
8) OECD 407, Repeat dose oral
toxicity (with FOB &
histopathology), 132-007

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**A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485
IN SPRAGUE-DAWLEY RATS**

DEC 09 2003

STUDY NUMBER: 132-007

SPONSOR

3M Corporate Toxicology
3M Center, Building 220-2E-02
P.O. Box 33220
St. Paul, MN 55133-3320

SPONSOR'S REPRESENTATIVE

Senior Laboratory Manager
Telephone:
FAX:

TESTING FACILITY

Primedica Redfield
Mail: P.O. Box 308
Deliveries: 100 East Boone St.
Redfield, AR 72132
Telephone: 501-397-2540
FAX: 501-397-2002

STUDY DATES

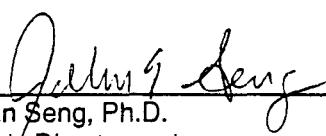
Study Initiation: August 29, 2000
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GLP COMPLIANCE STATEMENT

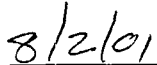
Study Number: 132-007

I certify that this study was performed in compliance with the Organization for Economic Cooperation and Development (OECD) Guidelines [C(81)30 (Final)] with the following exception. The analyses of the formulated test materials were not performed in accordance with Good Laboratory Practice guidelines.

The report accurately reflects the raw data.



John Seng, Ph.D.
Study Director
Primedica Redfield



Date

QUALITY ASSURANCE STATEMENT

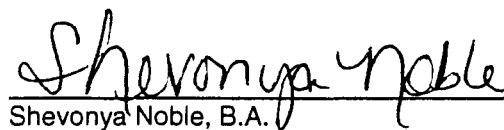
Study Number: 132-007

This study has been inspected and audited by the Quality Assurance Unit (QAU) as required by the Organization for Economic Cooperation and Development (OECD) Guidelines [(C(81)30 (Final)]. The following is a record of the dates that audits/inspections were performed and reported by the QAU.

DATE OF AUDIT/INSPECTION	TYPE OF AUDIT/INSPECTION	DATES REPORTED TO STUDY DIRECTOR AND MANAGEMENT
08/29/00	Protocol	08/29/00
08/31/00	Dosing	08/31/00
09/06/00	Formulations	09/06/00
09/18/00	Amendment #1	09/18/00
10/24/00, 10/26/00	Formulations Raw Data	10/26/00
10/24/00-10/26/00	In-Life Raw Data	10/26/00
10/30/00	Individual Animal Necropsy Records	10/30/00
11/01/00	Clinical Pathology	11/01/00
11/07/00	Tables	11/07/00
11/07/00	Gross Pathology	11/07/00
12/11/00-12/12/00	Draft Report	12/12/00
07/24/01	Final Report	07/24/01

The report accurately reflects the original data.

APPROVED BY:

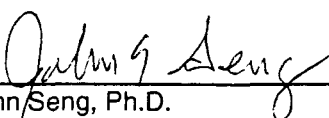
 8/2/01
Date

Shevonya Noble, B.A.
Quality Assurance Auditor
Primedica Redfield

TITLE

A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

APPROVED BY:



John Seng, Ph.D.
Study Director
Primedica Redfield

8/2/01
Date

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A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS**STUDY ABSTRACT**

The objective of this study was to evaluate the toxicity potential associated with oral (gavage) administration of T-7485 in Sprague-Dawley rats for a 28-day repeated dose with an approximate 14-day recovery period.

Healthy animals were acclimated for ten days prior to Study Day 1. Fifty males and fifty females were randomly assigned to groups and the study design was as follows:

Group Number	Group Designation	Dosage Level (mg/kg)	Dosage Concentration (mg/mL)	Dosage Volume (mL/kg)	Number of Animals*	
					Males	Females
1	Vehicle Control	0	0	25	10 (5)	10 (5)
2	Mid-dose	100	4	25	10	10
3	Mid-high dose	300	12	25	10	10
4	High-dose	900	36	25	10 (5)	10 (5)

*Number in parentheses indicates the number of Recovery animals

The animals were administered the test material or vehicle via oral gavage for 28 consecutive days. The first day of dosing was designated as Study Day 1. The dose volume was constant for all groups at 25 mL/kg. Individual dose volumes were calculated based on the most recently recorded body weight for each animal. Five animals/sex/group in the vehicle control and high-dose groups were designated as Recovery animals and allowed to recover for approximately 14 days.

No mortality was recorded during the 28-day administration of T-7485 or during the recovery period. Clinical observations consisted of localized alopecia (back, limbs, neck, and underside), urine-stained abdominal fur, scabbed area on back and neck, and soft or liquid feces. These findings are considered incidental and unrelated to test material administration. Additional cageside observations were all normal.

Assessment of neurological effects on animals treated with T-7485 included peripheral neuropathy, motor activity, and audio/visual evaluations. There were no test material-related effects on motor activity or audio/visual. Interpretation of peripheral neurological findings suggests no test material-related neuropathology, but within this evaluation the significant findings for the tail flick examination may suggest T-7485 induced a male-specific dose-independent hyperactivity.

There were no treatment-related effects on body weight for either Main Study or Recovery animals. On Study Day 36, the mean body weight in males that received 900 mg/kg/day T-7485 was decreased by 7% when compared to the corresponding controls. This finding was considered incidental.

Throughout the study, body weight changes and absolute feed consumption in treatment groups were calculated and compared to the corresponding control groups with no significant findings recorded for either Main Study or Recovery animals.

The reported significant hematological findings are considered incidental and not associated with test material administration.

Main Study clinical chemistry findings in males that received ≥ 300 mg/kg/day T-7485 indicate significant decreases in serum phosphorus (approximately 16% of the control values) and potassium (approximately 20% of the control values). In contrast, an increase in chloride levels in

males that received 900 mg/kg/day T-7485 (4% above the control values) was recorded. In the absence of similar findings in Recovery animals, the changes in phosphorus, potassium, and chloride levels appear to be associated with test material administration but do not appear to be toxicologically or biologically significant. Other incidental findings do not appear to be related to administration of test material.

Absolute and relative male liver (between 25% to 30%) and female kidney (9% to 11%) weights were significantly increased in animals that received 900 mg/kg/day T-7485 when compared to the corresponding controls. These significant changes were not recorded during the recovery period, and since there does not appear to be an effect of body weight on organ development, these data suggest the changes are test material-related. However, the biological and toxicological significance is unclear due to the lack of any supportive gross or histopathological findings. The remaining significant findings are considered incidental and unrelated to test material administration.

Only one gross lesion was recorded at necropsy and was not considered to be test material-related. The microscopic lesions observed in the test animals are considered to be incidental and in no way related to receiving the test material.

Oral (gavage) administration of T-7485 in Sprague-Dawley rats for a 28-day repeated dose with an approximate 14-day recovery period resulted in no mortality or abnormal clinical observations as well as no changes in body weights, feed consumption, peripheral neuropathy, motor activity, audio/visual response, hematology, clinical chemistry, gross pathology, and histopathology. These data suggest that administration of 900 mg/kg/day T-7485 resulted in significant increases in male liver and female kidney weights when compared to control animals and establishes the no-observable-adverse-effect-level (NOAEL) at 300 mg/kg/day T-7485. Furthermore, the T-7485 non-dose-dependent hyper-reactivity effect is gender specific and is therefore difficult to interpret.

OBJECTIVE

The objective of this study was to evaluate the toxicity potential associated with oral (gavage) administration of T-7485 in Sprague-Dawley rats for a 28-day repeated dose with an approximate 14-day recovery period.

MATERIALS AND METHODS

TEST AND CONTROL MATERIALS: The test material and vehicle control material were identified as follows:

Test Material:	T-7485 (Potassium Perfluorobutane Sulfonate, PFBS)
Lot Number:	2
Dates Received:	April 6, 2000; August 30, 2000
Physical Description:	White powder
Storage:	Room temperature, protected from light
Amount Received:	Total of 900 grams

Vehicle Material:	Carboxymethylcellulose (medium viscosity)
Lot Number:	69H0028
Supplier:	Sigma Chemical Company
Physical Description:	White powder
Storage:	Room temperature

The Sponsor assumed responsibility for characterization (identity, purity, and stability) determinations of the test material. The test material was inventoried when received at Primedica Redfield, and a record of all test material usage was maintained. The Certificate of Analysis for the test material is in Appendix 14. Reserve samples of each lot of test and vehicle control materials were retained at Primedica Redfield for archiving in accordance with Good Laboratory Practices.

The vehicle control material was prepared at Primedica Redfield by dissolving powdered carboxymethylcellulose in deionized water (from tap at Primedica Redfield) at a concentration of 1%.

Test material solutions were prepared to the required concentrations at Primedica Redfield by dissolving the test material in the prepared vehicle. Each batch of dosing solutions was prepared a maximum of 14 days prior to the last day of use. The formulated test materials were stored refrigerated in amber glass bottles.

A sample (5 mL) of each concentration of the formulated test material and vehicle was retained predose and on the last day of dosing for each batch. The samples were frozen at approximately -20°C. Prior to dosing, all predose samples were shipped to Southern Research Institution for analysis. All samples collected on the last day of dosing for each batch were shipped to Southern Research Institute for analysis after study termination.

TEST ANIMALS: Healthy male and female Crl: CD® (SD) out-bred albino rats were received from Charles River Laboratories, Inc., for use on the study. The animals were individually housed in screen-bottom stainless steel cages. Animal identification consisted of uniquely numbered ear tags and color-coded cage cards. On Study Day 1, the animals were approximately eight weeks old. The males weighed 209 to 253 grams, and the females weighed 178 to 212 grams.

Teklad Certified Rodent Diet #8728 and filtered tap water were provided *ad libitum*. The feed and water were routinely analyzed for contaminants. There were no known contaminants in the feed or water that would be expected to affect the results of the study. The results of these analyses are on file at Primedica Redfield.

Environmental controls were set to maintain temperatures of 18° to 26°C (64° to 79°F) with a relative humidity of 30% to 70%. These parameters were recorded at least once daily. A 12:12 hour light:dark cycle was maintained in the animal room.

GROUP DESIGNATION AND TREATMENT: The animals were acclimated for ten days prior to Study Day 1 and were examined by the Staff Veterinarian prior to being released for use on the study. Fifty males and fifty females were randomly assigned to groups by a computer generated weight-ordered distribution such that individual body weights did not exceed $\pm 20\%$ of the mean weight for each sex. The study design was as follows:

Group Number	Group Designation	Dosage Level (mg/kg)	Dosage Concentration (mg/mL)	Dosage Volume (mL/kg)	Number of Animals*	
					Males	Females
1	Vehicle Control	0	0	25	10 (5)	10 (5)
2	Mid-dose	100	4	25	10	10
3	Mid-high dose	300	12	25	10	10
4	High-dose	900	36	25	10 (5)	10 (5)

*Number in parentheses indicates the number of Recovery animals

The animals were administered the test material or vehicle via oral gavage for 28 consecutive days. The first day of dosing was designated as Study Day 1. The dose volume was constant for all groups at 25 mL/kg. Individual dose volumes were calculated based on the most recently recorded body weight for each animal. Five animals/sex/group in the vehicle control and high-dose groups were designated as Recovery animals and allowed to recover for approximately 14 days.

JUSTIFICATION FOR SPECIES SELECTION, ROUTE OF ADMINISTRATION, AND DOSE LEVEL: Rats are an animal model for studies of this type. In the assessment and evaluation of the toxic characteristics of a substance, determination of acute oral toxicity is usually an initial step. Dose levels were chosen by the Sponsor and based on the findings reported in Primedica Redfield Study Number 132-006.

CLINICAL OBSERVATIONS: Observations for mortality and moribundity were recorded twice daily (a.m. and p.m.). Cageside observations were recorded at approximately one to two hours postdose daily and when a change was noted.

Detailed clinical observations were recorded once before the first dose and at least weekly thereafter or when a change was noted.

During Week 4, each animal was assessed for sensory reactivity to stimuli of different types (e.g., auditory and visual), grip strength, and motor activity.

BODY WEIGHTS: Body weights were recorded pretest, on Study Day 1, approximately weekly, prior to terminal fasting, and prior to necropsy (fasted weight). The pretest body weights are not included in this report but are located in the raw data. The fasted body weights recorded prior to necropsy were used only for the calculation of relative organ weights.

FEED CONSUMPTION: Feed consumption was measured approximately weekly.

HEMATOLOGY: Blood samples for hematological analysis were obtained via cardiac puncture prior to necropsy. The animals were anesthetized with carbon dioxide for the collection. Feed was withheld overnight prior to collection. The blood samples were evaluated for the following parameters: total and relative differential leukocyte counts, erythrocyte counts, hemoglobin concentration, hematocrit value, mean corpuscular volume, mean corpuscular hemoglobin, mean

corpuscular hemoglobin concentration, platelet counts, prothrombin time, and activated partial thromboplastin time. Specific methods for hematology analyses are located in Appendix 1.

CLINICAL CHEMISTRY: Blood samples for clinical chemistry analysis were obtained via cardiac puncture prior to necropsy. The animals were anesthetized with carbon dioxide for the collection. Feed was withheld overnight prior to collection. The samples were processed and evaluated for the following parameters: total protein, albumin, globulin, albumin/globulin ratio, glucose, cholesterol, triglycerides, total bilirubin, urea nitrogen, creatinine, alanine aminotransferase, aspartate aminotransferase, alkaline phosphatase, gamma-glutamyltransferase, calcium, phosphorus, sodium, potassium, and chloride. Specific methods for clinical chemistry analyses are located in Appendix 1.

NECROPSY AND ORGAN WEIGHTS: On Study Day 29, all animals except for the Recovery animals were humanely euthanized via anesthesia with carbon dioxide to effect followed by exsanguination and submitted for a complete necropsy examination. On Study Day 44/43 (males/females), the Recovery animals (five animals/sex/group in Groups 1 and 4) were humanely euthanized and submitted for a complete necropsy examination. A complete necropsy was defined as examination of the external surface of the body; all orifices; and the cranial, thoracic, and abdominal cavities and their contents.

