prostate gland		INFLAMMATORY CELL FOCI, Minimal, Focal /Comments: Interstitial
Thyroid gland		FOLLICULAR HYPERTROPHY, Mild

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474100	M	4	92	Dosing	Final sacrifice

The following tissues were unremarkable microscopically:

Adrenal glands	Aorta	Bone marrow	Brain	Bronchi
Caecum	Cervical nodes	Colon	Duodenum	Epididymides
Eyes	Femur with joint	Heart	Ileum	Jejunum
Larynx	Mammary area	Mesenteric nodes	Nasopharynx	Oesophagus
Optic nerves	Pancreas	Parathyroid glands	Rectum	Salivary gland
Sciatic nerve	Seminal vesicles	Skeletal muscle	Skin	Spinal cord
Spleen	Stomach	Testes	Thymus	Trachea
Urinary bladder	GALT/PEYER'S PATCH			

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474102	M	4	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Heart		INFLAMMATORY CELL FOCI, Minimal, Focal /Comments: Myocardial
Liver	Abnormal shape, Swollen Abnormal size, Enlarged	Hepatocytic hypertrophy, Minimal, Multifocal /Comments: Panlobular, hepatocytes with cytoplasmatic eosinophilia INFLAMMATORY CELL FOCI, Minimal, Multifocal
Pituitary gland		BASOPHILIC CELL HYPERTROPHY, Mild /Comments: Pars distalis, like TSH secreting cells
Seminal vesicles		COLLOID DEPLETION, Mild, Bilateral
Thyroid gland		FOLLICULAR HYPERTROPHY, Mild

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474102	M	4	92	Dosing	Final sacrifice

The following tissues were unremarkable microscopically:

Adrenal glands	Aorta	Bone marrow	Brain	Bronchi
Caecum	Cervical nodes	Colon	Duodenum	Epididymides
Eyes	Femur with joint	Ileum	Jejunum	Kidneys
Larynx	Lungs	Mammary area	Mesenteric nodes	Nasopharynx
Oesophagus	Optic nerves	Pancreas	Parathyroid glands	Prostate gland
Rectum	Salivary gland	Sciatic nerve	Skeletal muscle	Skin
Spinal cord	Spleen	Stomach	Testes	Thymus
Trachea	Urinary bladder	GALT/PEYER'S PATCH		

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474104	M	4	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver	Abnormal size, Enlarged	INFLAMMATORY CELL FOCI, Minimal, Multifocal Hepatocytic hypertrophy, Mild, Diffuse /Comments: Centrilobular/midzonal, hepatocytes with cytoplasmatic eosinophilia
Lungs		MINERALIZATION, Mild, Focal /Comments: Vascular
Pituitary gland		BASOPHILIC CELL HYPERTROPHY, Mild /Comments: Pars distalis, like TSH secreting cells
Thyroid gland		FOLLICULAR HYPERTROPHY, Mild

The following tissues were unremarkable microscopically:

Adrenal glands	Aorta	Bone marrow	Brain	Bronchi
Caecum	Cervical nodes	Colon	Duodenum	Epididymides
Eyes	Femur with joint	Heart	Ileum	Jejunum
Kidneys	Larynx	Mammary area	Mesenteric nodes	Nasopharynx
Oesophagus	Optic nerves	Pancreas	Parathyroid glands	Prostate gland
Rectum	Salivary gland	Sciatic nerve	Seminal vesicles	Skeletal muscle
Skin	Spinal cord	Spleen	Stomach	Testes
Thymus	Trachea	Urinary bladder	GALT/PEYER'S PATCH	

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474106	M	4	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Heart		INFLAMMATORY CELL FOCI, Minimal, Focal /Comments: Myocardial
Liver	Abnormal shape, Swollen	INFLAMMATORY CELL FOCI, Mild, Multifocal Hepatocytic hypertrophy, Mild, Diffuse /Comments: Panlobular, hepatocytes with cytoplasmatic eosinophilia HEPATOCYTIC NECROSIS, Minimal, Focal
Pituitary gland		BASOPHILIC CELL HYPERTROPHY, Mild /Comments: Pars distalis, like TSH secreting cells
Thyroid gland		FOLLICULAR HYPERTROPHY, Mild

The following tissues were unremarkable microscopically:

Adrenal glands	Aorta	Bone marrow	Brain	Bronchi
Caecum	Cervical nodes	Colon	Duodenum	Epididymides
Eyes	Femur with joint	Ileum	Jejunum	Kidneys
Larynx	Lungs	Mammary area	Mesenteric nodes	Nasopharynx
Oesophagus	Optic nerves	Pancreas	Parathyroid glands	Prostate gland
Rectum	Salivary gland	Sciatic nerve	Seminal vesicles	Skeletal muscle
Skin	Spinal cord	Spleen	Stomach	Testes
Thymus	Trachea	Urinary bladder	GALT/PEYER'S PATCH	

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474108	M	4	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Kidneys		NEPHROPATHY, Mild, Bilateral
Liver	Abnormal shape, Swollen	Hepatocytic hypertrophy, Mild, Diffuse /Comments: Panlobular, hepatocytes with cytoplasmatic eosinophilia
Lungs		HAEMORRHAGE, Minimal, Focal /Comments: Alveolar
Pituitary gland		BASOPHILIC CELL HYPERTROPHY, Mild /Comments: Pars distalis, like TSH secreting cells
Prostate gland		INFLAMMATORY CELL FOCI, Minimal, Focal /Comments: Interstitial
Thyroid gland		FOLLICULAR HYPERTROPHY, Mild

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474108	M	4	92	Dosing	Final sacrifice

The following tissues were unremarkable microscopically:

Adrenal glands	Aorta	Bone marrow	Brain	Bronchi
Caecum	Cervical nodes	Colon	Duodenum	Epididymides
Eyes	Femur with joint	Heart	Ileum	Jejunum
Larynx	Mammary area	Mesenteric nodes	Nasopharynx	Oesophagus
Optic nerves	Pancreas	Parathyroid glands	Rectum	Salivary gland
Sciatic nerve	Seminal vesicles	Skeletal muscle	Skin	Spinal cord
Spleen	Stomach	Testes	Thymus	Trachea
Urinary bladder	GALT/PEYER'S PATCH			

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474110	M	4	92	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Heart		INFLAMMATORY CELL FOCI, Minimal, Focal /Comments: Myocardial
Liver	Abnormal shape, Swollen	INFLAMMATORY CELL FOCI, Minimal, Multifocal Hepatocytic hypertrophy, Mild, Multifocal /Comments: Panlobular, hepatocytes with cytoplasmatic eosinophilia HEPATOCYTIC NECROSIS, Mild, Multifocal CLEAR CELL FOCUS/I, Minimal, Focal
Pituitary gland		BASOPHILIC CELL HYPERTROPHY, Mild /Comments: Pars distalis, like TSH secreting cells
Seminal vesicles		COLLOID DEPLETION, Mild, Unilateral
Thyroid gland		FOLLICULAR HYPERTROPHY, Minimal

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474110	M	4	92	Dosing	Final sacrifice

The following tissues were unremarkable microscopically:

Adrenal glands	Aorta	Bone marrow	Brain	Bronchi
Caecum	Cervical nodes	Colon	Duodenum	Epididymides
Eyes	Femur with joint	Ileum	Jejunum	Kidneys
Larynx	Lungs	Mammary area	Mesenteric nodes	Nasopharynx
Oesophagus	Optic nerves	Pancreas	Parathyroid glands	Prostate gland
Rectum	Salivary gland	Sciatic nerve	Skeletal muscle	Skin
Spinal cord	Spleen	Stomach	Testes	Thymus
Trachea	Urinary bladder	GALT/PEYER'S PATCH		

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474112	M	4	57	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal Hepatocytic hypertrophy, Minimal, Multifocal /Comments: Centrilobular, hepatocytes with cytoplasmatic eosinophilia
Pituitary gland		BASOPHILIC CELL HYPERTROPHY, Mild /Comments: Pars distalis, like TSH secreting cells
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

Thyroid gland

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474114	M	4	57	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal HEPATOCYTIC NECROSIS, Minimal, Multifocal HEPATOCYTIC VACUOLATION, Mild, Multifocal /Comments: Fatty change like (micro and macrovesicular)
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

Pituitary gland Thyroid gland

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474116	M	4	57	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal Hepatocytic hypertrophy, Minimal, Multifocal /Comments: Centrilobular, hepatocytes with cytoplasmatic eosinophilia HEPATOCYTIC VACUOLATION, Minimal, Multifocal /Comments: Fatty change like (micro and macrovescicular)
Thyroid gland		FOLLICULAR HYPERTROPHY, Minimal
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

Pituitary gland

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474118	M	4	57	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Mild, Multifocal HEPATOCYTIC NECROSIS, Mild, Multifocal Hepatocytic hypertrophy, Minimal, Multifocal /Comments: Centrilobular, hepatocytes with cytoplasmatic eosinophilia
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

Pituitary gland Thyroid gland

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474120	M	4	57	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal Hepatocytic hypertrophy, Minimal, Multifocal /Comments: Centrilobular, hepatocytes with cytoplasmatic eosinophilia HEPATOCYTIC VACUOLATION, Mild, Multifocal /Comments: Fatty change like (micro and macrovescicular)
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

Pituitary gland Thyroid gland

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474001	F	1	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Kidneys		MINERALIZATION, Minimal, Bilateral /Comments: Cortico-medullary junction
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Uterus	Abnormal size, Distended - 3mm diam Abnormal contents, Clear, Fluid	Tissue is unremarkable

The following tissues were unremarkable microscopically:

Adrenal glands	Aorta	Bone marrow	Brain	Bronchi
Caecum	Cervical nodes	Cervix	Colon	Duodenum
Eyes	Femur with joint	Heart	Ileum	Jejunum
Larynx	Lungs	Mammary area	Mesenteric nodes	Nasopharynx
Oesophagus	Optic nerves	Ovaries	Oviducts	Pancreas
Parathyroid glands	Pituitary gland	Rectum	Salivary gland	Sciatic nerve
Skeletal muscle	Skin	Spinal cord	Spleen	Stomach
Thymus	Thyroid gland	Trachea	Urinary bladder	Vagina
GALT/PEYER'S PATCH				

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474003	F	1	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Kidneys		NEPHROPATHY, Minimal, Unilateral
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Thyroid gland		ECTOPIC THYMUS, Minimal
Uterus	Abnormal size, Distended - 5mm diam Abnormal contents, Clear, Fluid	DILATION, LUMEN, Mild

The following tissues were unremarkable microscopically:

Adrenal glands	Aorta	Bone marrow	Brain	Bronchi
Caecum	Cervical nodes	Cervix	Colon	Duodenum
Eyes	Femur with joint	Heart	Ileum	Jejunum
Larynx	Lungs	Mammary area	Mesenteric nodes	Nasopharynx
Oesophagus	Optic nerves	Ovaries	Oviducts	Pancreas
Parathyroid glands	Pituitary gland	Rectum	Salivary gland	Sciatic nerve
Skeletal muscle	Skin	Spinal cord	Spleen	Stomach
Thymus	Trachea	Urinary bladder	Vagina	GALT/PEYER'S PATCH

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474005	F	1	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Lungs		ALVEOLAR MACROPHAGE AGGREGATION, Mild, Multifocal
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

Adrenal glands	Aorta	Bone marrow	Brain	Bronchi
Caecum	Cervical nodes	Cervix	Colon	Duodenum
Eyes	Femur with joint	Heart	Ileum	Jejunum
Kidneys	Larynx	Mammary area	Mesenteric nodes	Nasopharynx
Oesophagus	Optic nerves	Ovaries	Oviducts	Pancreas
Parathyroid glands	Pituitary gland	Rectum	Salivary gland	Sciatic nerve
Skeletal muscle	Skin	Spinal cord	Spleen	Stomach
Thymus	Thyroid gland	Trachea	Urinary bladder	Uterus
Vagina	GALT/PEYER'S PATCH			

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474007	F	1	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Optic nerves		Both Missing
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

Adrenal glands	Aorta	Bone marrow	Brain	Bronchi
Caecum	Cervical nodes	Cervix	Colon	Duodenum
Eyes	Femur with joint	Heart	Ileum	Jejunum
Kidneys	Larynx	Lungs	Mammary area	Mesenteric nodes
Nasopharynx	Oesophagus	Ovaries	Oviducts	Pancreas
Parathyroid glands	Pituitary gland	Rectum	Salivary gland	Sciatic nerve
Skeletal muscle	Skin	Spinal cord	Spleen	Stomach
Thymus	Thyroid gland	Trachea	Urinary bladder	Uterus
Vagina	GALT/PEYER'S PATCH			

DRAFT - NOT FOR SIGNATURE

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474009	F	1	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		
		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Ovaries		
	Abnormal size, Enlarged - up to 5mm diam	
		Tissue is unremarkable

The following tissues were unremarkable microscopically:

Adrenal glands	Aorta	Bone marrow	Brain	Bronchi
Caecum	Cervical nodes	Cervix	Colon	Duodenum
Eyes	Femur with joint	Heart	Ileum	Jejunum
Kidneys	Larynx	Lungs	Mammary area	Mesenteric nodes
Nasopharynx	Oesophagus	Optic nerves	Oviducts	Pancreas
Parathyroid glands	Pituitary gland	Rectum	Salivary gland	Sciatic nerve
Skeletal muscle	Skin	Spinal cord	Spleen	Stomach
Thymus	Thyroid gland	Trachea	Urinary bladder	Uterus
Vagina	GALT/PEYER'S PATCH			

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474011	F	1	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Optic nerves		Both Missing
Parathyroid glands		Missing
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

Adrenal glands	Aorta	Bone marrow	Brain	Bronchi
Caecum	Cervical nodes	Cervix	Colon	Duodenum
Eyes	Femur with joint	Heart	Ileum	Jejunum
Kidneys	Larynx	Lungs	Mammary area	Mesenteric nodes
Nasopharynx	Oesophagus	Ovaries	Oviducts	Pancreas
Pituitary gland	Rectum	Salivary gland	Sciatic nerve	Skeletal muscle
Skin	Spinal cord	Spleen	Stomach	Thymus
Thyroid gland	Trachea	Urinary bladder	Uterus	Vagina
GALT/PEYER'S PATCH				