Organ weights were recorded for the following organs prior to fixation: adrenal glands, brain, heart, kidneys, liver, ovaries, spleen, thymus, and testes. Paired organs were weighed together.

The following organs and tissues were examined *in situ*, dissected free, and fixed in 10% neutral buffered formalin: adrenal glands, aorta, bone marrow (sternum), brain (brain stem, cerebellum, cerebrum), cervix, epididymides, esophagus, eyes (with optic nerve), femur (with articular surface), gross lesions, Harderian gland, heart, large intestine (cecum, colon, rectum), small intestine (duodenum, ileum, jejunum), kidneys, lacrimal gland, liver, lungs (with bronchi), lymph nodes (mesenteric, mandibular), mammary gland, ovaries, oviducts, pancreas, pituitary gland, prostate gland, salivary gland (mandibular), sciatic nerve, seminal vesicles, skeletal muscle, spinal cord (cervical, thoracic, lumbar), spleen, stomach (forestomach, glandular), testes, thymus, thyroid/parathyroid, tongue, trachea, uterus, urinary bladder, vagina, and Zymbal's gland.

HISTOPATHOLOGY: Histopathology was performed on all tissues from the vehicle control, high-dose, and Recovery animals and on all gross lesions.

Fixed tissues were shipped to Pathology Associates International where they were processed through paraffin, sectioned at approximately five microns, and stained with hematoxylin and eosin. The slides were evaluated microscopically by John Pletcher, D.V.M., DACVP.

STATISTICS: Means and standard deviations were calculated for all quantitative data. Treated groups of the same sex were compared to Group 1 (vehicle control) at common time points using an ANOVA with a *post hoc* Dunnett's t Test (Dunnett, C.W., J. Amer. Statis. Assoc., 50:1096-1121, 1955) or another appropriate test. A two-sided α of 0.05 or 0.01 was used to determine if statistically significant differences existed between the vehicle control and the treated groups.

ARCHIVAL STATEMENT

All original data and the original final report will be retained at Primedica Redfield's archives, located at 100 East Boone Street, Redfield, Arkansas, for a period of five years after issuance of the final report. Wet tissues, slides, and blocks (as appropriate) will be retained for at least one year. After this time, the Sponsor will be contacted for disposition instructions. All data not generated at Primedica Redfield will be archived at a facility chosen by the Sponsor.

RESULTS

FORMULATED TEST MATERIAL ANALYSIS: The formulated test material analysis report is located in Appendix 13.

A total of 24 formulated dose samples including blanks ranging from 4 to 40 mg/mL were analyzed to determine the concentration of T-7485 in the formulated mixture. All dose formulations were found to be acceptable by the Sponsor.

CLINICAL OBSERVATIONS: The summary of clinical observations is in Table 1. The individual clinical observations are in Appendix 4.

Clinical observations consisted of localized alopecia (back, limbs, neck, and underside), urine-stained abdominal fur, scabbed area on back and neck, and soft or liquid feces. These findings are considered incidental and unrelated to test material administration. Additional cageside observations were all normal.

NEUROLOGICAL FUNCTION OBSERVATIONS: The results of the neurological function examinations performed during Week 4 are located in Appendix 6. The summary and individual motor activity data are presented in Table 2 and Appendix 5, respectively.

Assessment of neurological effects on animals treated with T-7485 included peripheral neuropathy, motor activity, and audio/visual evaluations. There were no test material-related effects on motor activity or audio/visual. Interpretation of peripheral neurological findings suggests no test material-related neuropathology, but within this evaluation the significant findings for the tail flick examination may suggest that T-7485 induces a male-specific dose-independent hyperreactivity.

BODY WEIGHTS AND BODY WEIGHT CHANGES: The summaries of body weights and body weight changes are in Tables 3 and 4, respectively. The individual body weights are in Appendix 7.

There were no treatment-related effects on body weights for either Main Study or Recovery animals. On Study Day 36, the mean body weight in males that received 900 mg/kg/day T-7485 was decreased by 7% when compared to the corresponding controls. This finding was considered incidental.

Throughout the study, body weight changes in treatment groups were calculated and compared to the corresponding control groups with no significant findings recorded for either Main Study or Recovery animals.

FEED CONSUMPTION: The summary of absolute feed consumption is in Table 5. The individual data are in Appendix 8.

Throughout the study, absolute feed consumption per treatment group was calculated and compared to the corresponding control groups with no significant findings recorded for either Main Study or Recovery animals.

HEMATOLOGY: The summary of hematology data is in Table 6. The individual data are in Appendix 9.

The reported significant hematological findings are considered incidental and not associated with test material administration.

CLINICAL CHEMISTRY: The summary of clinical chemistry data is in Table 7. The individual data are in Appendix 10.

Main Study findings in males that received ≥ 300 mg/kg/day T-7485 indicate significant decreases in serum phosphorus (approximately 16% of the control values) and potassium (approximately 20% of the control values). In contrast, an increase in chloride levels in males that received 900 mg/kg/day T-7485 (4% above the control values) was recorded. In the absence of similar findings in Recovery animals, the changes in phosphorus, potassium, and chloride levels appear to be associated with test material administration but do not appear to be toxicologically or biologically significant, as indicated by historical data (Primedica, Appendix 11). Other incidental findings do not appear to be related to administration of the test material.

NECROPSY: The individual necropsy observations are in Appendix 2.

Only one gross lesion was recorded at necropsy and was not considered to be test material-related.

ORGAN WEIGHTS: The summary of organ weights is in Table 8. The individual data are in Appendix 12.

Absolute and relative male liver (between 25% to 30%) and female kidney (9% to 11%) weights were significantly increased in animals that received 900 mg/kg/day T-7485 when compared to the corresponding controls. These significant changes were not recorded during the recovery period, and since there does not appear to be an effect of body weight on organ development, these data suggest the changes are test material-related. However, the biological and toxicological significance is unclear due to the lack of any supportive gross or histopathological findings. The remaining significant findings are considered incidental and unrelated to test material administration.

HISTOPATHOLOGY: The histopathology report is located in Appendix 3.

The microscopic lesions observed in the test animals are considered to be incidental and in no way related to receiving the test material.

CONCLUSION

Oral (gavage) administration of T-7485 in Sprague-Dawley rats for a 28-day repeated dose with an approximate 14-day recovery period resulted in no mortality or abnormal clinical observations as well as no changes in body weights, feed consumption, peripheral neuropathy, motor activity, audio/visual response, hematology, clinical chemistry, gross pathology, and histopathology. These data suggest that administration of 900 mg/kg/day T-7485 resulted in significant increases in male liver and female kidney weights when compared to control animals and establishes the no-observable-adverse-effect-level (NOAEL) at 300 mg/kg/day T-7485. Furthermore, the T-7485 non-dose-dependent hyper-reactivity effect is gender specific and is therefore difficult to interpret.

TABLES

TABLE 1
SUMMARY OF CLINICAL OBSERVATIONS

PROTOCOL 132-007: A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

TABLE 1: CLINICAL OBSERVATIONS - SUMMARY - MALE RATS

DOSE GROUP (MG/KG/DAY)	1		2		3		4	
	0 (VEHICLE)		100		300		900	
MORTALITY	0		0		0		0	
LOCALIZED ALOPECIA, LIMBS	4/	1	0/	0	3/	1	4/	2
URINE-STAINED ABDOMINAL FUR	0/	0	0/	0	0/	0	1/	1
SOFT OR LIQUID FECES	0/	0	0/	0	0/	0	1/	1

N/N = NUMBER OF OBSERVATIONS/NUMBER OF ANIMALS

PROTOCOL 132-007: A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

TABLE 1: CLINICAL OBSERVATIONS - SUMMARY - FEMALE RATS

DOSE GROUP (MG/KG/DAY)	1 0 (VEHICLE)	2 100	3 300	4 900
MORTALITY	0	0	0	0
LOCALIZED ALOPECIA, BACK	0/ 0	2/ 1	0/ 0	0/ 0
LOCALIZED ALOPECIA, LIMBS	5/ 2	6/ 2	8/ 2	16/ 4
LOCALIZED ALOPECIA, NECK	0/ 0	0/ 0	5/ 1	0/ 0
LOCALIZED ALOPECIA, UNDERSIDE	0/ 0	10/ 2	0/ 0	1/ 1
SCABBED AREA, BACK	0/ 0	1/ 1	0/ 0	0/ 0
SCABBED AREA, NECK	0/ 0	0/ 0	5/ 1	0/ 0

N/N - NUMBER OF OBSERVATIONS/NUMBER OF ANIMALS

TABLE 2
SUMMARY OF MOTOR ACTIVITY DATA

PROTOCOL 132-007: A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

TABLE 2: MOTOR ACTIVITY - SUMMARY - MALE RATS

DOSE GROUP (MG/KG/DAY)		1 0 (VEHICLE)	2 100	3 300	4 900
RATS - TESTED		15	10	10	15
NUMBER OF MOVEMENTS					
BLOCK 1	MEAN $\pm$ S.D.	152.7 $\pm$ 14.3	154.0 $\pm$ 12.8	157.9 $\pm$ 7.4	153.3 $\pm$ 9.1
BLOCK 2	MEAN $\pm$ S.D.	146.5 $\pm$ 16.3	139.2 $\pm$ 10.0	156.0 $\pm$ 17.0	152.3 $\pm$ 15.6
BLOCK 3	MEAN $\pm$ S.D.	143.9 $\pm$ 17.7	107.8 $\pm$ 30.1	134.6 $\pm$ 24.1	128.1 $\pm$ 38.9
BLOCK 4	MEAN $\pm$ S.D.	120.3 $\pm$ 33.2	95.3 $\pm$ 47.3	106.3 $\pm$ 32.4	105.7 $\pm$ 52.5
BLOCK 5	MEAN $\pm$ S.D.	85.1 $\pm$ 58.3	57.9 $\pm$ 62.6	61.5 $\pm$ 50.5	82.4 $\pm$ 63.3
BLOCK 6	MEAN $\pm$ S.D.	71.4 $\pm$ 67.4	51.2 $\pm$ 66.9	26.7 $\pm$ 29.4	54.3 $\pm$ 60.2
TOTAL	MEAN $\pm$ S.D.	719.9 $\pm$ 148.0	605.4 $\pm$ 193.0	643.0 $\pm$ 106.9	676.1 $\pm$ 166.7
TIME (SECONDS) SPENT IN MOVEMENT					
BLOCK 1	MEAN $\pm$ S.D.	308.5 $\pm$ 47.8	306.7 $\pm$ 40.5	307.8 $\pm$ 48.0	313.2 $\pm$ 48.5
BLOCK 2	MEAN $\pm$ S.D.	259.0 $\pm$ 60.5	254.4 $\pm$ 49.0	261.2 $\pm$ 54.9	261.8 $\pm$ 53.8
BLOCK 3	MEAN $\pm$ S.D.	232.1 $\pm$ 60.6	167.1 $\pm$ 79.3	198.2 $\pm$ 43.2	202.7 $\pm$ 99.5
BLOCK 4	MEAN $\pm$ S.D.	175.7 $\pm$ 70.4	137.5 $\pm$ 93.6	143.0 $\pm$ 46.2	152.3 $\pm$ 94.1
BLOCK 5	MEAN $\pm$ S.D.	117.3 $\pm$ 97.4	74.0 $\pm$ 90.8	61.8 $\pm$ 55.2	113.2 $\pm$ 93.5
BLOCK 6	MEAN $\pm$ S.D.	93.2 $\pm$ 98.1	68.2 $\pm$ 97.7	24.5 $\pm$ 28.4	75.3 $\pm$ 99.2
TOTAL	MEAN $\pm$ S.D.	1185.7 $\pm$ 377.3	1007.9 $\pm$ 355.7	996.5 $\pm$ 173.4	1118.5 $\pm$ 423.3

TOTAL = SUM OF BLOCKS; EACH BLOCK CONSISTS OF A 10 MINUTE PERIOD.
There were no significant differences noted.

PROTOCOL 132-007: A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

TABLE 2: MOTOR ACTIVITY - SUMMARY - FEMALE RATS

DOSE GROUP (MG/KG/DAY)		1 0 (VEHICLE)	2 100	3 300	4 900
RATS - TESTED		15	10	10	15
NUMBER OF MOVEMENTS					
BLOCK 1	MEAN ± S.D.	150.1 ± 14.0	152.0 ± 14.2	148.3 ± 13.5	153.9 ± 12.8
BLOCK 2	MEAN ± S.D.	144.3 ± 13.9	147.3 ± 18.0	148.6 ± 17.1	144.5 ± 13.7
BLOCK 3	MEAN ± S.D.	138.3 ± 14.3	137.3 ± 24.6	118.2 ± 29.2	132.9 ± 32.7
BLOCK 4	MEAN ± S.D.	121.3 ± 22.5	124.9 ± 34.5	104.8 ± 34.2	116.5 ± 42.3
BLOCK 5	MEAN ± S.D.	103.9 ± 44.5	90.7 ± 45.4	86.3 ± 24.5	102.2 ± 51.9
BLOCK 6	MEAN ± S.D.	80.4 ± 52.7	76.2 ± 46.9	61.4 ± 48.9	87.3 ± 58.4
TOTAL	MEAN ± S.D.	738.4 ± 130.3	728.4 ± 124.8	667.6 ± 77.9	737.3 ± 177.4
TIME (SECONDS) SPENT IN MOVEMENT					
BLOCK 1	MEAN ± S.D.	313.3 ± 38.2	313.1 ± 47.1	305.9 ± 59.0	339.6 ± 36.7
BLOCK 2	MEAN ± S.D.	268.9 ± 46.8	269.9 ± 56.1	240.2 ± 50.4	291.6 ± 52.5
BLOCK 3	MEAN ± S.D.	236.1 ± 57.8	225.6 ± 74.3	170.3 ± 63.9	234.0 ± 81.2
BLOCK 4	MEAN ± S.D.	187.7 ± 54.5	173.7 ± 59.2	136.4 ± 52.6	175.4 ± 83.2
BLOCK 5	MEAN ± S.D.	139.3 ± 79.1	117.3 ± 79.4	95.4 ± 33.2	138.9 ± 84.8
BLOCK 6	MEAN ± S.D.	90.3 ± 79.7	94.7 ± 76.4	68.9 ± 59.9	109.0 ± 83.1
TOTAL	MEAN ± S.D.	1235.5 ± 285.3	1194.3 ± 316.4	1017.1 ± 218.2	1288.5 ± 345.4

TOTAL = SUM OF BLOCKS; EACH BLOCK CONSISTS OF A 10 MINUTE PERIOD.
There were no significant differences noted.