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474013	F	1	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Parathyroid glands		FIBROSIS, Minimal
Stomach	Abnormal area(s), Single, Dark red, Depressed - 2x1mm, glandular region	Tissue is unremarkable

The following tissues were unremarkable microscopically:

Adrenal glands	Aorta	Bone marrow	Brain	Bronchi
Caecum	Cervical nodes	Cervix	Colon	Duodenum
Eyes	Femur with joint	Heart	Ileum	Jejunum
Kidneys	Larynx	Liver	Lungs	Mammary area
Mesenteric nodes	Nasopharynx	Oesophagus	Optic nerves	Ovaries
Oviducts	Pancreas	Pituitary gland	Rectum	Salivary gland
Sciatic nerve	Skeletal muscle	Skin	Spinal cord	Spleen
Thymus	Thyroid gland	Trachea	Urinary bladder	Uterus
Vagina	GALT/PEYER'S PATCH			

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474015	F	1	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Kidneys		NEPHROPATHY, Minimal, Unilateral
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Oesophagus		CHRONIC INFLAMMATION, Mild, Focal /Comments: Muscular layer
Ovaries	Abnormal size, Enlarged - up to 3mm diam	Tissue is unremarkable
Uterus	Abnormal size, Distended - 3mm diam Abnormal contents, Clear, Fluid	DILATION, LUMEN, Mild

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474015	F	1	93	Dosing	Final sacrifice

The following tissues were unremarkable microscopically:

Adrenal glands	Aorta	Bone marrow	Brain	Bronchi
Caecum	Cervical nodes	Cervix	Colon	Duodenum
Eyes	Femur with joint	Heart	Ileum	Jejunum
Larynx	Lungs	Mammary area	Mesenteric nodes	Nasopharynx
Optic nerves	Oviducts	Pancreas	Parathyroid glands	Pituitary gland
Rectum	Salivary gland	Sciatic nerve	Skeletal muscle	Skin
Spinal cord	Spleen	Stomach	Thymus	Thyroid gland
Trachea	Urinary bladder	Vagina	GALT/PEYER'S PATCH	

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474017	F	1	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Lungs		MINERALIZATION, Minimal, Focal /Comments: Vascular
Stomach	Abnormal area(s), Two, Dark red, Depressed - up to 2x1mm, glandular region	Tissue is unremarkable
Uterus	Abnormal size, Distended - 5mm diam Abnormal contents, Clear, Fluid	DILATION, LUMEN, Moderate

The following tissues were unremarkable microscopically:

Adrenal glands	Aorta	Bone marrow	Brain	Bronchi
Caecum	Cervical nodes	Cervix	Colon	Duodenum
Eyes	Femur with joint	Heart	Ileum	Jejunum
Kidneys	Larynx	Mammary area	Mesenteric nodes	Nasopharynx
Oesophagus	Optic nerves	Ovaries	Oviducts	Pancreas
Parathyroid glands	Pituitary gland	Rectum	Salivary gland	Sciatic nerve
Skeletal muscle	Skin	Spinal cord	Spleen	Thymus
Thyroid gland	Trachea	Urinary bladder	Vagina	GALT/PEYER'S PATCH

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474019	F	1	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
GALT/PEYER'S PATCH		LYMPHOID HYPERPLASIA, Mild
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

Adrenal glands	Aorta	Bone marrow	Brain	Bronchi
Caecum	Cervical nodes	Cervix	Colon	Duodenum
Eyes	Femur with joint	Heart	Ileum	Jejunum
Kidneys	Larynx	Lungs	Mammary area	Mesenteric nodes
Nasopharynx	Oesophagus	Optic nerves	Ovaries	Oviducts
Pancreas	Parathyroid glands	Pituitary gland	Rectum	Salivary gland
Sciatic nerve	Skeletal muscle	Skin	Spinal cord	Spleen
Stomach	Thymus	Thyroid gland	Trachea	Urinary bladder
Uterus	Vagina			

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474021	F	1	58	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

No Tissues to list

DRAFT - Not for Circulation 2016

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474023	F	1	58	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		
		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Whole animal		
	No abnormalities detected	

The following tissues were unremarkable microscopically:

No Tissues to list

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474025	F	1	58	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Ovaries	Abnormal size, Small - up to 3mm diam	

The following tissues were unremarkable microscopically:

No Tissues to list

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474027	F	1	58	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Mild, Multifocal
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

No Tissues to list

DRAFT - NOT VALIDATED VERSION

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474029	F	1	58	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

No Tissues to list

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474031	F	2	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		
		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Uterus		
	Abnormal size, Distended - 3mm diam	DILATION, LUMEN, Mild
	Abnormal contents, Clear, Fluid	

The following tissues were unremarkable microscopically:

No Tissues to list

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474033	F	2	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Uterus	Abnormal size, Distended - 3mm diam Abnormal contents, Clear, Fluid	DILATION, LUMEN, Moderate

The following tissues were unremarkable microscopically:

No Tissues to list

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474035	F	2	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

No Tissues to list

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474037	F	2	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Ovaries		
	Abnormal size, Enlarged - up to 4mm diam	
		Tissue is unremarkable

The following tissues were unremarkable microscopically:

Liver

FDA - DRAFT - Not for distribution (b)(4)

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474039	F	2	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

No Tissues to list

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474041	F	2	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Ovaries	Abnormal size, Enlarged - up to 5mm diam	Tissue is unremarkable
Uterus	Abnormal size, Distended - 5mm diam Abnormal contents, Clear, Fluid	DILATION, LUMEN, Moderate

The following tissues were unremarkable microscopically:

No Tissues to list

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474043	F	2	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

No Tissues to list

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474045	F	2	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

No Tissues to list

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474047	F	2	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		
		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Uterus		
	Abnormal size, Distended - 3mm diam	DILATION, LUMEN, Mild
	Abnormal contents, Clear, Fluid	

The following tissues were unremarkable microscopically:

No Tissues to list

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474049	F	2	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Uterus	Abnormal size, Distended - 4mm diam Abnormal contents, Clear, Fluid	DILATION, LUMEN, Moderate

The following tissues were unremarkable microscopically:

No Tissues to list

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474051	F	2	58	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Skin		
	Staining, Brown - neck	
Thymus		
	Abnormal size, Small	
Uterus		
	Abnormal size, Distended - 4mm diam	
	Abnormal contents, Clear, Fluid	

The following tissues were unremarkable microscopically:
Liver

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474053	F	2	58	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Skin	Staining, Brown - neck	
Thymus	Abnormal size, Small	

The following tissues were unremarkable microscopically:

No Tissues to list

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474055	F	2	58	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		
		INFLAMMATORY CELL FOCI, Mild, Multifocal
Thymus		
	Abnormal size, Small	
Uterus		
	Abnormal size, Distended - 4mm diam	
	Abnormal contents, Clear, Fluid	

The following tissues were unremarkable microscopically:

No Tissues to list

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474057	F	2	58	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Mild, Multifocal
Uterus	Abnormal size, Distended - 4mm diam Abnormal contents, Clear, Fluid	

The following tissues were unremarkable microscopically:

No Tissues to list

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474059	F	2	58	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		
		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Thymus		
	Abnormal size, Small	

The following tissues were unremarkable microscopically:

No Tissues to list

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474061	F	3	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Brain	Abnormal shape, Irregular surface - right hemisphere, cerebral cortex, reduced	CONGENITAL ABNORMALITY, Marked, Unilateral /Comments: right hemisphere, Haemangioma
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Ovaries	Abnormal size, Enlarged - up to 3mm diam	Tissue is unremarkable

The following tissues were unremarkable microscopically:

No Tissues to list

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474063	F	3	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

No Tissues to list

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474065	F	3	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Ovaries	Abnormal size, Enlarged - up to 4mm diam	Tissue is unremarkable

The following tissues were unremarkable microscopically:

No Tissues to list

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474067	F	3	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

No Tissues to list

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474069	F	3	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		
		INFLAMMATORY CELL FOCI, Mild, Multifocal
		HEPATOCYTIC NECROSIS, Mild, Focal
Uterus		
	Abnormal size, Distended - 5mm diam	DILATION, LUMEN, Mild
	Abnormal contents, Clear, Fluid	

The following tissues were unremarkable microscopically:

No Tissues to list

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474071	F	3	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

No Tissues to list

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474073	F	3	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Uterus	Abnormal contents, Clear, Fluid	DILATION, LUMEN, Mild
	Abnormal size, Distended - 4mm diam	

The following tissues were unremarkable microscopically:

No Tissues to list

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474075	F	3	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

No Tissues to list

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474077	F	3	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Ovaries	Abnormal size, Enlarged - up to 3mm diam	Tissue is unremarkable
Uterus	Abnormal size, Distended - 5mm diam Abnormal contents, Clear, Fluid	DILATION, LUMEN, Moderate

The following tissues were unremarkable microscopically:

No Tissues to list

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474079	F	3	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		
		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Whole animal		
	No abnormalities detected	

The following tissues were unremarkable microscopically:

No Tissues to list

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474081	F	3	58	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

No Tissues to list

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474083	F	3	58	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

No Tissues to list

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474085	F	3	58	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

No Tissues to list

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474087	F	3	58	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		
		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Ovaries		
	Abnormal size, Enlarged - up to 4mm diam	
Pancreas		
	Abnormal colour, Pale	
Thymus		
	Abnormal size, Small	
Uterus		
	Abnormal size, Thickened	

The following tissues were unremarkable microscopically:

No Tissues to list

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474089	F	3	58	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

No Tissues to list

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474091	F	4	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal Hepatocytic hypertrophy, Minimal, Multifocal /Comments: Centrilobular/midzonal, hepatocytes with cytoplasmatic eosinophilia
Parathyroid glands		Missing
Thymus	Abnormal size, Small	Tissue is unremarkable

The following tissues were unremarkable microscopically:

Adrenal glands	Aorta	Bone marrow	Brain	Bronchi
Caecum	Cervical nodes	Cervix	Colon	Duodenum
Eyes	Femur with joint	Heart	Ileum	Jejunum
Kidneys	Larynx	Lungs	Mammary area	Mesenteric nodes
Nasopharynx	Oesophagus	Optic nerves	Ovaries	Oviducts
Pancreas	Pituitary gland	Rectum	Salivary gland	Sciatic nerve
Skeletal muscle	Skin	Spinal cord	Spleen	Stomach
Thyroid gland	Trachea	Urinary bladder	Uterus	Vagina
GALT/PEYER'S PATCH				

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474093	F	4	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		Hepatocytic hypertrophy, Minimal, Multifocal /Comments: Centrilobular/midzonal, hepatocytes with cytoplasmatic eosinophilia INFLAMMATORY CELL FOCI, Minimal, Multifocal
Ear(s)	Abnormal area(s), Ruptured - right	Tissue is unremarkable

The following tissues were unremarkable microscopically:

Adrenal glands	Aorta	Bone marrow	Brain	Bronchi
Caecum	Cervical nodes	Cervix	Colon	Duodenum
Eyes	Femur with joint	Heart	Ileum	Jejunum
Kidneys	Larynx	Lungs	Mammary area	Mesenteric nodes
Nasopharynx	Oesophagus	Optic nerves	Ovaries	Oviducts
Pancreas	Parathyroid glands	Pituitary gland	Rectum	Salivary gland
Sciatic nerve	Skeletal muscle	Skin	Spinal cord	Spleen
Stomach	Thymus	Thyroid gland	Trachea	Urinary bladder
Uterus	Vagina	GALT/PEYER'S PATCH		

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474095	F	4	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Adrenal glands		CYST/S, Mild, Unilateral /Comments: Focal, Haematic
Kidneys		NEPHROPATHY, Mild, Unilateral
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal Hepatocytic hypertrophy, Minimal, Multifocal /Comments: Centrilobular, hepatocytes with cytoplasmatic eosinophilia HEPATOCYTIC VACUOLATION, Minimal, Multifocal /Comments: Fatty change like (micro and macrovesicular)
Ovaries	Abnormal size, Enlarged - up to 3mm diam	Tissue is unremarkable
Uterus	Abnormal size, Distended - 6mm diam Abnormal contents, Clear, Fluid	DILATION, LUMEN, Moderate

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474095	F	4	93	Dosing	Final sacrifice

The following tissues were unremarkable microscopically:

Aorta	Bone marrow	Brain	Bronchi	Caecum
Cervical nodes	Cervix	Colon	Duodenum	Eyes
Femur with joint	Heart	Ileum	Jejunum	Larynx
Lungs	Mammary area	Mesenteric nodes	Nasopharynx	Oesophagus
Optic nerves	Oviducts	Pancreas	Parathyroid glands	Pituitary gland
Rectum	Salivary gland	Sciatic nerve	Skeletal muscle	Skin
Spinal cord	Spleen	Stomach	Thymus	Thyroid gland
Trachea	Urinary bladder	Vagina	GALT/PEYER'S PATCH	

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474097	F	4	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Kidneys		
		NEPHROPATHY, Minimal, Bilateral
		MINERALIZATION, Minimal, Unilateral /Comments: Cortico-medullary junction
Liver		
		INFLAMMATORY CELL FOCI, Minimal, Multifocal
		Hepatocytic hypertrophy, Minimal, Multifocal /Comments: Centrilobular/midzonal, hepatocytes with cytoplasmatic eosinophilia
		HEPATOCYTIC VACUOLATION, Minimal, Multifocal /Comments: Fatty change like (mainly macrovesicular)
Thymus		
	Abnormal size, Small	ATROPHY, Minimal
GALT/PEYER'S PATCH		
		LYMPHOID HYPERPLASIA, Mild

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474097	F	4	93	Dosing	Final sacrifice

The following tissues were unremarkable microscopically:

Adrenal glands	Aorta	Bone marrow	Brain	Bronchi
Caecum	Cervical nodes	Cervix	Colon	Duodenum
Eyes	Femur with joint	Heart	Ileum	Jejunum
Larynx	Lungs	Mammary area	Mesenteric nodes	Nasopharynx
Oesophagus	Optic nerves	Ovaries	Oviducts	Pancreas
Parathyroid glands	Pituitary gland	Rectum	Salivary gland	Sciatic nerve
Skeletal muscle	Skin	Spinal cord	Spleen	Stomach
Thyroid gland	Trachea	Urinary bladder	Uterus	Vagina