TABLE 3
SUMMARY OF BODY WEIGHTS

PROTOCOL 132-007: A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

TABLE 3: BODY WEIGHTS - SUMMARY - MALE RATS

DOSE GROUP (MG/KG/DAY)		1 0 (VEHICLE)	2 100	3 300	4 900
RATS - TESTED		15	10	10	15
BODY WEIGHT (G)					
SD 1	MEAN±S.D.	231.1 ± 10.3	231.1 ± 11.2	230.8 ± 14.8	231.7 ± 10.7
SD 8	MEAN±S.D.	282.1 ± 15.5	281.7 ± 13.0	280.3 ± 19.9	279.2 ± 14.4
SD 15	MEAN±S.D.	326.5 ± 19.9	324.4 ± 17.0	317.5 ± 28.5	321.5 ± 19.5
SD 22	MEAN±S.D.	361.4 ± 22.7	361.0 ± 18.5	349.5 ± 35.0	351.9 ± 23.9
SD 28	MEAN±S.D.	374.1 ± 24.9	375.0 ± 22.3	361.0 ± 37.1	358.0 ± 31.3
SD 36	MEAN±S.D.	421.0 ± 10.2 [5]a	a	a	393.0 ± 24.4* [5]a
SD 43	MEAN±S.D.	449.6 ± 20.1 [5]a	a	a	421.4 ± 29.9 [5]a

SD = STUDY DAY

[] = Number of values averaged.

a = Excludes values for animals that were a scheduled sacrifice.

* = Significantly different from Group 1 at p≤0.05.

PROTOCOL 132-007: A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

TABLE 3: BODY WEIGHTS - SUMMARY - FEMALE RATS

DOSE GROUP (MG/KG/DAY)		1 0 (VEHICLE)	2 100	3 300	4 900
RATS - TESTED		15	10	10	15
BODY WEIGHT (G)					
SD 1	MEAN±S.D.	194.3 ± 9.3	196.0 ± 8.2	195.5 ± 10.1	197.1 ± 7.4
SD 8	MEAN±S.D.	214.6 ± 11.0	211.7 ± 8.2	217.1 ± 10.4	217.1 ± 9.3
SD 15	MEAN±S.D.	227.5 ± 15.2	227.0 ± 10.2	232.2 ± 11.3	231.6 ± 8.7
SD 22	MEAN±S.D.	239.5 ± 12.6	235.0 ± 8.5	245.4 ± 15.7	243.7 ± 11.9
SD 28	MEAN±S.D.	241.1 ± 16.1	236.2 ± 10.4	242.4 ± 13.7	242.5 ± 12.2
SD 36	MEAN±S.D.	254.8 ± 17.0 { 5}a	a	a	255.6 ± 3.9 { 5}a
SD 42	MEAN±S.D.	260.0 ± 13.2 { 5}a	a	a	259.4 ± 4.6 { 5}a

SD = STUDY DAY

{ } = Number of values averaged.

a = Excludes values for animals that were a scheduled sacrifice.

There were no significant differences noted.

TABLE 4
SUMMARY OF BODY WEIGHT CHANGES

PROTOCOL 132-007: A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

TABLE 4: BODY WEIGHT CHANGES - SUMMARY - MALE RATS

DOSE GROUP (MG/KG/DAY)		1 0 (VEHICLE)	2 100	3 300	4 900
RATS - TESTED		15	10	10	15
BODY WEIGHT CHANGES (G)					
SD 1 - 8	MEAN±S.D.	+50.9 ± 8.0	+50.6 ± 4.7	+49.5 ± 8.6	+47.5 ± 7.8
SD 8 - 15	MEAN±S.D.	+44.4 ± 6.5	+42.7 ± 6.4	+37.2 ± 10.0	+42.3 ± 9.3
SD 15 - 22	MEAN±S.D.	+34.9 ± 6.7	+36.6 ± 5.8	+32.0 ± 7.8	+30.4 ± 6.5
SD 22 - 28	MEAN±S.D.	+12.7 ± 6.9	+14.0 ± 4.8	+11.5 ± 5.9	+6.1 ± 12.0
SD 28 - 36	MEAN±S.D.	+32.8 ± 3.1 [5]a	a	a	+32.0 ± 2.7 [5]a
SD 36 - 43	MEAN±S.D.	+28.6 ± 11.3 [5]a	a	a	+28.4 ± 5.8 [5]a
SD 1 - 28	MEAN±S.D.	+142.9 ± 20.3	+143.9 ± 16.7	+130.2 ± 26.5	+126.3 ± 27.3
SD 1 - 43	MEAN±S.D.	+217.2 ± 17.6 [5]a	a	a	+192.6 ± 24.5 [5]a

SD = STUDY DAY

[] = Number of values averaged.

a = Excludes values for animals that were a scheduled sacrifice.

There were no significant differences noted.

PROTOCOL 132-007: A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

TABLE 4: BODY WEIGHT CHANGES - SUMMARY - FEMALE RATS

DOSE GROUP (MG/KG/DAY)		1 0 (VEHICLE)	2 100	3 300	4 900
RATS - TESTED		15	10	10	15
BODY WEIGHT CHANGES (G)					
SD 1 - 8	MEAN±S.D.	+20.3 ± 5.7	+15.7 ± 7.0	+21.6 ± 6.5	+19.9 ± 6.7
SD 8 - 15	MEAN±S.D.	+12.9 ± 7.4	+15.3 ± 6.4	+15.1 ± 5.8	+14.5 ± 3.8
SD 15 - 22	MEAN±S.D.	+12.0 ± 6.8	+8.0 ± 5.4	+13.2 ± 8.1	+12.1 ± 6.7
SD 22 - 28	MEAN±S.D.	+1.7 ± 7.2	+1.2 ± 6.5	-3.0 ± 7.3	-1.2 ± 7.6
SD 28 - 36	MEAN±S.D.	+17.4 ± 6.8 [5]a	a	a	+12.8 ± 5.2 [5]a
SD 36 - 42	MEAN±S.D.	+5.2 ± 9.1 [5]a	a	a	+3.8 ± 5.7 [5]a
SD 1 - 28	MEAN±S.D.	+46.8 ± 11.7	+40.2 ± 8.3	+46.9 ± 9.5	+45.3 ± 10.1
SD 1 - 42	MEAN±S.D.	+65.6 ± 10.2 [5]a	a	a	+63.6 ± 2.3 [5]a

SD = STUDY DAY

[] = Number of values averaged.

a = Excludes values for animals that were a scheduled sacrifice.

There were no significant differences noted.

TABLE 5
SUMMARY OF ABSOLUTE FEED CONSUMPTION

PROTOCOL 132-007: A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

TABLE 5: ABSOLUTE FEED CONSUMPTION - SUMMARY - MALE RATS

DOSE GROUP (MG/KG/DAY)		1 0 (VEHICLE)	2 100	3 300	4 900
RATS - TESTED		15	10	10	15
FEED CONSUMPTION (G/DAY)					
SD 1 - 8	MEAN±S.D.	27.3 ± 2.2	27.4 ± 1.8	27.0 ± 2.5	27.7 ± 2.2
SD 8 - 15	MEAN±S.D.	27.8 ± 2.5	28.3 ± 2.1	26.8 ± 2.7	28.5 ± 2.9
SD 15 - 22	MEAN±S.D.	28.6 ± 2.4	29.6 ± 2.8	28.1 ± 3.3	29.6 ± 2.7
SD 22 - 28	MEAN±S.D.	29.4 ± 2.6	30.8 ± 3.1	28.7 ± 3.6	32.2 ± 5.5
SD 28 - 36	MEAN±S.D.	31.2 ± 1.9 [5]a	a	a	28.7 ± 3.5 [14]b [5]a
SD 36 - 43	MEAN±S.D.	34.1 ± 2.3 [5]a	a	a	31.5 ± 3.3 [5]a
SD 1 - 28	MEAN±S.D.	28.2 ± 2.3	29.0 ± 2.3	27.6 ± 3.0	29.3 ± 2.6
SD 1 - 43	MEAN±S.D.	30.4 ± 2.0 [5]a	a	a	29.1 ± 2.9 [5]a

SD = STUDY DAY

[] = Number of values averaged.

a = Excludes values for animals that were a scheduled sacrifice.

b = Excludes values for animals in which feed consumption could not be calculated.

There were no significant differences noted.

PROTOCOL 132-007: A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

TABLE 5: ABSOLUTE FEED CONSUMPTION - SUMMARY - FEMALE RATS

DOSE GROUP (MG/KG/DAY)		1 0 (VEHICLE)	2 100	3 300	4 900
RATS - TESTED		15	10	10	15
FEED CONSUMPTION (G/DAY)					
SD 1 - 8	MEAN±S.D.	21.0 ± 1.7	20.5 ± 1.3	21.5 ± 1.2	21.5 ± 1.1
SD 8 - 15	MEAN±S.D.	20.9 ± 2.1	21.1 ± 1.7	21.2 ± 1.7	21.9 ± 1.0
SD 15 - 22	MEAN±S.D.	21.4 ± 2.2	21.7 ± 1.7	22.2 ± 1.9	22.3 ± 1.7
SD 22 - 28	MEAN±S.D.	22.5 ± 1.9	21.8 ± 2.5	21.7 ± 2.3	22.3 ± 1.8
SD 28 - 36	MEAN±S.D.	20.5 ± 5.2 [5]a	a	a	22.0 ± 0.8 [5]a
SD 36 - 42	MEAN±S.D.	24.0 ± 2.1 [5]a	a	a	23.7 ± 1.7 [5]a
SD 1 - 28	MEAN±S.D.	21.4 ± 1.7	21.2 ± 1.7	21.7 ± 1.6	22.0 ± 1.2
SD 1 - 42	MEAN±S.D.	21.8 ± 2.1 [5]a	a	a	22.4 ± 0.8 [5]a

SD = STUDY DAY

[] = Number of values averaged.

a = Excludes values for animals that were a scheduled sacrifice.

There were no significant differences noted.

TABLE 6
SUMMARY OF HEMATOLOGY DATA

KEY TO HEMATOLOGY TABLES

<u>ABBREVIATION</u>	<u>TERMINOLOGY</u>	<u>UNITS</u>
WBC	White Blood Cells (Leukocytes)	$10^3/\text{cu mm}$
RBC	Red Blood Cells (Erythrocytes)	$10^6/\text{cu mm}$
HGB	Hemoglobin	g/dL
HCT	Hematocrit (Packed Cell Volume)	%
MCV	Mean Corpuscular Volume	fL or cu micron
MCH	Mean Corpuscular Hemoglobin	pg or picograms
MCHC	Mean Corpuscular Hemoglobin Concentration	%
PLT	Platelets	$10^3/\text{cu mm}$
NRBC	Nucleated Red Blood Cell Count	
Lymphocyte	Lymphocytes	$10^3/\text{cu mm}$
Segmented	Segmented Neutrophils	$10^3/\text{cu mm}$
Eosinophil	Eosinophils	$10^3/\text{cu mm}$
Abnormal L	Abnormal Lymphocytes	$10^3/\text{cu mm}$
APTT	Activated Partial Thromboplastin Time	seconds
PT	Prothrombin time	seconds
Other	Other Cells	$10^3/\text{cu mm}$

TABLE 6

Study Report for Hematology

SUMMARY REPORT
PERIOD: TERMINALSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: MALE

ANALYSIS OF VARIANCE FOLLOWED BY DUNNETT'S PROCEDURE

TEST(s):	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	PLT	PT
UNITS:	THSN/CU MM	MILL/CU MM	GRAMS/DL	% CU	MICRONS	PICO GRAMS	% THSN/CU MM	MM	seconds
Group: 1-M									
MEAN	10.0	6.91	15.5	42.1	60.9	22.5	36.9	1174	14.6
SD	4.44	0.805	1.54	4.87	2.69	1.01	1.25	149.5	0.95
N	10	10	10	10	10	10	10	10	10
Group: 2-M									
MEAN	12.2	7.02	15.8	42.8	61.0	22.5	36.8	1242	15.3
SD	2.99	0.473	0.54	2.24	1.45	1.02	1.03	101.9	0.69
N	10	10	10	10	10	10	10	10	9
Group: 3-M									
MEAN	10.4	6.90	15.6	41.6	60.5	22.6	37.4	1121	14.5
SD	2.99	0.328	0.46	1.27	2.41	0.87	0.44	112.8	0.62
N	10	10	10	10	10	10	10	10	10
Group: 4-M									
MEAN	9.5	6.65	15.0	39.8	59.9	22.6	37.7	1002*	14.6
SD	1.91	0.617	1.05	3.02	2.09	0.89	0.66	139.8	0.88
N	10	10	10	10	10	10	10	10	9

*-Significant Difference from Control P < .05

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TABLE 6

Study Report for Hematology

SUMMARY REPORT
PERIOD: TERMINALSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: MALE

ANALYSIS OF VARIANCE FOLLOWED BY DUNNETT'S PROCEDURE

TEST(s):	APTT	NRBC	Lymphocyte	Segmented	Bands	Monocytes	Eosinophil	Basophils	Abnormal L
UNITS:	seconds	COUNT	THSN/CU MM	THSN/CU MM	THSN/CU MM	THSN/CU MM	THSN/CU MM	THSN/CU MM	THSN/CU MM
Group: 1-M									
MEAN	25.9	0	9.2	0.6	0.0	0.0	0.1	0.0	0.0
SD	7.66	0.3	3.96	0.44	0.03	0.07	0.13	0.00	0.00
N	10	10	10	10	10	10	10	10	10
Group: 2-M									
MEAN	26.9	0	10.5	1.6**	0.0	0.0	0.1	0.0	0.0
SD	2.77	0.0	2.71	0.49	0.00	0.00	0.09	0.00	0.06
N	9	10	10	10	10	10	10	10	10
Group: 3-M									
MEAN	22.9	0	9.3	1.0	0.0	0.0	0.1	0.0	0.0
SD	3.70	0.0	2.79	0.75	0.00	0.03	0.10	0.00	0.00
N	10	10	10	10	10	10	10	10	10
Group: 4-M									
MEAN	25.1	0	8.5	0.9	0.0	0.1**	0.0	0.0	0.0
SD	5.06	0.0	1.87	0.36	0.00	0.09	0.07	0.00	0.00
N	9	10	10	10	10	10	10	10	10