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474095	F	4	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Kidneys		NEPHROPATHY, Minimal, Unilateral
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal Hepatocytic hypertrophy, Minimal, Multifocal /Comments: Centrilobular/midzonal, hepatocytes with cytoplasmatic eosinophilia
Skeletal muscle		INFLAMMATORY CELL FOCI, Minimal, Focal
Uterus	Abnormal size, Distended - 3mm diam Abnormal contents, Clear, Fluid	DILATION, LUMEN, Mild

The following tissues were unremarkable microscopically:

Adrenal glands	Aorta	Bone marrow	Brain	Bronchi
Caecum	Cervical nodes	Cervix	Colon	Duodenum
Eyes	Femur with joint	Heart	Ileum	Jejunum
Larynx	Lungs	Mammary area	Mesenteric nodes	Nasopharynx
Oesophagus	Optic nerves	Ovaries	Oviducts	Pancreas
Parathyroid glands	Pituitary gland	Rectum	Salivary gland	Sciatic nerve
Skin	Spinal cord	Spleen	Stomach	Thymus
Thyroid gland	Trachea	Urinary bladder	Vagina	GALT/PEYER'S PATCH

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474101	F	4	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Kidneys		INFLAMMATORY CELL FOCI, Minimal, Unilateral /Comments: Focal
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal Hepatocytic hypertrophy, Minimal, Multifocal /Comments: Centrilobular, hepatocytes with cytoplasmatic eosinophilia
Ovaries	Abnormal size, Enlarged - up to 5mm diam	Tissue is unremarkable
Uterus	Abnormal size, Distended - 6mm diam Abnormal contents, Clear, Fluid	DILATION, LUMEN, Moderate

The following tissues were unremarkable microscopically:

Adrenal glands	Aorta	Bone marrow	Brain	Bronchi
Caecum	Cervical nodes	Cervix	Colon	Duodenum
Eyes	Femur with joint	Heart	Ileum	Jejunum
Larynx	Lungs	Mammary area	Mesenteric nodes	Nasopharynx
Oesophagus	Optic nerves	Oviducts	Pancreas	Parathyroid glands
Pituitary gland	Rectum	Salivary gland	Sciatic nerve	Skeletal muscle
Skin	Spinal cord	Spleen	Stomach	Thymus
Thyroid gland	Trachea	Urinary bladder	Vagina	GALT/PEYER'S PATCH

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474103	F	4	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Kidneys		
		NEPHROPATHY, Minimal, Unilateral
Liver		
		INFLAMMATORY CELL FOCI, Minimal, Multifocal
		Hepatocytic hypertrophy, Minimal, Multifocal /Comments: Centrilobular, hepatocytes with cytoplasmatic eosinophilia
Pancreas		
		ACINAR CELL DEGENERATION, Minimal, Focal
Parathyroid glands		
		Missing
Uterus		
	Abnormal size, Distended - 4mm diam	DILATION, LUMEN, Moderate
	Abnormal contents, Clear, Fluid	
Ear(s)		
	Abnormal area(s), Ruptured - right	
		Tissue is unremarkable

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474103	F	4	93	Dosing	Final sacrifice

The following tissues were unremarkable microscopically:

Adrenal glands	Aorta	Bone marrow	Brain	Bronchi
Caecum	Cervical nodes	Cervix	Colon	Duodenum
Eyes	Femur with joint	Heart	Ileum	Jejunum
Larynx	Lungs	Mammary area	Mesenteric nodes	Nasopharynx
Oesophagus	Optic nerves	Ovaries	Oviducts	Pituitary gland
Rectum	Salivary gland	Sciatic nerve	Skeletal muscle	Skin
Spinal cord	Spleen	Stomach	Thymus	Thyroid gland
Trachea	Urinary bladder	Vagina	GALT/PEYER'S PATCH	

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474105	F	4	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal Hepatocytic hypertrophy, Minimal, Multifocal /Comments: Centrilobular, hepatocytes with cytoplasmatic eosinophilia HEPATOCYTIC VACUOLATION, Minimal, Multifocal /Comments: Fatty change like (micro and macrovescicular)
Parathyroid glands		Missing
Uterus		DILATION, LUMEN, Mild
Whole animal	No abnormalities detected	

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474105	F	4	93	Dosing	Final sacrifice

The following tissues were unremarkable microscopically:

Adrenal glands	Aorta	Bone marrow	Brain	Bronchi
Caecum	Cervical nodes	Cervix	Colon	Duodenum
Eyes	Femur with joint	Heart	Ileum	Jejunum
Kidneys	Larynx	Lungs	Mammary area	Mesenteric nodes
Nasopharynx	Oesophagus	Optic nerves	Ovaries	Oviducts
Pancreas	Pituitary gland	Rectum	Salivary gland	Sciatic nerve
Skeletal muscle	Skin	Spinal cord	Spleen	Stomach
Thymus	Thyroid gland	Trachea	Urinary bladder	Vagina
GALT/PEYER'S PATCH				

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474107	F	4	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		
	Abnormal shape, Swollen	INFLAMMATORY CELL FOCI, Minimal, Multifocal
		Hepatocytic hypertrophy, Minimal, Multifocal /Comments: Centrilobular, hepatocytes with cytoplasmatic eosinophilia
Ovaries		
	Abnormal size, Enlarged - up to 4mm diam	
		Tissue is unremarkable
Uterus		
	Abnormal size, Distended - 6mm diam	DILATION, LUMEN, Moderate
	Abnormal contents, Clear, Fluid	

The following tissues were unremarkable microscopically:

Adrenal glands	Aorta	Bone marrow	Brain	Bronchi
Caecum	Cervical nodes	Cervix	Colon	Duodenum
Eyes	Femur with joint	Heart	Ileum	Jejunum
Kidneys	Larynx	Lungs	Mammary area	Mesenteric nodes
Nasopharynx	Oesophagus	Optic nerves	Oviducts	Pancreas
Parathyroid glands	Pituitary gland	Rectum	Salivary gland	Sciatic nerve
Skeletal muscle	Skin	Spinal cord	Spleen	Stomach
Thymus	Thyroid gland	Trachea	Urinary bladder	Vagina
GALT/PEYER'S PATCH				

REDACTED AS TO TRADE NAMES

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474109	F	4	93	Dosing	Final sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal Hepatocytic hypertrophy, Minimal, Diffuse /Comments: Centrilobular, hepatocytes with cytoplasmatic eosinophilia
Thyroid gland		ECTOPIC THYMUS, Minimal
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

Adrenal glands	Aorta	Bone marrow	Brain	Bronchi
Caecum	Cervical nodes	Cervix	Colon	Duodenum
Eyes	Femur with joint	Heart	Ileum	Jejunum
Kidneys	Larynx	Lungs	Mammary area	Mesenteric nodes
Nasopharynx	Oesophagus	Optic nerves	Ovaries	Oviducts
Pancreas	Parathyroid glands	Pituitary gland	Rectum	Salivary gland
Sciatic nerve	Skeletal muscle	Skin	Spinal cord	Spleen
Stomach	Thymus	Trachea	Urinary bladder	Uterus
Vagina	GALT/PEYER'S PATCH			

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474111	F	4	58	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		
		INFLAMMATORY CELL FOCI, Mild, Multifocal
Ovaries		
	Abnormal size, Enlarged - up to 4mm diam	

The following tissues were unremarkable microscopically:

No Tissues to list

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474113	F	4	58	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Thymus	Abnormal size, Small	

The following tissues were unremarkable microscopically:

No Tissues to list

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474115	F	4	58	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		
		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Thymus		
	Abnormal size, Small	

The following tissues were unremarkable microscopically:

No Tissues to list

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474117	F	4	58	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Whole animal	No abnormalities detected	

The following tissues were unremarkable microscopically:

No Tissues to list

REDACTED AS TO TRADE NAMES

Macroscopic and microscopic observations - Individual data

Study: A1474
Study Title: 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

Animal No	Sex	Group	Day of Death	Phase	Status
A1474119	F	4	58	Recovery	Recovery sacrifice

Tissue	Macroscopic Observations	Microscopic Observations
Liver		
		INFLAMMATORY CELL FOCI, Minimal, Multifocal
Ovaries		
	Abnormal size, Enlarged - up to 4mm diam	
Skin		
	Staining, Brown - neck	
Thymus		
	Abnormal size, Small	

The following tissues were unremarkable microscopically:

No Tissues to list

10 ADDENDA

10 - 14th DT - 14th December 2016

ADDENDUM 1 - Computer abbreviations and symbols

[redacted] 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

COMPUTER ABBREVIATIONS AND SYMBOLS

STUDY NO.: A1474

Abbreviations	Parameters names	Units
HCT	HAEMATOCRIT	%
RBC	RED BLOOD CELL COUNT	x10^6/µL
HGB	HAEMOGLOBIN	g/dL
MCV	MEAN RED BLOOD CELL VOLUME	fL
MCH	MEAN CORPUSCULAR HAEMOGLOBIN	pg
MCHC	MEAN CORPUSCULAR HAEMOGLOBIN CONCENTRATION	g/dL
PLT	PLATELETS	x10^3/µL
WBC	WHITE BLOOD CELL COUNT	x10^3/µL
NEUR/NEU	NEUTROPHILS (relative or absolute)	% or x10^3/µL
LYMR/LYM	LYMPHOCYTES (relative or absolute)	% or x10^3/µL
MONR/MON	MONOCYTES (relative or absolute)	% or x10^3/µL
EOSR/EOS	EOSINOPHILS (relative or absolute)	% or x10^3/µL
BASR/BAS	BASOPHILS (relative or absolute)	% or x10^3/µL
LUCR/LUC	LARGE UNSTAINED CELLS (relative or absolute)	% or x10^3/µL
RETR/RET	RETICULOCYTES (relative or absolute)	% or x10^9/L
PT	PROTHROMBIN TIME	sec
ALP	ALKALINE PHOSPHATASE	U/L
ALT	ALANINE AMINOTRANSFERASE	U/L
AST	ASPARTATE AMINOTRANSFERASE	U/L
GGT	GAMMAGLUTAMYLTRANSFERASE	U/L
GLU	GLUCOSE	mg/dL
TBIL	TOTAL BILIRUBIN	mg/dL
CHOL	TOTAL CHOLESTEROL	mg/dL
TRIG	TRIGLYCERIDES	mg/dL
PROT	TOTAL PROTEIN	g/dL
ALB	ALBUMIN	g/dL
GLO	GLOBULIN	g/dL
A/G	ALBUMIN/GLOBULIN RATIO	
Na	SODIUM	mmol/L
K	POTASSIUM	mmol/L
Ca	CALCIUM	mmol/L
Cl	CHLORIDE	mmol/L
IP	INORGANIC PHOSPHORUS	mg/dL
UREA	UREA	mg/dL
CREA	CREATININE	mg/dL

ADDENDUM 1 - Computer abbreviations and symbols

[redacted] 13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD

COMPUTER ABBREVIATIONS AND SYMBOLS

STUDY NO.: A1474

Abbreviations	Parameters names	Units/Key
Ctls	Controls	
n/(n)	Number of animals or cages	
SD	Standard deviation	
TBW	Terminal body weight	
*D	Dunnett LSD Test Significant at the 0.05 level	
+D or +	Dunnett LSD Test Significant at the 0.01 level	
*C	Cochran and Cox Test Significant at the 0.05 level	
+C	Cochran and Cox Test Significant at the 0.01 level	
#C	Cochran and Cox Test Significant at the 0.001 level	
($)	Data inhomogeneous by Bartlett's test	
@	Number examined reduced due to excluded data	
e	Excluded	
CD	Counter display	

29 - [illegible] - 10th December 20[illegible]

REDACTED AS TO TRADE NAMES

[redacted] 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

NEUROTOXICITY ABBREVIATIONS AND SYMBOLS

STUDY NO.: A1474

OPEN FIELD MEASUREMENTS

Abbreviations	Parameter names	Key
AR	Arousal	1 = Normal; 2 = Very slow; 3 = Slow; 4 = Moderate; 5= Marked
MI	Mobility Impairment	1 = Absent; 2 = Slight; 3 = Moderate; 4 = Marked
GA	Gait	1 = Normal gait; 2 = Slight ataxia; 3 = Moderate ataxia; 4 = Marked ataxia; 5 = Slightly hunched; 6 = Moderately hunched; 7 = Severely hunched; 8 = Pronation; 9 = Slight forelimbs drag; 10 = Slight hindlimbs drag; 11 = Moderate forelimbs drag; 12 = Moderate hindlimbs drag; 13 = Marked forelimbs drag; 14 = Marked hindlimbs drag
RE	Rearing	0 = Absent; N. = More than 1
SP	Spasms	1 = Absent; 2 = Tonic spasms; 3 = Clonic spasms; 4 = Tonic-clonic spasms
MY	Myoclonia	Absent; Present
TR	Tremors	Absent; Present
VC	Vocalisation	Absent; Present
ST	Stereotypies	Absent; Present
BB	Bizarre behaviour	Absent; Present
UN	Unusual respiratory pattern	Absent; Present
UR	Urination	0 = Absent; N. = More than 1
DE	Defecation	0 = Absent; N. = More than 1

REMOVAL FROM CAGE

Abbreviations	Parameter names	Key
Removal	Removal (from cage)	1 = Easy; 2 = Difficult; 3 = Very difficult
HAN	Handling reactivity	1 = Slow; 2 = Normal; 3 = Moderate; 4 = Marked
LA	Lachrymation	1 = Absent; 2 = Slight; 3 = Marked
PA	Palpebral closure	1 = Absent; 2 = Slight; 3 = Moderate; 4 = Marked
SA	Salivation	1 = Absent; 2 = Slight; 3 = Marked
PI	Piloerection	Absent; Present

[redacted] 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

NEUROTOXICITY ABBREVIATIONS AND SYMBOLS

STUDY NO.: A1474

LANDING FOOT SPLAY

Abbreviations	Parameter names	Key
LAN1	Landing foot splay 1 (cm)	First measurement of distance between ink blots (cm)
LAN 2	Landing foot splay 2 (cm)	Second measurement of distance between ink blots (cm)
LAM	Landing foot splay mean (cm)	Averaged measurement of distance between ink blots (cm)

SENSORY REACTIVITY

Abbreviations	Parameter names	Key
APP	Approach response	0) no reaction; 1) rat slowly approaches and sniffs or turns away; 2) rat freezes, actual muscle contractions; 3) more energetic response than 1) or 2); 4) exaggerated reaction - jumps, bites, or attacks
TO	Touch response	0) no response; 1) rat may slowly turn or walk away, or vocalizations with little or no movement; 2) rat freezes, actual muscle contractions; 3) more energetic response than 1) or 2); 4) exaggerated reaction - jumps, bites, or attacks
CLI	Clicker response	0) no reaction; 1) slight reaction, some evidence that noise was heard; 2) rat freezes, actual muscle contractions; 3) more energetic response than 1) or 2); 4) exaggerated reaction - jumps, bites, or attacks
TPR	Tail pinch response	0) no reaction; 1) rat may turn or walk forward, or vocalizations with little or no movement; 2) rat freezes, actual muscle contractions; 3) more energetic response than 1) or 2); 4) exaggerated response - jumps, bites, or attacks
PU	Pupil response	Passed = pupil reflex present; Failed = pupil reflex absent
ARR	Air righting reflex	1) normal, rat lands on feet; 2) slightly uncoordinated; 3) lands on side; 4) lands on back
GRI1	Grip strength 1 (g)	First reading of the animal grips on horizontal with forelimbs
GRI2	Grip strength 2 (g)	Second reading of the animal grips on horizontal with forelimbs
GRM	Grip strength mean (g)	Averaged reading of the animal grips on horizontal with forelimbs

ADDENDUM 3 - Certificate of analysis

SOLVAY

R,D&T Analytical & Structural Characterization Department

Viale Lombardia, 20, 20021 Bollate (MI) Italy

Bollate 2015.07.29

Product Name:

[redacted] dry salt lot90409/86-II

Expiry Date: July 2020

Appearance: white powder

Stability: Stable in normal condition of storage and use

Scope of the Analysis:

Determination of concentration of N and M components, impurities , water content.

Method & Equipment:

Gas Chromatography, Karl Fisher, according to internal methods

Results

N2 = Cl $(CF_2CF(CF_3)O)_2$-CF_2-COOH	37.1 % w/w
M3 = Cl $(CF_2CF(CF_3)O)_2$-$CF(CF_3)$-O-CF_2-COOH	7.3 % w/w
N3 = Cl $(CF_2CF(CF_3)O)_3$-CF_2-COOH	18.2 % w/w
M4 = Cl $(CF_2CF(CF_3)O)_3$-$CF(CF_3)$-O-CF_2-COOH	5.9 % w/w
N4 = Cl $(CF_2CF(CF_3)O)_4$-CF_2-COOH	9.1 % w/w
N5 = Cl $(CF_2CF(CF_3)O)_5$-CF_2-COOH	1.3 % w/w
Tot = 78.9	

19-GRAPE-14th December 2016

SOLVAY SPECIALTY POLYMERS ITALY S.p.A.
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Cap. Soc. Euro 374.187.000 i.v. - Cod. Fisc. e P.IVA. 03521920961 - PEC: sspi@legalmail.it
www.solvay.com

SOLVAY

The remaining 20% are lighter acids, ketones, neutral substances
Water content = 0.58 % w/w

Margherita Albano

Analytical & Structural Characterization Department

a9 - DRAFT - 14th December 2016

[redacted]

13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

RTC STUDY NO. A1474

FORMULATION ANALYSIS REPORT

FRANCESCA ROMANA CALFAPIETRA

HEAD, ANALYTICAL CHEMISTRY

* *

Validation of the analytical method

The analytical method was validated in the present study in the range from 0.005 to 0.3 mg/mL. Linearity, accuracy and precision were within the limits stated in RTC SOPs for solutions ($r > 0.98$; accuracy 85-105%; precision CV < 5%).

Formulation sampling

Formulations of the test item were prepared as solutions in sterile water. Concentration was assessed for all levels by taking two analytical aliquots (approximately 1 mL). Each analytical aliquot was analysed separately. Concentration was evaluated as the mean of the two determinations.

Stability

In this study a 24 hour and 8 day stability at room temperature and at +4°C was verified in the range from 0.005 to 0.3 mg/mL. According to RTC SOPs, solutions are considered to be stable if concentration after the defined period of storage, is still acceptable (90-110%).

Assessment of formulation procedure (pre-treatment)

The proposed formulation procedure for the test item was checked in the range from 0.005 to 0.3 mg/mL by chemical analysis (concentration) during the pre-treatment period to confirm that the method was suitable. Final results for all levels were within the acceptability limits stated in RTC SOPs for concentration (90-110%).

Formulation analysis of dosing solutions

Samples of the formulations prepared on Day 1 and Week 13 were analysed to check the concentration. Results of the analyses were within the acceptability limits stated in RTC SOPs for concentration of solutions (90-110%).

Formulation analysis - Day 1 - Content check

		Concentration (mg/mL)		Recovery (%)	
		Intended	Found	Found	Limits
Group	Sex				
1	M+F	0	0	-	-
2	M+F	0.005	0.004524	90.48	90 - 110
3	M+F	0.01	0.009815	98.15	90 - 110
4	M+F	0.03	0.03255	108.51	90 - 110
Stock	M+F	0.3	0.3280	109.33	90 - 110

Formulation analysis - Week 13 - Content check

		Concentration (mg/mL)		Recovery (%)	
		Intended	Found	Found	Limits
Group	Sex				
1	M+F	0	0	-	-
2	M+F	0.005	0.00336	66.72*	90 - 110
3	M+F	0.01	0.004681	46.81*	90 - 110
4	M+F	0.03	0.02176	72.53*	90 - 110
Stock	M+F	0.3	0.2709	90.29	90 - 110

*results out of acceptance limits

Formulation analysis - Week 13 (repetition) - Content check

Group	Sex	Concentration (mg/mL) Intended	Found	Recovery (%) Found	Limits
1	M+F	0	0	-	-
2	M+F	0.005	0.004555	91.10	90 - 110
3	M+F	0.01	0.009984	99.84	90 - 110
4	M+F	0.03	0.02705	90.16	90 - 110

TITLE

[redacted] Determination in sterile water with LC-MS/MS detection.

1 STANDARD REFERENCES

- ISO Standard 78/2-1999 Layout for standards Part 2: Methods of chemical analysis.

2 DEFINITIONS

[redacted] is a product developed by the Sponsor.

The method described is used for the analysis of [redacted] in sterile water.

The concentration application range is from 5 µg/mL to 300 µg/mL for dosing solution. The theoretical linearity range for HPLC analysis around diluted working concentration (4.80 µg/mL) is from 3.84 µg/mL to 5.76 µg/mL.

3 PRINCIPLE

The method essentially consists of three steps:

- Sampling
- Dilution
- LC-MS/MS

4 REAGENTS AND MATERIALS

Note: During the analysis, unless otherwise stated, use only reagents of recognized analytical grade and distilled or demineralized water or water of equivalent purity.

4.1 Chemicals

1. Acetonitrile - CH_3CN, CAS No. [75-05-8]
2. Formic acid - HCOOH, CAS No. [64-18-6]

4.2 Mobile Phases

1. 0.1 % Formic acid in water: using a glass pipette (*EQP-6*), measure out 1 mL of formic acid (2) into a 1000 mL volumetric flask and dilute to volume with water.
2. 0.1 % Formic acid in acetonitrile: using a glass pipette (*EQP-6*), measure out 1 mL of formic acid (2) into a 1000 mL volumetric flask and dilute to volume with acetonitrile.

5 APPARATUS

5.1 Laboratory Supplies

EQP-1	Column Kinetex C18 100A 50×2.1 mm 2.6 µm (Phenomenex)
EQP-2	EASYPURE II System (Thermo Scientific)
EQP-3	Ultrasonic bath UnisetAC
EQP-4	HPLC microvials
EQP-5	Pasteur pipettes
EQP-6	Volumetric pipettes Grade A
EQP-7	Gilson pipette
EQP-8	Common glassware Grade A

5.2 Instrumentation

1. Analytical balance XP105 Delta range (Mettler) or equivalent
2. LC system: Alliance 2695 HPLC(Waters) or equivalent
3. Detector (MS/MS): API 2000

5.3 Software

1. Analyst 1.5.2 (AB Sciex)

6 SAMPLING

Two 1 mL samples are required from all formulated samples to be tested for the determination of concentration.

7 PROCEDURE

7.1 Preparation of Stock, Working Standard and Calibration Solutions

[redacted] is used as the analytical standard and the weighings are corrected for purity as described in the Certificate of Analysis (CoA) supplied by the Sponsor.

7.1.1 Stock and Working Standard Solutions

Two independently prepared analytical stock and standard solutions of [redacted] are compared by LC-MS/MS to check the accuracy of preparation prior to their use (acceptability criteria $\Delta < \pm 5\,\%$).

Stock Weigh approximately 30 mg of [redacted] into a 25 mL volumetric flask and dissolve with acetonitrile, obtaining an approximately 1200 µg/mL analytical stock solution. Due to the assigned Hazard Class, weighing should be performed in Formulation Unit.

Sol Using a glass pipette *EQP-6*, measure out 1 mL of analytical Stock A/B into a 50 mL volumetric flask and dilute to volume with water, obtaining an approximately 24 µg/mL solution (Sol A/B).

Standard Using a glass pipette *EQP-6*, measure out 1 mL of Sol A/B into a 5 mL volumetric flask and dilute to volume with water, obtaining an approximately 4.8 µg/mL solution (Std A/B).

7.1.2 Calibration Standards

Prepare a 5-point calibration curve by diluting samples of Sol A with water , as indicated in Table 1.

Table 1: Calibration standards

Name	Drawn vol. (mL)	From	Final vol. (mL)	Solvent	Conc. (µg/mL)
S1	0.8	Sol A	5	Water	3.84
S2	0.9		5		4.32
S3	1		5		4.80
S4	1.1		5		5.28
S5	1.2		5		5.76

7.2 Accuracy and Precision samples (for validation)

Low level (5 µg/mL)

Transfer 1.0 mL of Sol A into a 5 mL volumetric flask and dilute to volume with water (final concentration 4.8 µg/mL).

High level (30 µg/mL)

Transfer 0.5 mL of analytical Stock A into a 20 mL volumetric flask and dilute to volume with water (final concentration 30 µg/mL). Six replicate preparations are required: using a glass pipette *EQP-6*, measure out 0.8 mL of the resulting solution into a 5 mL volumetric flask and dilute to volume with water(final concentration 4.8 µg/mL).

Higher level (300 µg/mL)

Six replicate preparations are required: using a glass pipette *EQP-6*, transfer 0.8 mL of the stock solution at 300 µg/mL (prepared in the Formulation Unit for the dilution up to dosing solutions) into a 50 mL volumetric flask and dilute to volume with water(final concentration 4.8 µg/mL).

7.3 Blank

Blank: inject a sample of water as the blank sample.

7.4 Unknown samples

Remove unknown samples as per SOP (AMC/101/7) and dilute with water as outlined Table 2, sonicating, if necessary, after the first dilution.

Dilute any additional concentrations accordingly to fall within the range of the calibration curve.

Table 2: Unknown samples - dilution scheme

Concentration (mg/mL)		0	0.005	0.01	0.03	0.3
Dilution factor		1	1	2	6.25	62.5
Step	***Action***					
1	Transfer	as	as	1 mL	0.8 mL	0.8 mL
	Dilute to	supplied	supplied	2 mL	5 mL	50 mL

7.5 Assay Settings and Parameters

7.5.1 HPLC Settings

Set up the HPLC system as follows:

- Column: Phenomenex kinetex C18 2.6µm 100A 2.1×50 mm (*EQP-1*)

Mobile phase:

- 1: 0.1 % Formic acid in water
- 2: 0.1 % Formic acid in acetonitrile

Elution:

- Gradient

Time (min)	Flow (mL/min)	A%	B%	Curve
0.00	0.3	90	10	-
5		10	90	6
8		10	90	1
14		90	10	1

- Injection volume: 10 µL
- Column temperature: +50 °C
- Autosampler temperature: +20 °C
- Run time: 14 minutes
- Retention time: 6.18 minutes

7.5.2 Detector Parameters

Set up the MS system as follows:

- Ion Source: Turbo Ion Spray (API2000)
- Scan Type: MRM
- Ionization polarity: Negative Ion Mode

The mass spectrometer is optimised by infusing pure standard solutions of [redacted].
The following Q1 and Q3 masses have been selected for quantifyng [redacted]

[redacted]			
Q1 mass (amu)		Q3 mass (amu)	Retention Time (min)
367	⇒	201	6.18
	⇒	185	
483	⇒	201	
533	⇒	367	
	⇒	201	
649	⇒	483	
	⇒	201	
699	⇒	533	
	⇒	367	

Due to the calibration of the mass spectrometer, a ±0.5 amu variation in the exact mass may be observed. Chromatographic signal (TIC) for each analyte is obtained by the sum of each MRM transition extracted Ion Current (XIC).

7.5.3 System Suitability Test (SST)

Inject 10 µL of both [redacted] STD solutions as a SST. The system is suitable if the retention time of [redacted] peak falls in the range 4.18-8.18 minutes. The mobile phase composition can be modified in order to comply with this requirement.

7.5.4 Acceptance criteria for peak retention times

The chromatographic peak retention time for the Test Item must deviate by less than ±10% from the mean of all the retention times, for that Test Item, within the analytical session.

7.5.5 Data Processing

Detector output is recorded by the ANALYST software (1). Peaks are recognised and integrated. Peak areas and retention times are recorded.

7.5.6 Analytical Run Settings

Begin each analytical session with a freshly prepared calibration curve.

8 CALCULATIONS

8.1 Expression of Results

The following formulae are obtained from the software 1.

All data displayed in the method are expressed to four significant figures.

All data are calculated from the actual values without rounding off.

All areas displayed in the method are expressed in natural numbers.

All percentage data are expressed to two decimal places.

8.2 Formulae

8.2.1 Linearity

The chromatographic software generates a linear fit calibration curve drawing the best fit of a line to the [redacted] amount in µg/mL and the peak areas. The software uses a linear least-squares fit formula.