**-Significant Difference from Control P < .01

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TABLE 6

Study Report for Hematology

SUMMARY REPORT
PERIOD: TERMINALSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: MALE

ANALYSIS OF VARIANCE FOLLOWED BY DUNNETT'S PROCEDURE

TEST(s): Other
UNITS: THSN/CU MMGroup: 1-M
MEAN 0.0
SD 0.00
N 10Group: 2-M
MEAN 0.0
SD 0.00
N 10Group: 3-M
MEAN 0.0
SD 0.00
N 10Group: 4-M
MEAN 0.0
SD 0.00
N 10

TABLE 6

Study Report for Hematology

SUMMARY REPORT
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: MALE

ANALYSIS OF VARIANCE FOLLOWED BY DUNNETT'S PROCEDURE

TEST(s):	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	PLT	PT
UNITS:	THSN/CU MM	MILL/CU MM	GRAMS/DL	% CU	MICRONS	PICO GRAMS	% THSN/CU MM	MM	seconds
Group: 1-M									
MEAN	13.4	7.07	15.1	40.2	56.8	21.3	37.6	1256	12.6
SD	3.93	0.362	0.69	2.36	1.66	0.74	0.59	111.3	0.11
N	5	5	5	5	5	5	5	5	5
Group: 4-M									
MEAN	11.5	7.28	15.4	41.4	56.9	21.2	37.3	1118*	13.4**
SD	3.66	0.462	0.89	2.76	1.40	0.63	0.44	50.6	0.11
N	5	5	5	5	5	5	5	5	5

*-Significant Difference from Control P < .05

**-Significant Difference from Control P < .01

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TABLE 6

Study Report for Hematology

SUMMARY REPORT
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: MALE

ANALYSIS OF VARIANCE FOLLOWED BY DUNNETT'S PROCEDURE

TEST(s):	APTT	NRBC	Lymphocyte	Segmented	Bands	Monocytes	Eosinophil	Basophils	Abnormal L
UNITS:	seconds	COUNT	THSN/CU MM	THSN/CU MM	THSN/CU MM	THSN/CU MM	THSN/CU MM	THSN/CU MM	THSN/CU MM
Group: 1-M									
MEAN	17.6	0	12.0	1.3	0.0	0.0	0.1	0.0	0.0
SD	2.74	0.0	4.07	0.43	0.00	0.04	0.05	0.00	0.00
N	5	5	5	5	5	5	5	5	5
Group: 4-M									
MEAN	22.3*	0	10.1	1.2	0.0	0.1	0.0	0.0	0.0
SD	3.23	0.0	3.15	0.51	0.00	0.13	0.04	0.00	0.00
N	5	5	5	5	5	5	5	5	5

*-Significant Difference from Control $P < .05$

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TABLE 6

Study Report for Hematology

SUMMARY REPORT
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: MALE

ANALYSIS OF VARIANCE FOLLOWED BY DUNNETT'S PROCEDURE

TEST(s): Other
UNITS: THSN/CU MM

Group: 1-M

MEAN 0.0
SD 0.00
N 5

Group: 4-M

MEAN 0.0
SD 0.00
N 5

TABLE 6

Study Report for Hematology

SUMMARY REPORT
PERIOD: TERMINALSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

ANALYSIS OF VARIANCE FOLLOWED BY DUNNETT'S PROCEDURE

TEST(s):	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	PLT	PT
UNITS:	THSN/CU MM	MILL/CU MM	GRAMS/DL	% CU	MICRONS	PICO GRAMS	% THSN/CU MM		seconds
Group: 1-F									
MEAN	9.2	6.70	15.4	41.4	61.9	23.0	37.1	1090	14.4
SD	4.42	0.290	0.32	1.15	1.80	0.65	0.56	88.9	1.93
N	10	10	10	10	10	10	10	10	7
Group: 2-F									
MEAN	11.2	6.89	15.3	41.8	60.8	22.3	36.7	1155	14.9
SD	3.47	0.490	0.67	2.26	2.06	0.84	0.65	320.3	1.98
N	9	9	9	9	9	9	9	9	10
Group: 3-F									
MEAN	7.4	6.74	15.3	41.9	62.2	22.7	36.5	1118	14.4
SD	3.02	0.437	1.01	2.68	2.22	0.82	0.80	221.2	1.28
N	10	10	10	10	10	10	10	10	10
Group: 4-F									
MEAN	8.8	6.66	15.2	41.1	61.6	22.8	37.0	1167	15.6
SD	3.00	0.286	0.66	2.16	2.11	0.68	0.68	167.8	1.88
N	10	10	10	10	10	10	10	10	10

TABLE 6

Study Report for Hematology

SUMMARY REPORT
PERIOD: TERMINALSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

ANALYSIS OF VARIANCE FOLLOWED BY DUNNETT'S PROCEDURE

TEST(s): UNITS:	APTT seconds	NRBC COUNT	Lymphocyte THSN/CU MM	Segmented THSN/CU MM	Bands THSN/CU MM	Monocytes THSN/CU MM	Eosinophil THSN/CU MM	Basophils THSN/CU MM	Abnormal L THSN/CU MM
Group: 1-F									
MEAN	31.6	0	8.4	0.6	0.0	0.2	0.1	0.0	0.0
SD	8.89	0.0	4.16	0.41	0.00	0.18	0.17	0.00	0.00
N	7	10	10	10	10	10	10	10	10
Group: 2-F									
MEAN	31.8	0	10.1	0.8	0.0	0.1	0.1	0.0	0.0
SD	7.72	0.0	3.11	0.40	0.03	0.11	0.12	0.00	0.00
N	10	9	9	9	9	9	9	9	9
Group: 3-F									
MEAN	26.8	0	6.4	0.9	0.0	0.0**	0.0	0.0	0.0
SD	6.01	0.0	2.60	0.61	0.00	0.03	0.05	0.00	0.03
N	10	10	10	10	10	10	10	10	10
Group: 4-F									
MEAN	28.9	0	7.7	0.9	0.0	0.1	0.1	0.0	0.0
SD	8.60	0.3	2.86	0.47	0.00	0.11	0.12	0.00	0.03
N	10	10	10	10	10	10	10	10	10

**Significant Difference from Control P < .01

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TABLE 6

Study Report for Hematology

SUMMARY REPORT
PERIOD: TERMINALSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

ANALYSIS OF VARIANCE FOLLOWED BY DUNNETT'S PROCEDURE

TEST(s): Other
UNITS: THSN/CU MM

Group: 1-F

MEAN 0.0
SD 0.00
N 10

Group: 2-F

MEAN 0.0
SD 0.00
N 9

Group: 3-F

MEAN 0.0
SD 0.00
N 10

Group: 4-F

MEAN 0.0
SD 0.00
N 10

TABLE 6

Study Report for Hematology

SUMMARY REPORT
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

ANALYSIS OF VARIANCE FOLLOWED BY DUNNETT'S PROCEDURE

TEST(s):	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	PLT	PT
UNITS:	THSN/CU MM	MILL/CU MM	GRAMS/DL	% CU	MICRONS	PICO	GRAMS	% THSN/CU MM	seconds
Group: 1-F									
MEAN	9.7	7.15	15.1	41.7	58.3	21.2	36.4	1239	12.3
SD	2.10	0.351	0.70	2.02	2.23	0.96	0.42	143.9	0.45
N	5	5	5	5	5	5	5	5	5
Group: 4-F									
MEAN	8.6	6.89	15.0	40.6	58.9	21.7	36.8	994*	12.9*
SD	4.36	0.524	1.24	3.34	2.63	1.39	0.78	147.5	0.21
N	5	5	5	5	5	5	5	5	5

*-Significant Difference from Control P < .05

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TABLE 6

Study Report for Hematology

SUMMARY REPORT
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

ANALYSIS OF VARIANCE FOLLOWED BY DUNNETT'S PROCEDURE

TEST(s):	APTT	NRBC	Lymphocyte	Segmented	Bands	Monocytes	Eosinophil	Basophils	Abnormal L
UNITS:	seconds	COUNT	THSN/CU MM	THSN/CU MM	THSN/CU MM	THSN/CU MM	THSN/CU MM	THSN/CU MM	THSN/CU MM
Group: 1-F									
MEAN	18.5	0	8.9	0.8	0.0	0.0	0.0	0.0	0.0
SD	0.81	0.0	1.97	0.26	0.00	0.04	0.00	0.00	0.00
N	5	5	5	5	5	5	5	5	5
Group: 4-F									
MEAN	21.0*	0	7.5	1.0	0.0	0.1	0.0	0.0	0.0
SD	1.60	0.0	4.20	0.51	0.00	0.09	0.00	0.00	0.00
N	5	5	5	5	5	5	5	5	5

*-Significant Difference from Control P < .05

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TABLE 6

Study Report for Hematology

SUMMARY REPORT
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

ANALYSIS OF VARIANCE FOLLOWED BY DUNNETT'S PROCEDURE

TEST(s): Other
UNITS: THSN/CU MM

Group: 1-F

MEAN 0.0
SD 0.00
N 5

Group: 4-F

MEAN 0.0
SD 0.00
N 5

TABLE 7
SUMMARY OF CLINICAL CHEMISTRY DATA

KEY TO CLINICAL CHEMISTRY TABLES

<u>ABBREVIATION</u>	<u>TERMINOLOGY</u>	<u>UNITS</u>
ALP	Alkaline Phosphatase	U/L
AST	Aspartate Aminotransferase	U/L
ALT	Alanine Aminotransferase	U/L
CHOL	Cholesterol	mg/dL
GLU	Glucose	mg/dL
BUN	Blood Urea Nitrogen	mg/dL
CREAT	Creatinine	mg/dL
TRIG	Triglycerides	mg/dL
PHOS	Phosphorus (inorganic)	mg/dL
TP	Total Protein	g/dL
ALB	Albumin	g/dL
GLOB	Globulin	g/dL
A/G	Albumin/Globulin Ratio	
CA	Calcium	mg/dL
CL	Chloride	mEq/L or mmol/L
NA	Sodium	mEq/L or mmol/L
K	Potassium	mEq/L or mmol/L
GGT	Gamma-glutamyltransferase	U/L
T-BIL	Total Bilirubin	mg/dL

TABLE 7

Study Report for Clinical Chemistry

SUMMARY REPORT
PERIOD: TERMINALSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: MALE

ANALYSIS OF VARIANCE FOLLOWED BY DUNNETT'S PROCEDURE

TEST(s): UNITS:	TP g/dL	ALB g/dL	GLU mg/dL	CHOL mg/dL	T-BIL mg/dL	BUN mg/dL	CREAT mg/dL	ALT U/L	AST U/L
Group: 1-M									
MEAN	6.4	4.4	161	64	0.2	18	0.3	35	110
SD	0.47	0.33	42.7	18.8	0.07	2.4	0.05	5.9	18.1
N	10	10	10	10	10	10	10	10	10
Group: 2-M									
MEAN	6.2	4.2	169	61	0.2	18	0.3	37	111
SD	0.23	0.25	46.7	15.0	0.07	1.7	0.05	8.4	20.3
N	10	10	10	10	10	10	10	10	10
Group: 3-M									
MEAN	6.4	4.3	147	63	0.2	19	0.3	53	138
SD	0.35	0.23	22.1	19.9	0.08	2.7	0.06	40.0	71.3
N	10	10	10	10	10	10	10	10	10
Group: 4-M									
MEAN	6.3	4.4	137	50	0.2	20	0.3	46	133
SD	0.30	0.28	19.6	11.2	0.09	2.1	0.04	16.5	44.9
N	10	10	10	10	10	10	10	10	10

TABLE 7

Study Report for Clinical Chemistry

SUMMARY REPORT
PERIOD: TERMINALSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: MALE

ANALYSIS OF VARIANCE FOLLOWED BY DUNNETT'S PROCEDURE

TEST(s): UNITS:	ALP U/L	GGT U/L	CA mg/dL	PHOS mg/dL	TRIG mg/dL	NA mmol/L	K mmol/L	CL mmol/L	GLOB g/dL
Group: 1-M									
MEAN	162	1	11.4	10.8	32	146	7.7	96	2.0
SD	41.9	1.6	0.53	0.66	10.2	2.4	1.52	2.6	0.20
N	10	10	10	10	10	10	10	10	10
Group: 2-M									
MEAN	152	1	11.2	10.3	34	146	7.0	98	2.0
SD	35.5	2.2	0.48	0.95	18.0	1.4	1.24	2.8	0.13
N	10	10	10	10	10	10	10	10	10
Group: 3-M									
MEAN	150	0	11.2	9.4**	25	147	6.4*	98	2.1
SD	25.3	0.7	0.59	0.86	8.6	1.7	0.87	2.6	0.28
N	10	10	10	10	10	10	10	10	10
Group: 4-M									
MEAN	172	0	10.9	9.1**	23	147	6.2*	100*	1.9
SD	37.8	0.0	0.62	0.92	10.3	2.0	1.10	1.9	0.19
N	10	10	10	10	10	10	10	10	10

*-Significant Difference from Control P < .05

**-Significant Difference from Control P < .01

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TABLE 7

Study Report for Clinical Chemistry

SUMMARY REPORT
PERIOD: TERMINALSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: MALE