The result of the fitting is:

$$y = A + Bx \tag{1}$$

where:

y = Peak area of [redacted]
A = Intercept on the y-axis
B = Slope of the calibration curve
x = [redacted] concentration in µg/mL

Correlation coefficient is a rough indicator of the goodness of fit. The equations used to determine the correlation coefficient are as follows:

$$R^2 = 1 - \frac{(S_y)^2}{\sigma_y^2} \tag{2}$$

$$R = \sqrt{R^2} \tag{3}$$

where:

R^2	=	Determination Coefficient
R	=	Correlation coefficient
S_y	=	Standard error of estimate of y on x
σ_y^2	=	Variance

8.2.2 Standard Error and Standard Variance

The standard error is computed as follows:

$$S_y = \sqrt{\frac{1}{n}\sum_i^n w_i (\hat{y}_i - Y_i)^2} \tag{4}$$

where:

n	=	The number of values
w_i	=	The weights of the points (set to 1 if not weighted)
$\hat{y}_i$	=	The responses as predicted using the calibration curve
Y_i	=	The unique responses calculated by the Chromatographic software

The standard variance is computed as follows:

$$\sigma_y^2 = \frac{1}{n}\sum_i w_i (y_i - \overline{y})^2 \tag{5}$$

where:

$\overline{y} = \frac{\sum_i w_i y}{\sum_i w_i}$

The standard error of calibration is computed as follows:

$$E = \sqrt{\frac{1}{d}\left(\sum_i (\hat{y}_i - Y_i)\right)^2} \tag{6}$$

where:

E = Standard error using the calibration curve
d = Degrees of freedom

8.2.3 Mean, Accuracy and Precision

Mean is calculated as follows:

$$\overline{C} = \sum_{i}^{n} \frac{C_i}{n} \tag{7}$$

where:
$\overline{C}$ = The mean concentration of the compound found
C_i = The amount found obtained for each sample
n = The number of samples

Accuracy (as relative error, RE) is calculated as follows:

$$Accuracy = \frac{\overline{C}}{C_a} \cdot 100 \tag{8}$$

where:
$\overline{C}$ = The mean concentration of the compound found
C_a = The amount of compound added

or

accuracy is calculated as the mean of the recoveries at each level (if individual weighings are used), where the recovery is calculated as follows:

$$Recovery = \frac{C_f}{C_{th}} \cdot 100 \tag{9}$$

where:
C_f = the found concentration
C_{th} = the theoretical concentration

Precision, as the coefficient of variation as percentage, is calculated as follows:

$$CV\,\% = \frac{SD}{\overline{C}} \cdot 100 \tag{10}$$

$$SD = \sqrt{\sum_{i} \frac{(C_i - \overline{C})^2}{(n-1)}} \tag{11}$$

where:

$\overline{C}$	=	Mean concentration of the compound found
$CV\,\%$	=	Percentage coefficient of variation
C_i	=	The amount of compound found
SD	=	Standard deviation

8.2.4 Deviation as Percentage Bias

Deviation as percentage bias (Δ, Bias (%)) is calculated as follows:

$$\Delta = Bias\,(\%) = \frac{(C_f - C_{th})}{C_{th}} \tag{12}$$

8.2.5 Determination of the Test Item Concentration

Unknown samples are injected after the HPLC-MS/MS calibration. The [redacted] amount, in µg/mL, is obtained directly from the software report.

The software calculates the result as:

$$x = \frac{(y - A)}{B} \tag{13}$$

The [redacted] content in formulations, in mg/mL, is obtained as follows:

$$C = \frac{x \cdot DF \cdot d}{W \cdot CF} \tag{14}$$

where:

C	=	Content of [redacted] in sterile water in mg/mL
x	=	[redacted] amounts in µg/mL as read in the chromatogram result table
DF	=	Dilution factor
d	=	Density
W	=	Sample weight
CF	=	Conversion factor from µg/mL to mg/mL (= 1000)

1 VALIDATION RESULTS

1.1 Linearity

In order to assess linearity, calibration samples of [redacted] are prepared at five levels ranging from 3.840 to 5.760 µg/mL, then analysed and processed as described in the analytical method. The following correlation is found (see Table 1 for the results).

Equation	Response = (-1.74e+005) + 2.23e+005 × [redacted] concentration in µg/mL
r	0.9926
Response type	Peak area
Fit type	Linear
Weighting	None

1.2 Selectivity

To assess selectivity, samples of diluent (water) are injected in duplicate to check the presence of any peak. No interferences are present at the [redacted] retention time.

1.3 Accuracy and precision

Accuracy and precision are assessed in the range from 4.8 to 300 µg/mL by preparing and analysing six independent samples. The results, shown in Table 2, meet the acceptability criteria for accuracy (95 and 105 % of the theoretical values) and precision (CV < 5%).

2 FORMULATION PROCEDURE

Formulations are prepared as described below:

- Weigh the correct amount of test item
- Add the required volume of water to prepare the stock solution
- Dilute the stock solution up to the required dosing concentrations

3 FORMULATION RESULTS

3.1 Formulation analysis

Formulations of [redacted] in the vehicle are prepared at 5, 10 and 30 µg/mL, using the procedure described above. Concentration is assessed by taking two analytical aliquots, the lowest concentration is injected as supplied. Each aliquot is independently analysed and the concentration expressed as the mean of the two individual determinations. The results of formulations diluted from the stock solution at 300 µg/mL, shown in Tables 3 and 4, are within the acceptability criteria for concentration (90 to 110 % of the theoretical concentration) when prepared from the stock stored at both room temperature and +4°C, respectively.

4 FORMULATION STABILITY RESULTS

4.1 Stability at room temperature

The stability of stock and formulations of [redacted] in the vehicle in the range from 5 to 300 µg/mL is assessed after 24 hours and 8 days at room temperature. The results, shown in Tables 5 and 6, fulfil the acceptability criteria for concentration (90 to 110 % of the theoretical concentration), indicating that the stock and the formulations are stable under these conditions.

The stability results are summarised in Table 9.

4.2 Stability at +4 °C

The stability of stock and formulations of [redacted] in the vehicle in the range from 5 to 300 µg/mL is assessed after 24 hours and 8 days at + 4 °C. The results, shown in Tables 7 and 8, fulfil the acceptability criteria for concentration (90 to 110 % of the theoretical concentration), indicating that the stock and the formulations are stable under these conditions.

The stability results are summarised in Table 9.

5 TABLES

Formulation Analysis Report

TABLES

Table 1: Linearity results

Level (µg/mL)	*Peak area (µV·sec)*	*Calculated concentration (µg/mL)*
3.840	686556	3.861
4.320	778932	4.275
4.800	916908	4.894
5.280	972398	5.143
5.760	1125047	5.827

Table 2: Accuracy and precision

Theoretical concentration (µg/mL)	*Found concentration (µg/mL)*	*Accuracy (%)*	*Precision (CV%)*
4.8	4.810 4.908 4.544 4.636 4.850 4.524	98.17	3.51
30	31.50 31.80 31.44 29.99 31.61 31.55	104.39	2.11
300*	280.8 272.4 286.8 308.3 289.6 287.7	95.86	4.15

*Validation performed on Stock for formulation samples

Table 3: Formulation analysis results from stock solution stored at room temperature

Theoretical concentration (µg/mL)	***Found concentration (µg/mL)***		***Recovery (%)***
	Values	***Mean***	
30 Dosing solution	29.77 30.23	30.00	100.00
10 Dosing solution	9.064 9.470	9.267	92.67
5 Dosing solution	4.435 4.752	4.594	91.87

Table 4: Formulation analysis results from stock solution stored at +4°C

Theoretical concentration (µg/mL)	***Found concentration (µg/mL)***		***Recovery (%)***
	Values	***Mean***	
30 Dosing solution	33.29 32.24	32.77	109.22
10 Dosing solution	10.51 11.20	10.85	108.53
5 Dosing solution	5.395 5.471	5.433	108.66

TABLES

Table 5: Formulation stability results after 24 hours at room temperature

Theoretical concentration (µg/mL)	***Found concentration (µg/mL)***		***Recovery (%)***
	Values	***Mean***	
300 Stock solution	299.3 305.7	302.5	100.82
30 Dosing solution	27.59 28.69	28.13	93.78
10 Dosing solution	9.626 8.776	9.201	92.01
5 Dosing solution	4.603 4.602	4.603	92.05

Table 6: Formulation stability results after 8 days at room temperature

Theoretical concentration (µg/mL)	***Found concentration (µg/mL)***		***Recovery (%)***
	Values	***Mean***	
300 Stock solution	300.4 297.8	299.1	99.70
30 Dosing solution	28.33 30.66	29.49	98.30
10 Dosing solution	8.966 9.102	9.034	90.34
5 Dosing solution	4.709 4.791	4.750	95.00

Formulation Analysis Report

TABLES

Table 7: Formulation stability results after 24 hours at +4°C

Theoretical concentration (µg/mL)	***Found concentration (µg/mL)***		***Recovery (%)***
	Values	***Mean***	
300 Stock solution	325.4 331.4	328.4	109.48
30 Dosing solution	27.48 28.65	28.06	93.54
10 Dosing solution	9.388 *	9.388	93.88
5 Dosing solution	4.594 4.553	4.574	91.47

*sample out of acceptance limits, not considered in calculations

Table 8: Formulation stability results after 8 days at +4°C

Theoretical concentration (µg/mL)	***Found concentration (µg/mL)***		***Recovery (%)***
	Values	***Mean***	
300 Stock solution	345.6 367.9	356.7	*118.91**
30 Dosing solution	30.56 30.81	30.68	102.28
10 Dosing solution	10.71 7.422	9.064	90.64
5 Dosing solution	4.653 4.568	4.611	92.21

*result out of acceptance limits

Table 9: Summary of the formulation stability results

[redacted]			
Concentration (mg/mL)	***Storage Time***	***Temperature***	***Note***
300 Stock solution	24 hours	+4°C	A1474 session 4
	24 hours and 8 days	Room temperature	A1474 sessions 4,7
30 Dosing solution	24 hours and 8 days*	+4°C	A1474 session 5,8
	24 hours and 8 days*	Room temperature	A1474 session 5,8
10 Dosing solution	24 hours and 8 days*	+4°C	A1474 session 5,8
	24 hours and 8 days*	Room temperature	A1474 session 5,8
5 Dosing solution	24 hours and 8 days*	+4°C	A1474 session 5,8
	24 hours and 8 days*	Room temperature	A1474 session 5,8

*prepared from the Stock solution stored at room temperature

Ophthalmoscopy Report

[redacted]

13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

RTC STUDY NO. A1474

OPHTHALMOSCOPIC EVALUATION REPORT

LUCIA LUPERI, DVM
OPHTHALMOSCOPIC EVALUATION - VETERINARY SERVICES

*

Animals with no ocular abnormality were selected for the study by an ophthalmoscopic examination performed before the start of treatment.

No findings were detected in both eyes of all surviving animals, from high-dose and control groups, when they were re-examined during Week 13 of treatment.

19 - DRAFT - NOT FOR SIGNATURE

REDACTED AS TO TRADE NAMES

RTC Study No.: A1474

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ADDENDUM 6 - Clinical Pathology Report

[redacted]

13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

RTC STUDY NO. A1474

CLINICAL PATHOLOGY REPORT

ALBERTO MOSIELLO
HEAD, CLINICAL PATHOLOGY

*

Haematology

Dosing Phase

Some statistically significant differences between control and treated animals were recorded, such as: decrease of erythrocytes, haemoglobin, haematocrit in males dosed at 0.05 and 0.3 mg/kg/day, increase of mean corpuscular haemoglobin concentration in animals of both sexes dosed at 0.05 and 0.3 mg/kg/day, increase of mean corpuscular haemoglobin in males receiving 0.3 mg/kg/day, increase of erythrocytes in females dosed at 0.1 mg/kg, increase of neutrophils in females treated with 0.05 and 0.1 mg/kg/day. Changes of the red series parameters were 2% to 9%, while neutrophils in females of low and mid-dose groups were increased by 66%.

Due to the minimal severity and/or the absence of dose-relation, the above changes were considered of no toxicological relevance.

Coagulation

Dosing Phase

Prothrombin time was slightly decreased in animals dosed at 0.1 and 0.3 mg/kg/day. Due to the minimal severity (up to 8%) and the direction of changes, this finding was considered of no toxicological importance.

REDACTED AS TO TRADE NAMES

Clinical Chemistry

Dosing Phase

Fluctuations of some biochemical markers were recorded in treated animals, males being more sensitive than females.

In general, changes comprised liver/metabolic parameters and were of low severity, therefore they could reflect mainly metabolic/adaptive changes rather than tissue/organ injury.

Increases of both transaminases enzymes were recorded in a number of animals, including controls. Degenerative hepatic changes were described at histopathological examination for few high dose males; however, no correlation was recorded with these findings, therefore no clear conclusions could be drawn.

Data are reported in the following table. Control data are expressed in absolute values and data from treated groups as percentage differences with controls:

	1M	2M	3M	4M	1F	2F	3F	4F
ALP	163.27	-4	0	42*C	112.05	7	-13	-16
ALT	70.64	-5	-15	41	40.66	31	1	-15
AST	100.79	-21	-21	-13	72.58	38	-5	-20+C
GGT	0	NA	NA	NA	0.88	-17	-42	-18
TBIL	0.024	-46	-46	-79	0.082	10	-21	-61+C
CHOL	64.91	-20+D	-26+D	-13*D	81.64	-12	-11	-10
TRIG	64.88	-31	-54+C	-53*C	42.74	-3	-11	28*D
GLU	168.98	-30*C	-22	6	113.34	-12	-7	18*D
UREA	42.42	-19+C	3	24+C	41.29	-5	1	0
CREA	0.387	-27	-15	-10	0.443	-14*D	-1°+D	-22+D
Cl	106.3	-1	-2	-1	106.79	1	0	0
Ca	2.455	0	1	3*C	2.410	1	5+C	3*C
Na	142.39	1	1	1	143.35	-1	0	0
K	4.392	-19	-13	-12	3.374	33	0	3
IP	6.208	-10	0	4	5.736	5	-3	1
PROT	6.23	-2	-2	-3	5.81	3	6+D	4*D
ALB	3.69	-1	-3	-3	3.55	3	6+D	5*D
GLO	2.54	-3	-1	-2	2.26	2	5	4

*C = Cochran and Cox Test significant at 0.05 level, +C = Cochran and Cox Test significant at 0.01 level

*D = Dunnett LSD Test significant at 0.05 level, +D = Dunnett LSD Test significant at 0.01 level

REDACTED AS TO TRADE NAMES

Recovery Phase

Some of the fluctuations recorded during the Dosing Phase were still present or showed partial reversibility. In particular, triglycerides and creatinine were lower than controls in all treated males and glucose was higher than controls in females dosed at 0.3 mg/kg/day.