ANALYSIS OF VARIANCE FOLLOWED BY DUNNETT'S PROCEDURE

TEST(s): A/G
UNITS: none

Group: 1-M

MEAN 2.2
SD 0.21
N 10

Group: 2-M

MEAN 2.1
SD 0.21
N 10

Group: 3-M

MEAN 2.1
SD 0.33
N 10

Group: 4-M

MEAN 2.4
SD 0.30
N 10

TABLE 7

Study Report for Clinical Chemistry

SUMMARY REPORT
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: MALE

ANALYSIS OF VARIANCE FOLLOWED BY DUNNETT'S PROCEDURE

TEST(s):	TP	ALB	GLU	CHOL	T-BIL	BUN	CREAT	ALT	AST
UNITS:	g/dL	g/dL	mg/dL	mg/dL	mg/dL	mg/dL	mg/dL	U/L	U/L
Group: 1-M									
MEAN	6.7	4.4	161	65	0.2	18	0.3	43	125
SD	0.28	0.26	34.3	12.6	0.05	1.5	0.05	4.5	42.6
N	5	5	5	5	5	5	5	5	5
Group: 4-M									
MEAN	6.7	4.5	158	75	0.1	17	0.3	47	121
SD	0.38	0.36	46.1	21.6	0.04	1.2	0.10	6.0	36.9
N	5	5	5	5	5	5	5	5	5

TABLE 7

Study Report for Clinical Chemistry

SUMMARY REPORT
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: MALE

ANALYSIS OF VARIANCE FOLLOWED BY DUNNETT'S PROCEDURE

TEST(s):	ALP	GGT	CA	PHOS	TRIG	NA	K	CL	GLOB
UNITS:	U/L	U/L	mg/dL	mg/dL	mg/dL	mmol/L	mmol/L	mmol/L	g/dL
Group: 1-M									
MEAN	159	2	12.4	12.5	45	145	8.7	98	2.3
SD	18.3	2.0	0.47	2.14	19.3	1.5	1.66	1.9	0.23
N	5	5	5	5	5	5	5	5	5
Group: 4-M									
MEAN	149	2	12.5	11.8	55	147	8.3	99	2.2
SD	22.7	2.2	0.69	1.20	39.8	2.1	1.68	3.3	0.12
N	5	5	5	5	5	5	5	5	5

TABLE 7

Study Report for Clinical Chemistry

SUMMARY REPORT
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: MALE

ANALYSIS OF VARIANCE FOLLOWED BY DUNNETT'S PROCEDURE

TEST(s): A/G
UNITS: none

Group: 1-M

MEAN 1.9

SD 0.28

N 5

Group: 4-M

MEAN 2.0

SD 0.21

N 5

TABLE 7

Study Report for Clinical Chemistry

SUMMARY REPORT
PERIOD: TERMINALSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

ANALYSIS OF VARIANCE FOLLOWED BY DUNNETT'S PROCEDURE

TEST(s): UNITS:	TP g/dL	ALB g/dL	GLU mg/dL	CHOL mg/dL	T-BIL mg/dL	BUN mg/dL	CREAT mg/dL	ALT U/L	AST U/L
Group: 1-F									
MEAN	6.8	4.8	155	73	0.2	19	0.4	43	124
SD	0.35	0.27	25.4	12.5	0.03	3.0	0.05	14.7	30.6
N	10	10	10	10	10	10	10	10	10
Group: 2-F									
MEAN	6.9	5.0	154	71	0.2	20	0.4	35	111
SD	0.21	0.27	42.2	13.4	0.05	3.2	0.04	5.7	22.9
N	10	10	10	10	10	10	10	10	10
Group: 3-F									
MEAN	6.8	4.7	143	62	0.2	21	0.4	38	113
SD	0.34	0.34	29.4	15.0	0.06	1.9	0.06	6.4	14.7
N	10	10	10	10	10	10	10	10	10
Group: 4-F									
MEAN	6.6	4.6	129	73	0.2	21	0.4	36	109
SD	0.36	0.43	20.1	13.7	0.05	2.8	0.05	3.0	10.9
N	10	10	10	10	10	10	10	10	10

TABLE 7

Study Report for Clinical Chemistry

SUMMARY REPORT
PERIOD: TERMINALSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

ANALYSIS OF VARIANCE FOLLOWED BY DUNNETT'S PROCEDURE

TEST(s):	ALP	GGT	CA	PHOS	TRIG	NA	K	CL	GLOB
UNITS:	U/L	U/L	mg/dL	mg/dL	mg/dL	mmol/L	mmol/L	mmol/L	g/dL
Group: 1-F									
MEAN	90	1	11.8	9.9	37	144	7.8	103	2.1
SD	28.3	1.0	0.34	0.96	7.7	1.8	1.21	1.8	0.18
N	10	10	10	10	10	10	10	10	10
Group: 2-F									
MEAN	79	1	11.9	10.1	31	143	9.1*	102	2.0
SD	20.7	1.6	0.33	0.70	7.9	1.6	1.42	2.5	0.13
N	10	10	10	10	10	10	10	10	10
Group: 3-F									
MEAN	101	0	11.6	10.5	34	144	8.4	104	2.1
SD	7.4	0.4	0.31	0.83	8.6	1.5	0.99	1.6	0.22
N	10	10	10	10	10	10	10	10	10
Group: 4-F									
MEAN	90	0	11.4	9.6	32	145	7.0	104	2.0
SD	17.3	0.5	0.50	1.03	9.9	1.5	0.83	1.4	0.16
N	10	10	10	10	10	10	10	10	10

*-Significant Difference from Control P < .05

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TABLE 7

Study Report for Clinical Chemistry

SUMMARY REPORT
PERIOD: TERMINALSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

ANALYSIS OF VARIANCE FOLLOWED BY DUNNETT'S PROCEDURE

TEST(s): A/G
UNITS: noneGroup: 1-F
MEAN 2.3
SD 0.23
N 10Group: 2-F
MEAN 2.5
SD 0.29
N 10Group: 3-F
MEAN 2.3
SD 0.32
N 10Group: 4-F
MEAN 2.4
SD 0.38
N 10

TABLE 7

Study Report for Clinical Chemistry

SUMMARY REPORT
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

ANALYSIS OF VARIANCE FOLLOWED BY DUNNETT'S PROCEDURE

TEST(s):	TP	ALB	GLU	CHOL	T-BIL	BUN	CREAT	ALT	AST
UNITS:	g/dL	g/dL	mg/dL	mg/dL	mg/dL	mg/dL	mg/dL	U/L	U/L
Group: 1-F									
MEAN	7.3	5.3	166	84	0.2	21	0.4	53	194
SD	0.43	0.33	73.3	22.5	0.00	6.0	0.11	14.3	63.9
N	5	5	5	5	5	5	5	5	5
Group: 4-F									
MEAN	7.1	5.1	135	72	0.2	21	0.4	37*	189
SD	0.37	0.40	55.2	11.0	0.08	5.2	0.12	5.1	78.4
N	5	5	5	5	5	5	5	5	5

*-Significant Difference from Control P < .05

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03-NOV-2000

TABLE 7

Study Report for Clinical Chemistry

SUMMARY REPORT
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

ANALYSIS OF VARIANCE FOLLOWED BY DUNNETT'S PROCEDURE

TEST(s):	ALP	GGT	CA	PHOS	TRIG	NA	K	CL	GLOB
UNITS:	U/L	U/L	mg/dL	mg/dL	mg/dL	mmol/L	mmol/L	mmol/L	g/dL
Group: 1-F									
MEAN	83	1	12.9	12.3	45	144	9.2	102	2.0
SD	10.3	0.8	0.40	1.05	14.2	1.7	1.52	2.9	0.38
N	5	5	5	5	5	5	5	5	5
Group: 4-F									
MEAN	82	1	12.3	10.7	32	145	7.8	104	2.0
SD	16.7	1.1	0.54	1.74	11.2	2.2	1.53	2.0	0.09
N	5	5	5	5	5	5	5	5	5

TABLE 7

Study Report for Clinical Chemistry

SUMMARY REPORT
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

ANALYSIS OF VARIANCE FOLLOWED BY DUNNETT'S PROCEDURE

TEST(s):
UNITS: A/G
none

Group: 1-F

MEAN 2.6
SD 0.48
N 5

Group: 4-F

MEAN 2.5
SD 0.25
N 5

TABLE 8
SUMMARY OF ORGAN WEIGHTS

TABLE 8

ORGAN WEIGHT SUMMARY (ABSOLUTE)

STUDY: T-7485

SEX: MALE

FATES: SCHEDULED SACRIFICE DAYS: 29-29 ALL BALANCES
ANALYSIS OF VARIANCE USING DUNNETT'S PROCEDURE

GROUP: 1-M 2-M 3-M 4-M

BODY WEIGHT (G)(ABSOLUTE)

MEAN	344.300	348.900	337.200	335.800
SD	27.6970	21.9315	33.6512	32.4886
N	10	10	10	10

ADRENAL GLANDS (G)(ABSOLUTE)

MEAN	0.068	0.075	0.067	0.068
SD	0.0049	0.0118	0.0117	0.0133
N	10	10	10	10

BRAIN (G)(ABSOLUTE)

MEAN	1.992	2.058	2.061	1.992
SD	0.1023	0.0824	0.1254	0.1136
N	10	10	10	10

HEART (G)(ABSOLUTE)

MEAN	1.219	1.234	1.185	1.169
SD	0.0939	0.0852	0.1309	0.0895
N	10	10	10	10

KIDNEYS (G)(ABSOLUTE)

MEAN	2.751	2.774	2.899	2.868
SD	0.2997	0.2146	0.4427	0.3493
N	10	10	10	10

LIVER (G)(ABSOLUTE)

MEAN	10.042	10.599	10.838	12.672**
SD	1.0649	1.2931	1.4978	1.6538
N	10	10	10	10

SPLEEN (G)(ABSOLUTE)

MEAN	0.652	0.720	0.708	0.655
SD	0.0848	0.1236	0.0878	0.1094
N	10	10	10	10

** - Significant difference P<.01

PRIMEDICA REDFIELD STUDY NUMBER 132-007

TABLE 8

ORGAN WEIGHT SUMMARY (ABSOLUTE)

STUDY: T-7485

SEX: MALE

FATES: SCHEDULED SACRIFICE DAYS: 29-29 ALL BALANCES
ANALYSIS OF VARIANCE USING DUNNETT'S PROCEDURE

GROUP: 1-M 2-M 3-M 4-M

TESTES (G)(ABSOLUTE)

MEAN	3.233	2.946	3.271	3.250
SD	0.2537	0.3320	0.3896	0.1937
N	10	10	10	10

THYMUS (G)(ABSOLUTE)

MEAN	0.507	0.532	0.495	0.516
SD	0.0799	0.1231	0.0600	0.1313
N	10	10	10	10

PRIMEDICA REDFIELD STUDY NUMBER 132-007

TABLE 8

ORGAN WEIGHT SUMMARY (ABSOLUTE)

STUDY: T-7485

SEX: MALE

FATES: SCHEDULED SACRIFICE DAYS: 44-44 ALL BALANCES
ANALYSIS OF VARIANCE USING DUNNETT'S PROCEDURE

GROUP:	1-M	2-M	3-M	4-M
BODY WEIGHT (G)(ABSOLUTE)				
MEAN	424.800	0.000	0.000	397.200
SD	17.6692	NA	NA	28.2524
N	5	0	0	5
ADRENAL GLANDS (G)(ABSOLUTE)				
MEAN	0.073	0.000	0.000	0.069
SD	0.0128	NA	NA	0.0139
N	5	0	0	5
BRAIN (G)(ABSOLUTE)				
MEAN	2.142	0.000	0.000	2.200
SD	0.0995	NA	NA	0.0807
N	5	0	0	5
HEART (G)(ABSOLUTE)				
MEAN	1.434	0.000	0.000	1.459
SD	0.1301	NA	NA	0.1861
N	5	0	0	5
KIDNEYS (G)(ABSOLUTE)				
MEAN	3.488	0.000	0.000	3.594
SD	0.1967	NA	NA	0.3547
N	5	0	0	5
LIVER (G)(ABSOLUTE)				
MEAN	15.145	0.000	0.000	14.697
SD	1.1353	NA	NA	1.9888
N	5	0	0	5
SPLEEN (G)(ABSOLUTE)				
MEAN	0.844	0.000	0.000	0.711
SD	0.1300	NA	NA	0.1192
N	5	0	0	5

NA-Not Applicable

PRIMEDICA REDFIELD STUDY NUMBER 132-007

TABLE 8

ORGAN WEIGHT SUMMARY (ABSOLUTE)

STUDY: T-7485

SEX: MALE

FATES: SCHEDULED SACRIFICE

DAYS: 44-44

ALL BALANCES

ANALYSIS OF VARIANCE USING DUNNETT'S PROCEDURE

GROUP: 1-M 2-M 3-M 4-M

TESTES (G)(ABSOLUTE)

MEAN	3.038	0.000	0.000	3.430*
SD	0.2203	NA	NA	0.2355
N	5	0	0	5

THYMUS (G)(ABSOLUTE)

MEAN	0.540	0.000	0.000	0.543
SD	0.0557	NA	NA	0.0740
N	5	0	0	5

* - Significant difference P<.05

NA-Not Applicable

PRIMEDICA REDFIELD STUDY NUMBER 132-007

TABLE 8

 ORGAN WEIGHT SUMMARY (ABSOLUTE)

STUDY: T-7485

SEX: FEMALE

 FATES: SCHEDULED SACRIFICE DAYS: 29-29 ALL BALANCES
 ANALYSIS OF VARIANCE USING DUNNETT'S PROCEDURE

GROUP:	1-F	2-F	3-F	4-F
BODY WEIGHT (G)(ABSOLUTE)				
MEAN	225.300	220.600	227.300	230.100
SD	15.9028	11.0675	15.2100	14.1378
N	10	10	10	10
ADRENAL GLANDS (G)(ABSOLUTE)				
MEAN	0.084	0.081	0.081	0.079
SD	0.0151	0.0093	0.0103	0.0091
N	10	10	10	10
BRAIN (G)(ABSOLUTE)				
MEAN	1.931	1.950	1.930	1.934
SD	0.1029	0.0684	0.0710	0.0720
N	10	10	10	10
HEART (G)(ABSOLUTE)				
MEAN	0.886	0.890	0.861	0.848
SD	0.0573	0.0767	0.0881	0.0739
N	10	10	10	10
KIDNEYS (G)(ABSOLUTE)				
MEAN	1.820	1.925	1.864	2.015**
SD	0.1718	0.1152	0.1244	0.1158
N	10	10	10	10
LIVER (G)(ABSOLUTE)				
MEAN	6.915	7.100	7.101	7.362
SD	1.0021	0.5100	0.5348	0.7272
N	10	10	10	10
OVARIES (G)(ABSOLUTE)				
MEAN	0.108	0.103	0.109	0.109
SD	0.0151	0.0135	0.0129	0.0235
N	10	10	10	10