As for the Dosing Phase, changes were mainly indicative of adaptive changes.

Animal no. A1474116 showed moderate increases of both transaminases enzymes. Since this finding was not recorded during the Dosing Phase, it cannot be conclusively attributed to treatment.

The other statistically significant changes recorded (calcium, protein and albumin in males, bilirubin, creatinine, chloride and potassium in females) were of low severity and/or not dose-related, therefore considered of no toxicological significance.

Data are reported in the following table. Control data are expressed in absolute values and data from treated groups as percentage differences with controls:

	1M	2M	3M	4M	1F	2F	3F	4F
ALP	190.56	-12	-15	-2	104.18	-8	-15	-5
ALT	41.46	20	77	159	44.16	-12	-12	-17
AST	64.00	9	30	27	65.95	-2	7	-3
GGT	0.50	NA	-48	-30	1.80	-92	NA	-86
TBIL	0.022	-36	45	-45	0.046	151+D	61	-35
CHOL	80.28	-20	-11	-10	94.66	-12	-17	-4
TRIG	82.16	-27*D	-29*D	-59+D	72.86	-31	-23	-22
GLU	158.88	-16	-29	-6	80.94	23	33*D	49+D
UREA	43.38	-16	9	1	37.78	-9	16	9
CREA	0.474	-19*D	-20+D	-19*D	0.514	-12*D	3	-11
Cl	101.80	4	2	2	108.70	-7+D	-5	-3
Ca	2.394	3	2	6+D	2.350	3	4	3
Na	141.66	-1	0	0	141.14	-1	0	-1
K	4.110	-9	-8	-9	3.562	-6	-15+D	-11
IP	4.478	5	14	22	4.264	-6	11	9
PROT	6.30	-2	-5*D	1	6.30	0	-1	-2
ALB	3.72	-2	-6+D	1	3.74	3	0	-1
GLO	2.58	-2	-2	1	2.56	-5	-3	-5

*D = Dunnett LSD Test significant at 0.05 level, +D = Dunnett LSD Test significant at 0.01 level

Pathology Report

[redacted]

13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD

RTC STUDY NO. A1474
FINALPATHOLOGY REPORT

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Detailed macroscopic observations were reported for individual animals in the study[1].

Histopathological evaluation was performed on all control and high dose group animals, as well as on all abnormalities detected at *post mortem*. On the basis of the treatment-related findings detected in the liver of both sexes and in the thyroid and pituitary of males only, the histopathological evaluation was extended to the above-mentioned organs/tissues in the intermediate groups (low and medium dosages) and in the animals sacrificed after 8 weeks of recovery period.

For ease and clarity of reporting, only tissues with findings are reported in the incidence tables.

Macroscopic observations

Final sacrifice

Treatment-related changes were noted at *post mortem* examination in the liver of most males and in one female receiving 0.3 mg/kg/day. Enlarged and/or swelling liver was the only macroscopic change observed in such treated animals.

Reduced size of the thymus was only noted in 2 out of 10 high dose females.

[1]The individual macroscopic and microscopic observations, as well as group incidence data, are included in the report as tables and appendices.

Recovery sacrifice

No treatment-related changes were noted at *post mortem* in the animals sacrificed after 8 weeks of recovery period.

Microscopic observations

Final sacrifice

Hepatocytic hypertrophy, associated with cytoplasmic eosinophilia, was seen in the liver of males and females receiving 0.3 mg/kg/day. In addition, males receiving [redacted] at ≥ 0.1 mg/kg/day also showed follicular cell hypertrophy in the thyroid, associated only in males dosed at 0.3 mg/kg/day with basophilic cell hypertrophy in the pars distalis of the pituitary.

The pathogenesis seen in males dosed at ≥ 0.1 mg/kg/day is a well-known mechanism, which initiates with the hepatic microsomal enzyme induction (hepatocytic hypertrophy), then subsequently with an increased clearance of the thyroid hormone and consequently the activation of the hypothalamus-pituitary-thyroid axis with the thyroid-releasing hormone (TRH) secretion, which develops the hypertrophy of thyrotrophs/basophilic cells in the pituitary gland (high dose males only), and then stimulates the hypertrophy of the follicular cell in the thyroid gland (increased synthesis and release of T3 and T4) (1) (2).

Hepatocytic hypertrophy was seen in high dose males with an increased severity degree and a major extention in the hepatic lobule (centrilobular/midzonal and in some occasions panlobular), when compared with that observed in males dosed at 0.1 mg/kg/day or in high dose females (0.3 mg/kg/day). Hepatocytic degenerative changes such as necrosis were also reported in few high dose males.

Micro and/or macrovescicular hepatocytic vacuolation, most like consistent with fatty change (steatosis), was noted in most males dosed at 0.05 and 0.1 mg/kg/day, as well as in few high dose females.

Recovery sacrifice

Hepatocytic hypertrophy, associated with cytoplasmic eosinophilia, sporadic hepatocytic necrosis and/or micro and/or macrovescicular hepatocytic vacuolation was observed in the liver of high dose males.

Micro and/or macrovescicular hepatocytic vacuolation was the only relevant liver change noted in the remaining treated males (low and medium dosages) sacrificed after 8 weeks of recovery period.

The remanining lesions reported in control and treated animals, in final and recovery sacrifice, were considered to be an expression of spontaneous and/or incidental pathology commonly seen in this species and age under our experimental conditions.

Conclusions

Hepatocellular hypertrophy may be considered an adaptive and reversible change that does not compromise functional integrity, in particular in all treated females and probably in males dosed at 0.05 and 0.1 mg/kg/day. On the other hand, in the presence of hepatic degenerative changes such as: hepatocyte necrosis, and/or steatotic vacuolar degeneration, micro and/or macro-vescicular vacuolation, observed in the high dose males and still present after 8 weeks of recovery period, the liver pathology may be considered adverse.

References

1) Liver Hypertrophy: A Review of Adaptive (Adverse and Non-adverse) Changes—Conclusions from the 3rd International ESTP Expert Workshop - Toxicologic Pathology, 40: 971-994, 2012

2) Characterization of Xenobiotic-Induced Hepatocellular Enzyme Induction in Rats: Anticipated Thyroid Effects and Unique Pituitary Gland Findings - Toxicologic Pathology, 39: 664-677, 2011

ADDENDUM 8 - Study Protocol and Protocol Amendment(s)

[redacted]

**13 WEEK ORAL TOXICITY STUDY IN RATS
FOLLOWED BY A 8 WEEK RECOVERY PERIOD**

Final Protocol
prepared for

SOLVAY SPECIALTY POLYMERS ITALY S.p.A.
Viale Lombardia, 20
20021 Bollate (MI)
Italy

a9 - DRAFT - 14th September 2016

by

RESEARCH TOXICOLOGY CENTRE S.p.A.
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Società soggetta all'attività di direzione e coordinamento di A. Menarini Industrie Farmaceutiche Riunite S.r.l. - Via Sette Santi 3 - 50131 Firenze - P.I. 00395270481

ADDENDUM 8 - Study Protocol and Protocol Amendment(s)

1. INTRODUCTION

1.1 Objective

The purpose of this study is to investigate the toxicity of [redacted] in rats after daily oral administration for 13 weeks and recovery from any treatment-related effects during a recovery period of 8 weeks. In addition, supplemental analyses will be conducted to investigate parameters that could be used as liver injury biomarkers.

1.2 Species

The Sprague Dawley SD rat is the species and strain of choice because it is accepted by many regulatory authorities and there is ample experience and background data on this species and strain.

1.3 Route of administration

The test item will be administered orally, by gavage. The oral route has been selected as it is a suitable route of testing generally considered appropriate for assessing potential adverse effects and perform risk assessment in man.

1.4 Regulatory compliance

This study will be conducted in compliance with the GLP regulations of:

- Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004;
- ENV/MC/CHEM(98)17 "OECD principles on Good Laboratory Practice – as revised in 1997";
- Decreto Legislativo no. 50 of 2 March 2007 and subsequent revisions.

The Sponsor has affirmed that the test item is a chemical product and that the study will be performed to comply with the relevant legislation for safety assessment, for notification or for submission to Regulatory Authorities.

This study design is in agreement with the procedures described in:

- OECD Guideline no. 408 'Repeated Dose 90-day Oral Toxicity Study in Rodents' adopted 21 September 1998.
- Test method B.26. "Sub-chronic Oral Toxicity Test repeated Dose 90-Day Oral Toxicity Study in Rodents " described in Council Regulation (EC) No. 440/2008 and subsequent revisions.

1.5 Animal welfare

Procedures and facilities will comply with the requirements of the Directive 2010/63/EU on the protection of animals used for scientific purposes. The national transposition of the Directive is defined in *Decreto Legislativo 26/2014.*
RTC test facility is fully accredited by AAALAC. Aspects of the protocol concerning animal welfare have been approved by RTC animal-welfare body.

2. TEST ITEM

2.1 Characterisation

It will be the responsibility of the Sponsor to determine, for each batch of test item, the identity, strength, purity and composition, or other characteristics which appropriately define the test item, before its use in the study. The determination of the stability of the test item will also be the Sponsor's responsibility.
A certificate of analysis for the test item should also be supplied.

2.2 Identity

The test item will be [redacted]

The following information refers to the original batch of test item received for the study:

Batch number	:	90409
Date of expiry	:	July 2020
Appearance	:	White solid
Storage conditions	:	Ambient

Should further batches be required to complete the study, full details of batch usage will be maintained in the formulation records but protocol amendments will not be issued.
The amount of test item received and used at RTC will be recorded according to RTC standard procedures.

2.3 Safety precautions

The precautions necessary when handling either the test item or prepared formulations of the test item are based on information supplied by the Sponsor. The minimum safety precautions necessary are detailed under the RTC Hazard Classification System, according to RTC standard procedures.

2.4 Vehicle

The vehicle will be sterile water.

2.5 Formulation procedure

The required amount of [redacted] will be dissolved in the vehicle. The formulation will be prepared daily (concentrations of 0.005, 0.01 and 0.03 mg/mL), unless specified otherwise. Concentrations will be calculated and expressed in terms of test item as supplied.

2.6 Formulation analysis

Validation of the analytical method will be carried as part of RTC Study No. A1474.
Analysis will be performed to confirm that the proposed formulation procedure is acceptable and that the stability of the formulation is satisfactory.
Samples of the formulations prepared in weeks 1 and 13 of the study will also be analysed to check the concentration.
Chemical analysis will be carried out by the Analytical Chemistry Department at RTC. The software used for this activity will be Analyst 1.6.2.

2.7 Disposal

Approximately 1 year after the final report has been issued, remaining amounts of the test item, with the exception of the reserve samples taken for archival purposes, will be destroyed by incineration.

3. TEST SYSTEM

3.1 Animal supply and acclimatisation

A total of 140 Hsd: Sprague Dawley SD rats (70 males and 70 females), 27-29 days old and with body weight of approximately 75-99 g, will be ordered from Harlan Italy s.r.l., San Pietro al Natisone (UD), Italy.
After arrival the weight range for each sex will be determined and the animals will be temporarily identified within the cage by means of a coloured mark on the tail. A health check will then be performed by a veterinarian.
An acclimatisation period of approximately 2 weeks will be allowed before the start of treatment, during which time the health status of the animals will be assessed by thorough observations. Rats considered unsatisfactory will be killed and where appropriate subjected to pathological examination. Unsatisfactory batches of animals will be rejected before the start of treatment.

3.2 Animal husbandry

The animals will be housed in a limited access rodent facility. Animal room controls will be set to maintain temperature and relative humidity at 22°C ± 2°C and 55% ± 15% respectively; actual conditions will be monitored, recorded and the records retained. There will be approximately 15 to 20 air changes per hour and the rooms will be lit by artificial light for 12 hours each day.
The animals will be housed up to 5 of one sex to a cage, in clear polysulphone solid bottomed cages as indicated in the relevant SOP. Nesting material will be provided inside suitable bedding bags; nesting material will be changed at least twice a week.
Drinking water will be supplied *ad libitum* to each cage via water bottles, except as noted in section 4.3.
A commercially available laboratory rodent diet (4 RF 21, Mucedola S.r.l., Via G. Galilei, 4, 20019 Settimo Milanese (MI), Italy) will be offered *ad libitum* throughout the study, except as noted in section 4.3.
There is no information available to indicate that any non-nutrient substance likely to influence the effect of the test item is present in the drinking water or the diet. Records of analyses of water and diet are kept on file at RTC.
Dated and signed records of activities relating to the day to day running and maintenance of the study in the animal house will be recorded.

3.3 Allocation to groups

On the day of allocation (about 7 days prior to the start of treatment) all animals will be weighed. Animals at the extremes of the weight distribution and/or any animal showing signs of ill health will be excluded to leave the required number of animals. The rats will be allocated to groups by computerised stratified randomisation to give approximately equal initial group mean body weights.

Individuals will be uniquely identified within the study by sex, tattoo on the hind feet and ear notch and housed up to 5 of one sex per cage.
The cages will be identified by a label recording the study number, animal numbers and details of treatment. The arrangement of cages in batteries will be such that cages from each treatment group will be evenly distributed across the battery (Annex 2) to minimise possible environmental effects.
Any animal showing signs of ill health during the period between allocation and the start of treatment will be subjected to pathological examination as considered appropriate, and replaced with a surplus animal selected from the same batch. No replacements will occur after the first dose is administered.

4. EXPERIMENTAL PROCEDURE

4.1 Treatment

4.1.1 Selection of dose levels

Dose levels have been selected in consultation with the Sponsor based on information from preliminary studies.

4.1.2 Dose levels, group size and identification

Each main group will comprise 10 male and 10 female rats. Each dose groups will include 5 additional animals per sex to be sacrificed after 8 weeks of recovery. The group identification and animal numbers assigned to the treatment are summarised below:

Group Number	Treatment (mg/kg/day)+	Level	Rat Numbers			
			Main phase		Recovery phase	
			M (even)	F (odd)	M (even)	F (odd)
1	0	Control	2-20	1-19	22-30	21-29
2	0.05	Low	32-50	31-49	52-60	51-59
3	0.1	Medium	62-80	61-79	82 - 90	81-89
4	0.3	High	92-110	91-109	112-120	111-119
+: in terms of test item as supplied						

The rat numbers listed above will form the last digits of a computer generated 8 figure animal number (the remaining digits of the animal number will be different for each concurrent study and will serve to ensure unique animal numbering for any study employing computerised data collection). The computerised system used in this study will be Pristima, Version 6.3.2.