 ** - Significant difference P<.01

PRIMEDICA REDFIELD STUDY NUMBER 132-007

TABLE 8

ORGAN WEIGHT SUMMARY (ABSOLUTE)

STUDY: T-7485

SEX: FEMALE

FATES: SCHEDULED SACRIFICE

DAYS: 29-29

ALL BALANCES

ANALYSIS OF VARIANCE USING DUNNETT'S PROCEDURE

GROUP:	1-F	2-F	3-F	4-F
SPLEEN (G)(ABSOLUTE)				
MEAN	0.496	0.535	0.474	0.520
SD	0.0480	0.0920	0.0625	0.0542
N	10	10	10	10
THYMUS (G)(ABSOLUTE)				
MEAN	0.446	0.461	0.432	0.434
SD	0.0808	0.0774	0.0457	0.0898
N	10	10	10	10

PRIMEDICA REDFIELD STUDY NUMBER 132-007

TABLE 8

ORGAN WEIGHT SUMMARY (ABSOLUTE)				
STUDY: T-7485				
SEX: FEMALE				
FATES: SCHEDULED SACRIFICE				
DAYS: 44-44				
ALL BALANCES				
ANALYSIS OF VARIANCE USING DUNNETT'S PROCEDURE				
GROUP:	1-F	2-F	3-F	4-F
BODY WEIGHT (G)(ABSOLUTE)				
MEAN	243.200	0.000	0.000	242.000
SD	12.4780	NA	NA	4.3589
N	5	0	0	5
ADRENAL GLANDS (G)(ABSOLUTE)				
MEAN	0.080	0.000	0.000	0.089
SD	0.0124	NA	NA	0.0119
N	5	0	0	5
BRAIN (G)(ABSOLUTE)				
MEAN	1.978	0.000	0.000	1.967
SD	0.0996	NA	NA	0.0784
N	5	0	0	5
HEART (G)(ABSOLUTE)				
MEAN	0.959	0.000	0.000	0.934
SD	0.0743	NA	NA	0.0696
N	5	0	0	5
KIDNEYS (G)(ABSOLUTE)				
MEAN	2.135	0.000	0.000	2.227
SD	0.2176	NA	NA	0.2213
N	5	0	0	5
LIVER (G)(ABSOLUTE)				
MEAN	8.547	0.000	0.000	8.825
SD	1.1297	NA	NA	0.9359
N	5	0	0	5
OVARIES (G)(ABSOLUTE)				
MEAN	0.104	0.000	0.000	0.102
SD	0.0196	NA	NA	0.0115
N	5	0	0	5
NA-Not Applicable				
PRIMEDICA REDFIELD STUDY NUMBER 132-007				

TABLE 8

ORGAN WEIGHT SUMMARY (ABSOLUTE)

STUDY: T-7485

SEX: FEMALE

FATES: SCHEDULED SACRIFICE

DAYS: 44-44

ALL BALANCES

ANALYSIS OF VARIANCE USING DUNNETT'S PROCEDURE

GROUP:	1-F	2-F	3-F	4-F
--------	-----	-----	-----	-----

SPLEEN (G)(ABSOLUTE)

MEAN	0.547	0.000	0.000	0.546
SD	0.0716	NA	NA	0.0310
N	5	0	0	5

THYMUS (G)(ABSOLUTE)

MEAN	0.506	0.000	0.000	0.420
SD	0.1406	NA	NA	0.0834
N	5	0	0	5

NA-Not Applicable

PRIMEDICA REDFIELD STUDY NUMBER 132-007

TABLE 8

 ORGAN WEIGHT SUMMARY (% BODY WEIGHT)

STUDY: T-7485

SEX: MALE

FATES: SCHEDULED SACRIFICE

DAYS: 29-29

ALL BALANCES

ANALYSIS OF VARIANCE USING DUNNETT'S PROCEDURE

 GROUP: 1-M 2-M 3-M 4-M

ADRENAL GLANDS (% BODY WEIGHT)

MEAN	0.020	0.021	0.020	0.020
SD	0.0023	0.0028	0.0028	0.0030
N	10	10	10	10

BRAIN (% BODY WEIGHT)

MEAN	0.583	0.591	0.616	0.596
SD	0.0694	0.0355	0.0631	0.0405
N	10	10	10	10

HEART (% BODY WEIGHT)

MEAN	0.355	0.355	0.352	0.349
SD	0.0237	0.0273	0.0314	0.0158
N	10	10	10	10

KIDNEYS (% BODY WEIGHT)

MEAN	0.800	0.795	0.858	0.855
SD	0.0724	0.0261	0.0886	0.0775
N	10	10	10	10

LIVER (% BODY WEIGHT)

MEAN	2.913	3.030	3.208*	3.774**
SD	0.1273	0.2376	0.2478	0.3286
N	10	10	10	10

SPLEEN (% BODY WEIGHT)

MEAN	0.189	0.206	0.210	0.195
SD	0.0201	0.0304	0.0111	0.0237
N	10	10	10	10

TESTES (% BODY WEIGHT)

MEAN	0.941	0.848	0.970	0.973
SD	0.0665	0.1201	0.0633	0.0794
N	10	10	10	10

* - Significant difference P<.05

** - Significant difference P<.01

PRIMEDICA REDFIELD STUDY NUMBER 132-007

TABLE 8

ORGAN WEIGHT SUMMARY (% BODY WEIGHT)

STUDY: T-7485

SEX: MALE

FATES: SCHEDULED SACRIFICE

DAYS: 29-29

ALL BALANCES

ANALYSIS OF VARIANCE USING DUNNETT'S PROCEDURE
-----GROUP: 1-M 2-M 3-M 4-M

THYMUS (% BODY WEIGHT)

MEAN	0.147	0.153	0.147	0.153
SD	0.0211	0.0350	0.0166	0.0297
N	10	10	10	10

PRIMEDICA REDFIELD STUDY NUMBER 132-007

TABLE 8

ORGAN WEIGHT SUMMARY (% BODY WEIGHT)

STUDY: T-7485

SEX: MALE

FATES: SCHEDULED SACRIFICE DAYS: 44-44 ALL BALANCES
ANALYSIS OF VARIANCE USING DUNNETT'S PROCEDURE

GROUP:	1-M	2-M	3-M	4-M
ADRENAL GLANDS (% BODY WEIGHT)				
MEAN	0.017	0.000	0.000	0.017
SD	0.0025	NA	NA	0.0023
N	5	0	0	5
BRAIN (% BODY WEIGHT)				
MEAN	0.505	0.000	0.000	0.556
SD	0.0250	NA	NA	0.0460
N	5	0	0	5
HEART (% BODY WEIGHT)				
MEAN	0.337	0.000	0.000	0.367
SD	0.0249	NA	NA	0.0346
N	5	0	0	5
KIDNEYS (% BODY WEIGHT)				
MEAN	0.824	0.000	0.000	0.905
SD	0.0809	NA	NA	0.0685
N	5	0	0	5
LIVER (% BODY WEIGHT)				
MEAN	3.566	0.000	0.000	3.691
SD	0.2505	NA	NA	0.3024
N	5	0	0	5
SPLEEN (% BODY WEIGHT)				
MEAN	0.199	0.000	0.000	0.181
SD	0.0328	NA	NA	0.0411
N	5	0	0	5
TESTES (% BODY WEIGHT)				
MEAN	0.716	0.000	0.000	0.866**
SD	0.0501	NA	NA	0.0660
N	5	0	0	5

** - Significant difference P<.01

NA-Not Applicable

PRIMEDICA REDFIELD STUDY NUMBER 132-007

TABLE 8

ORGAN WEIGHT SUMMARY (% BODY WEIGHT)

STUDY: T-7485

SEX: MALE

FATES: SCHEDULED SACRIFICE

DAYS: 44-44

ALL BALANCES

ANALYSIS OF VARIANCE USING DUNNETT'S PROCEDURE

GROUP:	1-M	2-M	3-M	4-M
THYMUS (% BODY WEIGHT)				
MEAN	0.127	0.000	0.000	0.137
SD	0.0145	NA	NA	0.0183
N	5	0	0	5

NA-Not Applicable

PRIMEDICA REDFIELD STUDY NUMBER 132-007

TABLE 8

ORGAN WEIGHT SUMMARY (% BODY WEIGHT)				
STUDY: T-7485				
SEX: FEMALE				
FATES: SCHEDULED SACRIFICE				
DAYS: 29-29				
ALL BALANCES				
ANALYSIS OF VARIANCE USING DUNNETT'S PROCEDURE				
GROUP:	1-F	2-F	3-F	4-F
ADRENAL GLANDS (% BODY WEIGHT)				
MEAN	0.037	0.037	0.036	0.035
SD	0.0055	0.0047	0.0066	0.0049
N	10	10	10	10
BRAIN (% BODY WEIGHT)				
MEAN	0.859	0.886	0.853	0.844
SD	0.0531	0.0512	0.0639	0.0599
N	10	10	10	10
HEART (% BODY WEIGHT)				
MEAN	0.394	0.404	0.379	0.370
SD	0.0223	0.0360	0.0320	0.0397
N	10	10	10	10
KIDNEYS (% BODY WEIGHT)				
MEAN	0.809	0.874	0.822	0.879*
SD	0.0664	0.0477	0.0592	0.0733
N	10	10	10	10
LIVER (% BODY WEIGHT)				
MEAN	3.066	3.221	3.130	3.203
SD	0.3517	0.2249	0.2314	0.2816
N	10	10	10	10
OVARIES (% BODY WEIGHT)				
MEAN	0.048	0.047	0.048	0.048
SD	0.0065	0.0065	0.0055	0.0098
N	10	10	10	10
SPLEEN (% BODY WEIGHT)				
MEAN	0.220	0.243	0.208	0.226
SD	0.0155	0.0419	0.0214	0.0228
N	10	10	10	10
* - Significant difference P<.05				
PRIMEDICA REDFIELD STUDY NUMBER 132-007				

TABLE 8

ORGAN WEIGHT SUMMARY (% BODY WEIGHT)

STUDY: T-7485

SEX: FEMALE

FATES: SCHEDULED SACRIFICE DAYS: 29-29 ALL BALANCES
ANALYSIS OF VARIANCE USING DUNNETT'S PROCEDURE
-----GROUP: 1-F 2-F 3-F 4-F

THYMUS (% BODY WEIGHT)

MEAN	0.198	0.210	0.191	0.188
SD	0.0320	0.0370	0.0234	0.0321
N	10	10	10	10

PRIMEDICA REDFIELD STUDY NUMBER 132-007

TABLE 8

 ORGAN WEIGHT SUMMARY (% BODY WEIGHT)

STUDY: T-7485

SEX: FEMALE

FATES: SCHEDULED SACRIFICE DAYS: 44-44 ALL BALANCES

ANALYSIS OF VARIANCE USING DUNNETT'S PROCEDURE

 GROUP: 1-F 2-F 3-F 4-F

ADRENAL GLANDS (% BODY WEIGHT)

MEAN	0.033	0.000	0.000	0.037
SD	0.0048	NA	NA	0.0051
N	5	0	0	5

BRAIN (% BODY WEIGHT)

MEAN	0.814	0.000	0.000	0.813
SD	0.0467	NA	NA	0.0360
N	5	0	0	5

HEART (% BODY WEIGHT)

MEAN	0.394	0.000	0.000	0.387
SD	0.0149	NA	NA	0.0315
N	5	0	0	5

KIDNEYS (% BODY WEIGHT)

MEAN	0.878	0.000	0.000	0.920
SD	0.0731	NA	NA	0.0856
N	5	0	0	5

LIVER (% BODY WEIGHT)

MEAN	3.512	0.000	0.000	3.648
SD	0.4185	NA	NA	0.4010
N	5	0	0	5

OVARIES (% BODY WEIGHT)

MEAN	0.043	0.000	0.000	0.042
SD	0.0071	NA	NA	0.0046
N	5	0	0	5

SPLEEN (% BODY WEIGHT)

MEAN	0.225	0.000	0.000	0.226
SD	0.0286	NA	NA	0.0116
N	5	0	0	5

NA-Not Applicable

PRIMEDICA REDFIELD STUDY NUMBER 132-007

TABLE 8

ORGAN WEIGHT SUMMARY (% BODY WEIGHT)

STUDY: T-7485

SEX: FEMALE

FATES: SCHEDULED SACRIFICE

DAYS: 44-44

ALL BALANCES

ANALYSIS OF VARIANCE USING DUNNETT'S PROCEDURE
-----GROUP: 1-F 2-F 3-F 4-F

THYMUS (% BODY WEIGHT)

MEAN	0.207	0.000	0.000	0.174
SD	0.0531	NA	NA	0.0365
N	5	0	0	5

NA-Not Applicable

PRIMEDICA REDFIELD STUDY NUMBER 132-007

TABLE 8

ORGAN WEIGHT SUMMARY (% BRAIN WEIGHT)

STUDY: T-7485

SEX: MALE

FATES: SCHEDULED SACRIFICE

DAYS: 29-29

ALL BALANCES

ANALYSIS OF VARIANCE USING DUNNETT'S PROCEDURE

GROUP:	1-M	2-M	3-M	4-M
ADRENAL GLANDS (% BRAIN WEIGHT)				
MEAN	3.448	3.645	3.237	3.377
SD	0.3766	0.5446	0.5385	0.5620
N	10	10	10	10
HEART (% BRAIN WEIGHT)				
MEAN	61.471	59.998	57.621	58.727
SD	6.7183	4.2516	6.8878	3.9519
N	10	10	10	10
KIDNEYS (% BRAIN WEIGHT)				
MEAN	138.528	134.756	140.611	143.659
SD	17.6779	8.4422	19.4984	12.2345
N	10	10	10	10
LIVER (% BRAIN WEIGHT)				
MEAN	506.171	514.455	527.859	634.112**
SD	66.3457	53.3894	83.2392	52.9397
N	10	10	10	10
SPLEEN (% BRAIN WEIGHT)				
MEAN	32.839	35.042	34.455	32.780
SD	4.8587	6.2017	4.4519	4.4595
N	10	10	10	10
TESTES (% BRAIN WEIGHT)				
MEAN	162.754	143.189*	159.161	163.221
SD	15.9438	15.6986	20.9146	7.0780
N	10	10	10	10
THYMUS (% BRAIN WEIGHT)				
MEAN	25.550	25.886	23.944	25.784
SD	4.4202	6.1433	2.0155	5.8661
N	10	10	10	10