4.1.3 Administration of test item

The test item will be administered orally by gavage at a dose volume of 10 mL/kg body weight. Control animals will receive the vehicle alone at the same dose volume.
The dose will be administered to each animal on the basis of the most recently recorded body weight and the volume administered will be recorded for each animal.

4.1.4 Duration of treatment

All animals will be dosed once a day, 7 days a week, for a minimum of 13 consecutive weeks. Animals in the main phase will be dosed up until the day before necropsy. Following end of treatment, recovery group animals (5 males and 5 females per group) will be observed for a recovery period of 8 weeks.

4.2 *In vivo* observations

Full records will be maintained for all measurements and observations.

4.2.1 Mortality

Throughout the study, all animals will be checked early in each working day and again in the afternoon. At weekends and Public Holidays a similar procedure will be followed except that the final check will be carried out at approximately mid-day. This will allow *post mortem* examinations to be carried out during the working period of that day. Severely debilitated animals will be observed carefully. Animals judged to be *in extremis* will be killed. A complete necropsy will be performed in all cases as detailed in section 4.4.2 below.

4.2.2 Clinical signs and neurotoxicity assessment

All clinical signs will be recorded for individual animals.
Once before commencement of treatment and once daily during the study, each animal will be observed and any clinical signs will be recorded.
Observations will be performed at the same time interval each day, the interval will be selected taking into consideration the presence of post-dose reactions.
Once before commencement of treatment and at least once per week from the start of treatment, each animal will be given a detailed clinical examination. Each animal will be observed in an open arena. The test will include observation of changes in gait and posture, reactivity to handling, presence of clonic or tonic movements, stereotypies or bizarre behaviour and effects on the autonomic nervous system (e.g. lachrymation, piloerection, unusual respiratory pattern). Changes in fur, skin, eyes, mucous membranes, occurrences of secretions and excretions will also be recorded.
Once during weeks 12 or 13 of treatment and once during week 8 of recovery an evaluation of sensory reactivity to stimuli of different modalities (e.g. auditory, visual and proprioceptive stimuli) and an assessment of grip strength will also be performed.

4.2.3 Motor activity assessment (MA)

The motor activity (MA) of all animals will be measured once during week 12 or 13 of treatment and once during week 8 of recovery by an automated activity recording. Measurements will be performed using a computer generated random order.

4.2.4 Body weight

Each animal will be weighed on the day of allocation to treatment group, on the day that treatment commences, weekly thereafter and just prior to necropsy.

4.2.5 Food consumption

The weight of food consumed by each cage of rats will be recorded at weekly intervals following allocation. The group mean daily intake per rat will be calculated.

4.2.6 Ophthalmoscopy

Both eyes of all animals assigned to the study will be examined just prior to the commencement of treatment by means of an ophthalmoscope, and by a slit-lamp microscope, after the instillation of 0.5% Tropicamide (Visumidriatic®, Visufarma, Rome, Italy). Where possible, animals with non-resolving lesions will be replaced with spare animals showing no ocular abnormality, from the batch initially ordered for the study. In the first instance the eyes of all animals from high-dose and control groups will be re-examined during week 13 of treatment. If treatment-related changes are observed the examination will be extended to the other treated groups (additional cost). Ophthalmoscopy will also be repeated during week 8 of recovery if considered necessary (additional cost).

4.3 Clinical pathology investigations

Prior to necropsy of main phase animals, blood samples will be taken in fasting conditions from the abdominal vena cava under isofluorane anaesthesia.
At the end of week 8 of the recovery period blood samples may also be taken (after consultation with the Sponsor) from all surviving animals under identical conditions in order to re-evaluate all those parameters which showed treatment-related changes at measurements performed during the treatment period (additional cost).

Blood samples will be collected and analysed in the same order. The blood samples collected will be divided into tubes as follows:

EDTA anticoagulant	for haematological investigations
Heparin anticoagulant	for biochemical tests
Citrate anticoagulant	for coagulation tests

The measurements to be performed on blood samples are listed below:

4.3.1 Haematology

Haematocrit
Haemoglobin
Red blood cell count
Reticulocyte count
Mean red blood cell volume
Mean corpuscular haemoglobin
Mean corpuscular haemoglobin concentration
White blood cell count
Differential leucocyte count
- Neutrophils
- Lymphocytes
- Eosinophils
- Basophils
- Monocytes
- Large unstained cells

Platelets

These parameters will be analysed by Siemens Advia 120.

<u>Coagulation</u>
Prothrombin time

This parameter will be analysed by Instrumentation Laboratory ACL 3000 PLUS.

4.3.2 Clinical chemistry

Alkaline phosphatase
Alanine aminotransferase
Aspartate aminotransferase
Gamma-glutamyltransferase
Urea
Creatinine
Glucose
Triglycerides
Phosphorus
Total bilirubin
Total cholesterol
Total protein
Albumin
Globulin
A/G Ratio
Sodium
Potassium
Calcium
Chloride

These parameters will be analysed by Siemens Advia 1200.

4.3.3 Additional investigations (Liver injury panel biomarkers determination and miRNA-122)

Once pre-dose and at the end of weeks 1, 4, 8 of and 13 treatment, additional blood samples will be withdrawn from the tail vein or, under isofluorane anaesthesia, from the abdominal vena cava of all main phase animals, under conditions of food deprivation.
The collected blood samples will be divided in two 0.5 mL aliquots with no anticoagulant and one 0.4 mL aliquot with Heparin anticoagulant.

Blood samples will be collected into tubes as indicated above, centrifuged and serum or plasma samples will be frozen at approximately -80°C until analysis. Analyses will be carried out using a stepwise approach according to the Decisional Tree indicated in Annex 3, and after consultation with the Sponsor.
At the end of week 8 of the recovery period, blood samples may also be taken (after consultation with the Sponsor) from all surviving animals under identical conditions in order to re-evaluate any parameter which showed treatment-related changes at measurements performed during the treatment period.

The analyses described in the sections below (4.3.3.1 and 4.3.3.2) will not be performed in full GLP compliance. Nevertheless the weight of GLP deviation is considered minor since these analyses will produce supporting data, not necessary for safety evaluation, but useful to determine the mechanism of liver injury and time of toxicity onset.

In the first instance analyses will be performed on samples taken after 1 and 4 weeks of treatment. Following result discussion, the investigation will proceed using a stepwise approach according to the Decisional Tree indicated in Annex 3, and after consultation with the Sponsor. In case of equivocal results analysis of pre-dose samples will be performed on selected animals.

4.3.3.1 Liver injury panel biomarkers determination

From the first frozen aliquot of serum sample the following parameters will be determined:

Arginase 1 (ARG1)
Aspartate aminotransferase 1 (GOT1)
Glutathione-S-Transferase alpha (GSTα)
Ecto-5'-nucleotidase (5'NT/CD73)
Sorbitol Dehydrogenase (SDH)

These parameters will be analysed by Luminex Magpix® with Milliplex® kit (Merk Millipore).

From the frozen aliquot of plasma sample the following parameter will be determined:

Alanine aminotransferase (ALT)

This parameter will be analysed by Siemens Advia 1200

4.3.3.2 miRNA-122 determination non- GLP external site

The purpose of these analyses is to evaluate serum levels of miRNA-122, a well known liver injury biomarker, in order to supply additional information on mechanisms of hepatic toxicity.

The second aliquot of frozen serum sample will be despatched directly to the following laboratory under dry ice conditions:

Attn: #
YLICHRON S.r.l.
Via Anguillarese, 301
00123 S.Maria di Galeria (Roma)
Italy
Tel : #
Fax : #
e-mail: #

This is a non-GLP certified laboratory (chosen in agreement with the Sponsor). Nevertheless for this kind of specialised investigations, expertise in molecular biology procedures is considered the most important factor. Raw data, records and documentation generated during this analytical phase, will be returned to the Sponsor after the issue of the Final Report.
Information about the actual dosing time, actual sampling time (hh:mm; 24h format, midnight as 00:00), number of samples obtained and storage conditions will be sent with the samples, when delivered to the Principal Scientist. A copy of this information will also be kept in the Study Records.
A Report of this activity will be provided to the Study Director and inserted in the report as an Addendum.

#: To be added in a protocol amendment

4.4 Terminal studies

4.4.1 Euthanasia

Animals *in extremis* and those that have completed the scheduled test period will be killed by exsanguination under isofluorane anaesthesia. All animals, including those found dead, will be subjected to necropsy, supervised by a pathologist, as detailed below.

4.4.2 Necropsy

The clinical history of the animal will be studied and a detailed *post mortem* examination will be conducted (including examination of the external surface and orifices).
Changes will be noted, the requisite organs weighed and the required tissue samples preserved in fixative and processed for histopathological examination (see sections 4.4.3 to 4.4.5).
Representative photographs will be taken of any significant findings, if considered appropriate.

4.4.3 Organ weights

From all animals completing the scheduled test period, the organs indicated in Annex 1 will be dissected free of fat and weighed.
The ratios of organ weight to body weight will be calculated for each animal.
At the discretion of the pathologist, organs may be weighed from animals dying or killed prior to terminal kill.

4.4.4 Tissues fixed and preserved

Samples of all the tissues listed in Annex 1 will be fixed and preserved in 10% neutral buffered formalin (except eyes, testes and epididymides which will be fixed in Modified Davidson's fluid and preserved in 70% ethyl alcohol).

A small liver sample will be processed as follows for possible further investigations. Tissue samples will be rinsed with cold saline solution, divided into two aliquots, weighed, flash-frozen in liquid nitrogen and stored at approximately -80°C pending analysis.

4.4.5 Histopathological examination

The tissues required for histopathological examination are listed in Annex 1. After dehydration and embedding in paraffin wax, sections of the tissues will be cut at 5 micrometre thickness and stained with haematoxylin and eosin.

In the first instance the examination will be as detailed below:

a) Tissues specified in Annex 1 from all animals in the control and high dose groups dying during the treatment period or killed at the end of the 13 weeks of treatment.
b) Tissues specified in Annex 1 from all animals killed or dying during the treatment period
c) All abnormalities in all main phase groups

The examination could then be extended to include, from all other animals killed after 13 weeks of treatment or 8 weeks of recovery, those tissues in which there is any suspicion of treatment-related change at the high dose level.

All histopathological activities which cannot be foreseen before the start of the study (i.e. processing of: abnormalities in all groups, tissues of unscheduled deaths in the low and medium dose groups, target tissues in the low, medium dose and recovery groups) will incur an additional cost.

4.4.6 Photomicrographs

Representative photomicrographs may be taken of any treatment-related lesions. Other photomicrographs may be taken as required by the Sponsor (additional cost).

5. ANALYSIS OF DATA

5.1 Presentation of data

The data will be summarised and presented in the form of tables or figures. Individual observations and findings for each animal will also be tabulated.

5.2 Statistics

For continuous variables the significance of the differences amongst group means will be assessed by Dunnett's test or a modified *t* test, depending on the homogeneity of data.
Statistical analysis of histopathological findings will be carried out by means of the non-parametric Kolmogorov-Smirnov test.

6. AMENDMENTS TO THE PROTOCOL

It is not intended to make any amendment to this protocol without authorisation by the Sponsor. However, in the event of difficulty in contacting the Sponsor and/or for humane reasons and/or for the protection of scientific integrity, the testing laboratory retains the right to take independent action.

7. REPORTING

7.1 Interim report

Any unexpected findings during the course of the study will be reported to the Sponsor's Monitoring Scientist immediately.

7.2 Final report

A Draft Report will be sent to the Sponsor together with the Draft Report Approval Form. With the exception of signatures, the Draft Report will contain all information and data included in the Final Report.
Comments made by the Sponsor may be incorporated and the Final Report will be issued. If comments are not received within 6 months from despatch of the Draft Report, the Final Report will be issued.

The Final Report will include the information and data required by current internationally recognised regulations. The Final Report, digitally signed or with handwritten signatures, will be issued as PDF file, searchable, bookmarked and hyperlinked, fully compliant with the standard PDF/A-1b (ISO 19005-1 Level B), suitable for long term archiving of electronic document.

7.3 Corrections or additions to the final report

Corrections or additions to the approved (i.e. signed) version of the final report will be in the form of an amendment by the Study Director.

8. RECORDS AND ARCHIVES

Full records will be maintained of all aspects of study conduct, together with results of all measurements and observations. Prior to final archiving of the study data, a full list will be prepared of all records associated with the study.
A reserve sample of each batch of the test item will be taken and kept under the storage conditions of the bulk supply at RTC. The reserve sample(s) of the test items and control item will be retained within RTC archives for a period of 10 years and then destroyed.
Any biological samples obtained for analytical measurements or similar determinations will be managed as indicated by the Sponsor in the Draft Report Approval Form or otherwise destroyed at no charge within 3 months from the issue of the Final Report.
The Final Protocol, the Final Report and electronic raw data generated by RTC main validated systems (Pristima, Analyst, Empower, where used) will be archived at RTC.

All other specimens, raw data, records and documentation generated during the course of this study will be archived at RTC for a period of 3 years, after which the Sponsor will be contacted for shipment or disposal of the material (expenses will be charged to the Sponsor).

9. QUALITY ASSURANCE

According to the RTC quality assurance programme, defined in the RTC QA SOPs, this study will be subjected to the following procedures:

- the protocol will be inspected,
- study/process based inspections of procedures/facilities will be carried out at intervals adequate to assure the integrity of the study,
- the report will be inspected to assure that it accurately describes the methods and Standard Operating Procedures and that the results accurately reflect the raw data.

Periodic reports on these activities will be made to management and the Study Director.
All raw data pertaining to the study will be available for inspection by the Sponsor's representative and regulatory authorities.

10. LOCATION OF THE STUDY

Research Toxicology Centre S.p.A.
Via Tito Speri, 12/14
00071 Pomezia (Roma)
Italy

11. PROJECTED TIME PLAN

		Date
1.	Start of treatment	: First week of October 2015
2.	End of *in vivo* phase	: First week of March 2016
3.	End of histopathological examination	: Second week of March 2016
4.	QA-audited draft report to Sponsor	: 12 weeks from the end of the *in vivo* phase

Any change in the experimental design and/or any additional activity requested to maintain the scientific or regulatory integrity might cause a change in the time frame.

ANNEX 1. TISSUE PROCESSING

Organs / Tissues	Weight	Fixation Preservation	Microscopic Examination
Abnormalities		✓	✓
Adrenal glands	✓	✓	✓
Aorta		✓	✓
Bone marrow (from sternum)		✓	✓
Brain (cerebrum, cerebellum, medulla/pons)	✓	✓	✓
Caecum		✓	✓
Colon		✓	✓
Duodenum		✓	✓
Epididymides	✓	✓	✓
Eyes		✓	✓
Femur with joint		✓	✓
Heart	✓	✓	✓
Ileum		✓	✓
Jejunum (including Peyer's patches)		✓	✓
Kidneys	✓	✓	✓
Larynx		✓	✓
Liver	✓	✓	✓
Lungs (including mainstem bronchi)		✓	✓
Lymph nodes - cervical		✓	✓
Lymph nodes - mesenteric		✓	✓
Mammary area		✓	✓
Nasopharynx		✓	✓
Oesophagus		✓	✓
Optic nerves		✓	✓
Ovaries	✓	✓	✓
Oviducts[a]		✓	✓
Pancreas		✓	✓
Parathyroid glands[b]		✓	✓
Pituitary gland		✓	✓
Prostate gland		✓	✓
Rectum		✓	✓
Salivary glands		✓	✓
Sciatic nerve		✓	✓
Seminal vesicles		✓	✓
Skeletal muscle		✓	✓
Skin		✓	✓
Spinal column		✓	
Spinal cord (cervical, mid-thoracic, lumbar)		✓	✓
Spleen	✓	✓	✓
Stomach		✓	✓
Testes	✓	✓	✓

a: weighed and preserved with ovaries
b: preserved with thyroid gland
*: to be examined if indicated by signs of toxicity or target organ involvement.

Organs / Tissues	Weight	Fixation Preservation	Microscopic Examination
Thymus (where present)	✓	✓	✓
Thyroid		✓	✓
Trachea		✓	✓
Urinary bladder		✓	✓
Uterus – cervix	✓	✓	✓
Vagina		✓	✓

ANNEX 2. GROUP AND CAGE ARRANGEMENT ON BATTERY

MAIN PHASE

Group Number	Treatment (mg/kg/day)+	Level	Rat numbers		Cage numbers	
			M (even)	F (odd)	M	F
1	0	Control	2-20	1-19	1 - 2	13 - 14
2	0.05	Low	32-50	31-49	4 - 5	16 - 17
3	0.1	Medium	62-80	61-79	7 - 8	19 - 20
4	0.3	High	92-110	91-109	10 - 11	22 - 23

RECOVERY PHASE°

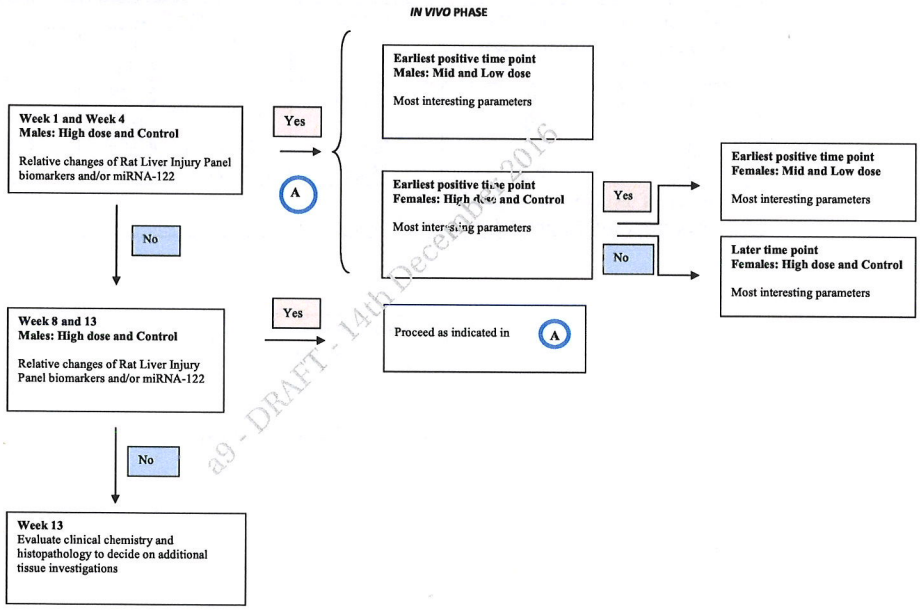
Group Number	Treatment (mg/kg/day)+	Level	Rat numbers		Cage numbers	
			M (even)	F (odd)	M	F
1	0	Control	22-30	21-29	3	15
2	0.05	Low	52-60	51-59	6	18
3	0.1	Medium	82 - 90	81-89	9	21
4	0.3	High	112-120	111-119	12	24

+ In terms of test item as supplied.
° No treatment will be given during the recovery period.

Group/Sex
Cage no.

To be inserted in the Final Report

ANNEX 3. DECISION TREE



a9 - DRAFT - 14th December 2015

PROTOCOL APPROVAL PAGE

for

R.T.C. S.p.A.

VERIFIED BY : Luca Luperi — 14 Sept. 2015
L. Luperi, D.V.M.
Senior Veterinarian & Head, Veterinary Services - Representative of animal-welfare body
Date

VERIFIED BY : [signature] — 14 Sept. 2015
S. Venturella, Biol.D.
Associate Scientific Director - Senior Scientist & Head, Study Directors
Date

a9 - DRAFT - 14th September 2016

VERIFIED BY : [signature] — 14 Sept. 2015
M. Eileraas, Pharm.D.
Expert in General Toxicology & Coordinator of Study Directors
Date

APPROVED BY : Anna Longobardi — 14-Sep-15
C. Longobardi, Biol.D.
Study Director
Date

PROTOCOL APPROVAL PAGE

for

SOLVAY SPECIALTY POLYMERS ITALY S.p.A.

AUTHORISED BY : _____ 15 Sept. 2015
Date

Name and Title * : Annie BUARD, Regulatory Toxicologist

* Please print or type your name and company status below your signature.

Date of Protocol Authorization: n/a

RTC Research Toxicology Centre

PROTOCOL AMENDMENT (1)

STUDY TITLE	:	[redacted] 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD
STUDY NO.	:	A1474
DATE OF PROTOCOL APPROVAL	:	14 September 2015

THE FOLLOWING SECTIONS ARE TO BE AMENDED:

4.3 Clinical pathology investigations (page 7)

Delete	:	Prior to necropsy of main phase animals, blood samples will be taken in fasting conditions from the abdominal vena cava under isofluorane anaesthesia. At the end of week 8 of the recovery period blood samples may also be taken (after consultation with the Sponsor) from all surviving animals under identical conditions in order to re-evaluate all those parameters which showed treatment-related changes at measurements performed during the treatment period (additional cost).
Insert	:	Prior to necropsy of main phase animals, blood samples will be taken in fasting conditions from the abdominal vena cava under isofluorane anaesthesia. At the end of week 8 of the recovery period blood samples will also be taken (in agreement with the Sponsor) from all surviving animals under identical conditions in order to re-evaluate clinical chemistry parameters, since potential treatment-related changes were observed at measurements performed at the end of treatment period.
Reason	:	Additional evaluations required at the end of recovery.

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Società soggetta all'attività di direzione e coordinamento di A. Menarini Industrie Farmaceutiche Riunite S.r.l. - Via Sette Santi 3 - 50131 Firenze - P.I. 00395270481

PROTOCOL AMENDMENT (1)

4.3.3 Additional investigations (Liver injury panel biomarkers determination and miRNA-122) (page 8)

Delete	:	At the end of week 8 of the recovery period, blood samples may also be taken (after consultation with the Sponsor) from all surviving animals under identical conditions in order to re-evaluate any parameter which showed treatment-related changes at measurements performed during the treatment period.
Insert	:	At the end of week 8 of the recovery period, blood samples will also be taken (in agreement with the Sponsor) from all surviving animals under identical conditions in order to have the possibility to re-evaluate any parameter which showed treatment-related changes at measurements performed during the treatment period.
Reason	:	To allow possible additional evaluations at the end of recovery.

DRAFT - Until Executed

PROTOCOL AMENDMENT (1)

APPROVAL PAGE

for

R.T.C. S.p.A.

VERIFIED BY : L. Luperi, D.V.M. — Date: 26 Feb. 2016
Senior Veterinarian & Head, Veterinary Services - Representative of animal-welfare body

VERIFIED BY : S. Venturelia, Biol.D. — Date: 26 Feb 2016
Associate Scientific Director - Senior Scientist & Head, Study Directors

a9 - DRAFT - November 2015

VERIFIED BY : M. Eileraas, Pharm.D. — Date: 26 Feb. 2016
Expert in General Toxicology & Coordinator of Study Directors

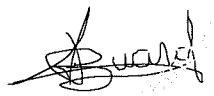
APPROVED BY : C. Longobardi, Biol.D. — Date: 26-Feb-2016
Study Director

PROTOCOL AMENDMENT (1)

APPROVAL PAGE

for

SOLVAY SPECIALTY POLYMERS ITALY S.p.A.

AUTHORISED BY : 

February 29, 2016
Date

Name and Title * : Annie Buard, Solvay PRA-PS, Regulatory toxicologist

* Please print or type your name and company status below your signature.

ADDENDUM 8 - Study Protocol and Protocol Amendment(s)

RTC Research Toxicology Centre

PROTOCOL AMENDMENT (2)

STUDY TITLE	:	[redacted] 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD
STUDY NO.	:	A1474
DATE OF PROTOCOL APPROVAL	:	14 September 2015

THE FOLLOWING SECTION IS TO BE AMENDED:

4.4.5 Histopathological examination (page 10)

Delete	:	The examination could then be extended to include, from all other animals killed after 13 weeks of treatment or 8 weeks of recovery, those tissues in which there is any suspicion of treatment-related change at the high dose level.
Insert	:	The examination will be extended to include the liver from female animals killed after 13 weeks of treatment (main phase groups 2 and 3) and 8 weeks of recovery (recovery phase groups 1, 2, 3 and 4) and the liver, thyroid gland and pituitary gland from male animals of the same groups, since there is suspicion of treatment-related changes at the high dose level.
Reason	:	Additional evaluations required at the end of recovery.

a9 - DRAFT - 14 October 2015

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PROTOCOL AMENDMENT (2)

APPROVAL PAGE

for

R.T.C. S.p.A.

VERIFIED BY : _____ 06 Apr. 2016
L. Luperi, D.V.M. Date
Senior Veterinarian & Head, Veterinary Services -
Representative of animal-welfare body

VERIFIED BY : _____ 06 Apr 2016
S. Venturella, Biol.D. Date
Associate Scientific Director - Senior Scientist &
Head, Study Directors

VERIFIED BY : _____ 06 Apr. 2016
M. Eileraas, Pharm.D. Date
Expert in General Toxicology &
Coordinator of Study Directors

APPROVED BY : _____ 06 Apr. 2016
C. Longobardi, Biol.D. Date
Study Director

PROTOCOL AMENDMENT (2)

APPROVAL PAGE

for

SOLVAY SPECIALTY POLYMERS ITALY S.p.A.

as DRAFT - 14th December 2016

AUTHORISED BY : _____ 06 April 2016
Date

Name and Title * : A. BUARD Regulatory Toxicologist.

* Please print or type your name and company status below your signature.

RTC Research Toxicology Centre

PROTOCOL AMENDMENT (3)

STUDY TITLE	:	[redacted] 13 WEEK ORAL TOXICITY STUDY IN RATS FOLLOWED BY A 8 WEEK RECOVERY PERIOD
STUDY NO.	:	A1474
DATE OF PROTOCOL APPROVAL	:	14 September 2015

THE FOLLOWING SECTIONS ARE TO BE AMENDED:

4.3.3 Additional investigations (Liver injury panel biomarkers determination and miRNA-122) (page 8)

Delete : Whole section

4.3.3.1 Liver injury panel biomarkers determination and
4.3.3.2 miRNA-122 determination non- GLP external site (page 9)

Delete : Whole sections

Insert : Once pre-dose and at the end of weeks 1, 4, 8 of and 13 treatment, additional blood samples will be withdrawn from the tail vein or, under isofluorane anaesthesia, from the abdominal vena cava of all main phase animals, under conditions of food deprivation.
The collected blood samples will be divided in two 0.5 mL aliquots with no anticoagulant and one 0.4 mL aliquot with Heparin anticoagulant.
Blood samples will be collected into tubes as indicated above, centrifuged and serum or plasma samples will be frozen at approximately -80°C until analysis.
Following Sponsor's request, no analyses will be carried out on the above samples. They will be eliminated within 3 months from the issue of Final Report.

Reason : Evaluations not required as requested by the Sponsor.

ANNEX 3. DECISION TREE (page 17)

Delete : Whole Annex

Reason : Evaluations not required as requested by the Sponsor.

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Società con unico azionista - capitale sociale € 17.000.000,00 i.v. - REA n. 375736 del CCIAA di Roma - C.F. 00653120584 - P.I. IT00920611001
Società soggetta all'attività di direzione e coordinamento di A. Menarini Industrie Farmaceutiche Riunite S.r.l. - Via Sette Santi 3 - 50131 Firenze - P.I. 00395270481

PROTOCOL AMENDMENT (3)

APPROVAL PAGE

for

R.T.C. S.p.A.

VERIFIED BY : _____ 13 Dec. 2016
L. Luperi, D.V.M. Date
Senior Veterinarian & Head, Veterinary Services -
Representative of animal-welfare body

VERIFIED BY : _____ 13 Dec 2016
S. Venturella, Biol.D. Date
Associate Scientific Director - Senior Scientist &
Head, Study Directors

ag - DRAFT - 13 December 2016

VERIFIED BY : _____ 13 Dec. 2016
M. Eileraas, Pharm.D. Date
Expert in General Toxicology &
Coordinator of Study Directors

APPROVED BY : _____ 13-Dic-2016
C. Longobardi, Biol.D. Date
Study Director

PROTOCOL AMENDMENT (3)

APPROVAL PAGE

for

SOLVAY SPECIALTY POLYMERS ITALY S.p.A.

AUTHORISED BY : _____ 13 December 2016
Date

Name and Title : A. Buard
Regulatory Toxicologist