* - Significant difference $P < .05$ ** - Significant difference $P < .01$

PRIMEDICA REDFIELD STUDY NUMBER 132-007

TABLE 8

ORGAN WEIGHT SUMMARY (% BRAIN WEIGHT)

STUDY: T-7485

SEX: MALE

FATES: SCHEDULED SACRIFICE DAYS: 44-44 ALL BALANCES
ANALYSIS OF VARIANCE USING DUNNETT'S PROCEDURE

GROUP:	1-M	2-M	3-M	4-M
ADRENAL GLANDS (% BRAIN WEIGHT)				
MEAN	3.410	0.000	0.000	3.134
SD	0.5265	NA	NA	0.7291
N	5	0	0	5
HEART (% BRAIN WEIGHT)				
MEAN	66.964	0.000	0.000	66.236
SD	5.9684	NA	NA	6.9501
N	5	0	0	5
KIDNEYS (% BRAIN WEIGHT)				
MEAN	163.194	0.000	0.000	163.258
SD	13.8442	NA	NA	12.8100
N	5	0	0	5
LIVER (% BRAIN WEIGHT)				
MEAN	706.862	0.000	0.000	668.866
SD	41.2554	NA	NA	95.8205
N	5	0	0	5
SPLEEN (% BRAIN WEIGHT)				
MEAN	39.630	0.000	0.000	32.354
SD	7.4456	NA	NA	5.3903
N	5	0	0	5
TESTES (% BRAIN WEIGHT)				
MEAN	141.894	0.000	0.000	155.866*
SD	9.3046	NA	NA	8.3186
N	5	0	0	5
THYMUS (% BRAIN WEIGHT)				
MEAN	25.224	0.000	0.000	24.720
SD	2.2726	NA	NA	3.4212
N	5	0	0	5

* - Significant difference P<.05

NA-Not Applicable

PRIMEDICA REDFIELD STUDY NUMBER 132-007

TABLE 8

ORGAN WEIGHT SUMMARY (% BRAIN WEIGHT)

STUDY: T-7485

SEX: FEMALE

FATES: SCHEDULED SACRIFICE

DAYS: 29-29

ALL BALANCES

ANALYSIS OF VARIANCE USING DUNNETT'S PROCEDURE

GROUP:	1-F	2-F	3-F	4-F
ADRENAL GLANDS (% BRAIN WEIGHT)				
MEAN	4.341	4.142	4.222	4.081
SD	0.8352	0.5258	0.5661	0.4782
N	10	10	10	10
HEART (% BRAIN WEIGHT)				
MEAN	45.976	45.579	44.656	43.927
SD	2.9349	2.7052	4.8562	4.5627
N	10	10	10	10
KIDNEYS (% BRAIN WEIGHT)				
MEAN	94.429	98.811	96.744	104.359
SD	9.5441	6.1946	8.1046	7.7444
N	10	10	10	10
LIVER (% BRAIN WEIGHT)				
MEAN	358.130	364.641	368.399	381.530
SD	46.9672	30.7329	32.2870	45.0936
N	10	10	10	10
OVARIES (% BRAIN WEIGHT)				
MEAN	5.590	5.294	5.681	5.656
SD	0.6268	0.6363	0.7200	1.2472
N	10	10	10	10
SPLEEN (% BRAIN WEIGHT)				
MEAN	25.666	27.541	24.590	26.860
SD	1.9341	5.2675	3.3877	2.5176
N	10	10	10	10
THYMUS (% BRAIN WEIGHT)				
MEAN	23.119	23.730	22.422	22.431
SD	3.8556	4.4214	2.6258	4.5613
N	10	10	10	10

PRIMEDICA REDFIELD STUDY NUMBER 132-007

TABLE 8

ORGAN WEIGHT SUMMARY (% BRAIN WEIGHT)

STUDY: T-7485

SEX: FEMALE

FATES: SCHEDULED SACRIFICE

DAYS: 44-44

ALL BALANCES

ANALYSIS OF VARIANCE USING DUNNETT'S PROCEDURE

GROUP:	1-F	2-F	3-F	4-F
--------	-----	-----	-----	-----

ADRENAL GLANDS (% BRAIN WEIGHT)

MEAN	4.036	0.000	0.000	4.548
SD	0.6184	NA	NA	0.6118
N	5	0	0	5

HEART (% BRAIN WEIGHT)

MEAN	48.492	0.000	0.000	47.576
SD	3.1436	NA	NA	4.0621
N	5	0	0	5

KIDNEYS (% BRAIN WEIGHT)

MEAN	107.766	0.000	0.000	113.046
SD	6.7108	NA	NA	7.9481
N	5	0	0	5

LIVER (% BRAIN WEIGHT)

MEAN	432.210	0.000	0.000	448.022
SD	54.7403	NA	NA	33.2786
N	5	0	0	5

OVARIES (% BRAIN WEIGHT)

MEAN	5.254	0.000	0.000	5.174
SD	0.8064	NA	NA	0.3977
N	5	0	0	5

SPLEEN (% BRAIN WEIGHT)

MEAN	27.666	0.000	0.000	27.774
SD	3.5032	NA	NA	1.4843
N	5	0	0	5

THYMUS (% BRAIN WEIGHT)

MEAN	25.744	0.000	0.000	21.336
SD	7.8943	NA	NA	3.8449
N	5	0	0	5

NA-Not Applicable

PRIMEDICA REDFIELD STUDY NUMBER 132-007

APPENDICES

APPENDIX 1
METHODS USED FOR CLINICAL PATHOLOGY PROCEDURES

HEMATOLOGY

The Baker System 9110 + Plus Automated Cell Counter is used for complete blood counts.

White Blood Cell (WBC), Red Blood Cell (RBC) and Platelet counts - The instrument electronically counts WBC, RBC, and platelets by employing the impedance principle. This principle of electronic counting and sizing is based on the difference in conductivity between blood cells and the diluent in which they are suspended. Pulse editing is used to discriminate between red blood cells and platelets.

Mean Corpuscular Volume (MCV) - Measurement of MCV is based on the RBC impedance pulse amplitude. RBC pulses are sized according to their voltage and an average is taken. The average is then compared to the MCV reference that is set during the Hematocrit calibration.

Hemoglobin - The hemoglobin determination is accomplished by a cyanmethemoglobin procedure. The color intensity of this reaction is measured by a photometric cell.

Hematocrit (HCT), Mean Corpuscular Hemoglobin (MCH) and Mean Corpuscular Hemoglobin Concentration (MCHC) - calculated from the measured parameters using the following formulas:

$$\text{HCT} = \frac{\text{MCV} \times \text{RBC}}{10}$$

$$\text{MCH} = \frac{\text{HGB} \times 10}{\text{RBC}}$$

$$\text{MCHC} = \frac{\text{HGB} \times 100}{\text{HCT}}$$

Differentials and RBC morphology are done manually.
Stain used - VOLU-SOL Wright's stain.

COAGULATION

MCA 110 - a fully integrated microprocessor driven instrument designed to perform coagulation tests on plasma specimens.

The MCA 110 operates on the principles of optical density measurement enhanced by electronic light amplification, differentiation and signal processing. Utilizing light generated by light diodes and solid state photo-detectors.

Prothrombin Time

Bio/Data Corporation

Plastinex Thromboplastin Reagent

No. 101158

Activated Partial Thromboplastin Time

Bio/Data Corporation

Cephalinex Activated PTT Reagent (Silica Activated)

No. 101162

CLINICAL CHEMISTRY

The Boehringer Mannheim Hitachi - 717 Analyzer is a fully automated computerized chemistry analyzer. It is a multi-channel, discrete instrument capable of performing potentiometric and photometric assays of a wide range of analyses.

The Hitachi - 717 utilizes a unique reagent and sampling system which allows the analysis of 750 test/hour including Ion Selective Electrodes.

Total Protein (Biuret)	Albumin (Bromcresol Green)
Colorimetric Determination	Colorimetric Determination
BMC	BMC
Glucose (Hexokinase)	Cholesterol
Enzymatic Determination	Enzymatic Determination
BMC	BMC
Blood Urea Nitrogen (RATE)	Creatinine
Enzymatic Determination	Kinetic Determination
BMC	BMC
Total Bilirubin	Alanine Aminotransferase
Colorimetric Determination	Kinetic Determination
BMC	BMC
Aspartate Aminotransferase	Alkaline Phosphatase
Kinetic Determination	Kinetic Determination
BMC	BMC
Creatine Kinase	Lactate Dehydrogenase
Kinetic Determination	Kinetic Determination
BMC	BMC
Gamma-Glutamyltransferase	Triglyceride (GPO-Trinder)
Kinetic Determination	Enzymatic Determination
BMC	BMC
Calcium	Phosphorus (Inorganic)
Colorimetric Determination	Ultraviolet Determination
BMC	BMC
Direct Bilirubin	Amylase/EPS
Colorimetric Determination	Enzymatic Colorimetric Test
BMC	BMC
Lipase	Sorbitol Dehydrogenase
Ultraviolet Determination	Enzymatic Determination
BMC	Sigma

Sodium - Ion Selective Electrode, Boehringer Mannheim Procedure

Potassium - Ion Selective Electrode, Boehringer Mannheim Procedure

Chloride - Ion Selective Electrode, Boehringer Mannheim Procedure

BMC = Boehringer Mannheim Corporation Reagents

APPENDIX 2
INDIVIDUAL NECROPSY OBSERVATIONS

REPORTS CODE TABLE

TGL

Trackable Gross Lesion

PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL NECROPSY OBSERVATIONS

132-007 - A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

Group: 1 Dose: 0 Sex: Male

Animal Number	Mode Of Death	Death Day (Week)	Observation(s)
7569	SCHEDULED SACRIFICE	29 (5)	No Visible Lesions
7571	SCHEDULED SACRIFICE	29 (5)	No Visible Lesions
7573	SCHEDULED SACRIFICE	29 (5)	No Visible Lesions
7575	SCHEDULED SACRIFICE	29 (5)	No Visible Lesions
7577	SCHEDULED SACRIFICE	29 (5)	No Visible Lesions
7579	SCHEDULED SACRIFICE	29 (5)	No Visible Lesions
7581	SCHEDULED SACRIFICE	29 (5)	No Visible Lesions
7583	SCHEDULED SACRIFICE	29 (5)	No Visible Lesions
7585	SCHEDULED SACRIFICE	29 (5)	No Visible Lesions
7587	SCHEDULED SACRIFICE	29 (5)	No Visible Lesions
7589	SCHEDULED SACRIFICE	44 (7)	No Visible Lesions
7591	SCHEDULED SACRIFICE	44 (7)	No Visible Lesions
7593	SCHEDULED SACRIFICE	44 (7)	No Visible Lesions
7595	SCHEDULED SACRIFICE	44 (7)	No Visible Lesions
7597	SCHEDULED SACRIFICE	44 (7)	No Visible Lesions

INDIVIDUAL NECROPSY OBSERVATIONS

132-007 - A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

Group: 2 Dose: 100 Sex: Male

Animal Number	Mode Of Death	Death		Observation(s)
		Day	(Week)	
7599	SCHEDULED SACRIFICE	29	(5)	No Visible Lesions
7601	SCHEDULED SACRIFICE	29	(5)	No Visible Lesions
7603	SCHEDULED SACRIFICE	29	(5)	No Visible Lesions
7605	SCHEDULED SACRIFICE	29	(5)	No Visible Lesions
7607	SCHEDULED SACRIFICE	29	(5)	TESTES; RIGHT; SMALL (TGL) Any remaining protocol required tissues, which have been examined, have no visible lesions
7609	SCHEDULED SACRIFICE	29	(5)	No Visible Lesions
7611	SCHEDULED SACRIFICE	29	(5)	No Visible Lesions
7613	SCHEDULED SACRIFICE	29	(5)	No Visible Lesions
7615	SCHEDULED SACRIFICE	29	(5)	No Visible Lesions
7617	SCHEDULED SACRIFICE	29	(5)	No Visible Lesions

INDIVIDUAL NECROPSY OBSERVATIONS

132-007 - A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

Group: 3 Dose: 300 Sex: Male

Animal Number	Mode Of Death	Death Day (Week)	Observation(s)
7619	SCHEDULED SACRIFICE	29 (5)	No Visible Lesions
7621	SCHEDULED SACRIFICE	29 (5)	No Visible Lesions
7623	SCHEDULED SACRIFICE	29 (5)	No Visible Lesions
7625	SCHEDULED SACRIFICE	29 (5)	No Visible Lesions
7627	SCHEDULED SACRIFICE	29 (5)	No Visible Lesions
7629	SCHEDULED SACRIFICE	29 (5)	No Visible Lesions
7631	SCHEDULED SACRIFICE	29 (5)	No Visible Lesions
7633	SCHEDULED SACRIFICE	29 (5)	No Visible Lesions
7635	SCHEDULED SACRIFICE	29 (5)	No Visible Lesions
7637	SCHEDULED SACRIFICE	29 (5)	No Visible Lesions

INDIVIDUAL NECROPSY OBSERVATIONS

132-007 - A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

Group: 4 Dose: 900 Sex: Male

Animal Number	Mode Of Death	Death Day (Week)	Observation(s)
7639	SCHEDULED SACRIFICE	29 (5)	No Visible Lesions
7641	SCHEDULED SACRIFICE	29 (5)	No Visible Lesions
7643	SCHEDULED SACRIFICE	29 (5)	No Visible Lesions
7645	SCHEDULED SACRIFICE	29 (5)	No Visible Lesions
7647	SCHEDULED SACRIFICE	29 (5)	No Visible Lesions
7649	SCHEDULED SACRIFICE	29 (5)	No Visible Lesions
7651	SCHEDULED SACRIFICE	29 (5)	No Visible Lesions
7653	SCHEDULED SACRIFICE	29 (5)	No Visible Lesions
7655	SCHEDULED SACRIFICE	29 (5)	No Visible Lesions
7657	SCHEDULED SACRIFICE	29 (5)	No Visible Lesions
7659	SCHEDULED SACRIFICE	44 (7)	No Visible Lesions
7661	SCHEDULED SACRIFICE	44 (7)	No Visible Lesions
7663	SCHEDULED SACRIFICE	44 (7)	No Visible Lesions
7665	SCHEDULED SACRIFICE	44 (7)	No Visible Lesions
7667	SCHEDULED SACRIFICE	44 (7)	No Visible Lesions

A 28-Day Oral Toxicity Study in Sprague-Dawley Rats

Study Number: 132-007

INDIVIDUAL NECROPSY OBSERVATIONS

132-007 - A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

Group: 1 Dose: 0 Sex: Female

Animal Number	Mode Of Death	Death		Observation(s)
		Day	(Week)	
7570	SCHEDULED SACRIFICE	30	(5)	No Visible Lesions
7572	SCHEDULED SACRIFICE	30	(5)	No Visible Lesions
7574	SCHEDULED SACRIFICE	30	(5)	No Visible Lesions
7576	SCHEDULED SACRIFICE	30	(5)	No Visible Lesions
7578	SCHEDULED SACRIFICE	30	(5)	No Visible Lesions
7580	SCHEDULED SACRIFICE	30	(5)	No Visible Lesions
7582	SCHEDULED SACRIFICE	30	(5)	No Visible Lesions
7584	SCHEDULED SACRIFICE	30	(5)	No Visible Lesions
7586	SCHEDULED SACRIFICE	30	(5)	No Visible Lesions
7588	SCHEDULED SACRIFICE	30	(5)	No Visible Lesions
7590	SCHEDULED SACRIFICE	44	(7)	No Visible Lesions
7592	SCHEDULED SACRIFICE	44	(7)	No Visible Lesions
7594	SCHEDULED SACRIFICE	44	(7)	No Visible Lesions
7596	SCHEDULED SACRIFICE	44	(7)	No Visible Lesions
7598	SCHEDULED SACRIFICE	44	(7)	No Visible Lesions

INDIVIDUAL NECROPSY OBSERVATIONS

132-007 - A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

Group: 2 Dose: 100 Sex: Female

Animal Number	Mode Of Death	Death Day (Week)	Observation(s)
7600	SCHEDULED SACRIFICE	30 (5)	No Visible Lesions
7602	SCHEDULED SACRIFICE	30 (5)	No Visible Lesions
7604	SCHEDULED SACRIFICE	30 (5)	No Visible Lesions
7606	SCHEDULED SACRIFICE	30 (5)	No Visible Lesions
7608	SCHEDULED SACRIFICE	30 (5)	No Visible Lesions
7610	SCHEDULED SACRIFICE	30 (5)	No Visible Lesions
7612	SCHEDULED SACRIFICE	30 (5)	No Visible Lesions
7614	SCHEDULED SACRIFICE	30 (5)	No Visible Lesions
7616	SCHEDULED SACRIFICE	30 (5)	No Visible Lesions
7618	SCHEDULED SACRIFICE	30 (5)	No Visible Lesions

INDIVIDUAL NECROPSY OBSERVATIONS

132-007 - A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

Group: 3 Dose: 300 Sex: Female

Animal Number	Mode Of Death	Death Day (Week)	Observation(s)
7620	SCHEDULED SACRIFICE	30 (5)	No Visible Lesions
7622	SCHEDULED SACRIFICE	30 (5)	No Visible Lesions
7624	SCHEDULED SACRIFICE	30 (5)	No Visible Lesions
7626	SCHEDULED SACRIFICE	30 (5)	No Visible Lesions
7628	SCHEDULED SACRIFICE	30 (5)	No Visible Lesions
7630	SCHEDULED SACRIFICE	30 (5)	No Visible Lesions
7632	SCHEDULED SACRIFICE	30 (5)	No Visible Lesions
7634	SCHEDULED SACRIFICE	30 (5)	No Visible Lesions
7636	SCHEDULED SACRIFICE	30 (5)	No Visible Lesions
7638	SCHEDULED SACRIFICE	30 (5)	No Visible Lesions

INDIVIDUAL NECROPSY OBSERVATIONS

132-007 - A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

Group: 4 Dose: 900 Sex: Female

Animal Number	Mode Of Death	Death Day (Week)	Observation(s)
7640	SCHEDULED SACRIFICE	30 (5)	No Visible Lesions
7642	SCHEDULED SACRIFICE	30 (5)	No Visible Lesions
7644	SCHEDULED SACRIFICE	30 (5)	No Visible Lesions
7646	SCHEDULED SACRIFICE	30 (5)	No Visible Lesions
7648	SCHEDULED SACRIFICE	30 (5)	No Visible Lesions
7650	SCHEDULED SACRIFICE	30 (5)	No Visible Lesions
7652	SCHEDULED SACRIFICE	30 (5)	No Visible Lesions
7654	SCHEDULED SACRIFICE	30 (5)	No Visible Lesions
7656	SCHEDULED SACRIFICE	30 (5)	No Visible Lesions
7658	SCHEDULED SACRIFICE	30 (5)	No Visible Lesions
7660	SCHEDULED SACRIFICE	44 (7)	No Visible Lesions
7662	SCHEDULED SACRIFICE	44 (7)	No Visible Lesions
7664	SCHEDULED SACRIFICE	44 (7)	No Visible Lesions
7666	SCHEDULED SACRIFICE	44 (7)	No Visible Lesions
7668	SCHEDULED SACRIFICE	44 (7)	No Visible Lesions

**APPENDIX 3
HISTOPATHOLOGY REPORT**



PATHOLOGY REPORT
FOR
A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN
SPRAGUE-DAWLEY RATS
PRIMEDICA REDFIELD PROTOCOL NUMBER: 132-007

PREPARED FOR
PRIMEDICA REDFIELD

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I. Pathology Narrative

Final Pathology Report
Redfield Laboratories, Inc.: 132-007

A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

Primedica Redfield Protocol Number 132-007

INTRODUCTION

This report by Pathology Associates-A Charles River Company (PAI), formerly Pathology Associates International, for Primedica Redfield, 100 East Boone Street, Redfield, AR 72132, presents the results of pathology support for Protocol Number 132-007, an oral toxicity study in rats. The objective of this study was to evaluate the toxicity potential associated with oral (gavage) administration of T-7485 in Sprague-Dawley rats for a 28-day repeated dose with an approximate 14-day recovery period. The portions of this study performed by Pathology Associates (PAI) were conducted to the standards of the Organization for Economic Cooperation and Development (OECD) regulations, C(81)30 (Final).

STUDY DESIGN AND METHODS

One hundred Sprague-Dawley rats (50 males and 50 females) were randomly assigned to four groups and treated as is depicted in Table 1. Three dose levels of the test material and a vehicle control group were evaluated. Doses were administered via oral gavage for twenty-eight consecutive days. The dose volume was 25 mL/kg. The dose for each animal was calculated based upon the most recent body weight. Rats (5/sex/group) in the vehicle control and high dose groups were allowed a recovery period of approximately fourteen days. On Study Day 29, the animals were sacrificed by rotating sequentially through groups for each sex. Recovery animals were sacrificed rotating sequentially through the groups for each sex on approximately Study Day 44. Animals were euthanized via carbon dioxide asphyxiation followed by exsanguination. Comprehensive necropsies were performed on all scheduled sacrifices by Primedica personnel. These included macroscopic examination of the external surface of the body, all orifices and the cranial, thoracic, and abdominal cavities and their contents. Specified organ weights were measured and gross lesions were recorded during the necropsies, and protocol specified tissues were collected and preserved in 10% neutral buffered formalin or other suitable fixative.

Table 1. Study Design

Group Number	Group Designation	Dosage Level (mg/kg)	Dosage Concentration (mg/mL)	Dosage Volume (mL/kg)	Number of Animals*	
					Males	Females
1	Vehicle Control	0	0	25	10 (5)	10 (5)
2	Mid-dose	100	4	25	10	10
3	Mid-high dose	300	12	25	10	10
4	High-dose	900	36	25	10 (5)	10 (5)

* Number in parenthesis indicates the number of recovery animals.

Final Pathology Report
Redfield Laboratories, Inc.: 132-007

Protocol specified tissues from animals in the control and high dose groups and on all gross lesions were sent to PAI's Frederick, Maryland facility where they were processed through paraffin, sectioned at approximately 5 microns, and stained with hematoxylin and eosin (H&E). Sections were then evaluated for pathological changes by the undersigned Study Pathologist. All microscopic lesions were graded according to the following severity scale: 1(minimal), 2(mild), 3(moderate), or 4(marked).

RESULTS

Unscheduled Deaths There were no early deaths. All study animals survived to their scheduled sacrifice date (Day 29 or Day 44).

Gross Lesions Only one gross lesion was recorded at necropsy and was not considered to be test article-related.

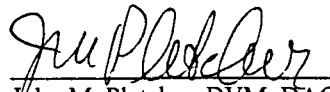
Microscopic Pathology Microscopic findings are presented in tabular format in Sections II and III. Summary data are presented by gender, group and time point in the Summary of Histologic Findings (Section II), while individual diagnoses can be found in the Individual Animal Histologic Findings (Section III). The macroscopic lesions, as well as the corresponding microscopic correlates, when present, are recorded in Section IV of this report (Gross and Microscopic Correlation of Findings). Tissue comments, where applicable, are provided in the Comment Report (Section V). Symbols used for lesion severity and distribution are explained in the Reports Code Table (Appendix 1), and abbreviations used in LABCAT tables are explained in Appendix 2.

The microscopic lesions observed in the animals of this study are considered incidental and in no way related to receiving the test article.

SUMMARY AND CONCLUSIONS

One hundred Sprague-Dawley rats were randomly assigned to four groups and treated as is depicted in Table 1. Doses were administered via oral gavage for twenty-eight consecutive days. Comprehensive necropsies were performed on all study animals by Primedica personnel. Protocol specified tissues were processed through paraffin and rendered to approximately 5 micron sections stained with H&E. These sections were then evaluated microscopically.

The one gross lesion noted at necropsy is not considered to be related to receiving the test article. The microscopic lesions observed in the test animals are also considered to be incidental and in no way related to receiving the test article.


John M. Pletcher, DVM, DACVP
Study Pathologist

6/29/01
Date

Appendix 1:
Reports Code Table

PATHOLOGY ASSOCIATES INTERNATIONAL
A 28-DAY ORAL (GAVAGE) TOXICITY STUDY T-7485 IN SPRAGUE-DAWLEY RATS
PRIMEDICA REDFIELD PROTOCOL NUMBER: 132-007

Reports Code Table

N	Tissues within normal histological limits
A	Autolysis precluding adequate evaluation
U	Tissues unavailable/unsuitable for evaluation
R	Recut/retrim requested
*	Tissues not submitted for evaluation
1	minimal
2	mild
3	moderate
4	marked
()	focal
[]	diffuse
< >	multifocal
P	Present
B	Neoplasm, Benign
M	Neoplasm, Malignant without Metastasis
C	Neoplasm, Malignant with Metastasis
X	Metastatic Site (+)
L	Unilateral
I	Bilateral
-	Diagnosis not applicable to animal/tissue; no data entered

Appendix 2:
Abbreviations List

PATHOLOGY ASSOCIATES INTERNATIONAL
A 28-DAY ORAL (GAVAGE) TOXICITY STUDY T-7485 IN SPRAGUE-DAWLEY RATS
PRIMEDICA REDFIELD PROTOCOL NUMBER: 132-007

Abbreviations List

# EX	Number Examined
MANDIB	Mandibular
SM	Small
LG	Large
W/	With
ARTIC	Articular

II. Summary of Histologic Findings

SUMMARY OF HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

SEX: MALE

INCIDENCE OF MICROSCOPIC FINDINGS

GROUP:		1	2	4
NUMBER OF ANIMALS:		10	1	10
		#	#	#
ESOPHAGUS	# EX	10	0	10
MUSCULAR TUNIC- DEGENERATION		0	0	1
HEART	# EX	10	0	10
CARDIOMYOPATHY		2	0	1
KIDNEYS	# EX	10	0	10
HYDRONEPHROSIS		2	0	1
CORTEX- SUBACUTE INFLAMMATION		1	0	0
CYST(S)		1	0	0
LACRIMAL GLAND	# EX	10	0	10
LYMPHOCYTE INFILTRATION		0	0	1
LG INTESTINE, RECTUM	# EX	10	0	10
MUSCULAR TUNIC- PERIVASCULAR INFLAMMATION		1	0	0
SUBMUCOSA- PERIVASCULAR INFLAMMATION		1	0	0
LIVER	# EX	10	0	10
SUBACUTE INFLAMMATION		10	0	7
LUNGS WITH BRONCHI	# EX	10	0	10
ALVEOLI- EOSINOPHILIC CRYSTALS		1	0	0
HEMORRHAGE		1	0	0
INFLAMMATION		3	0	1
LYMPH NODES, MANDIBULAR	# EX	10	0	10
HEMORRHAGE		1	0	0
LYMPH NODES, MESENTERIC	# EX	10	0	10
HEMORRHAGE		0	0	1
PANCREAS	# EX	10	0	10
SUBACUTE INFLAMMATION		1	0	0
TESTES	# EX	10	1	10
TUBULAR DEGENERATION		0	1	0

PRIMEDICA REDFIELD STUDY NUMBER 132-007

SUMMARY OF HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

SEX: MALE

INCIDENCE OF MICROSCOPIC FINDINGS

GROUP:		1	2	4
NUMBER OF ANIMALS:		10	1	10

		#	#	#
THYMUS	# EX	10	0	10
HEMORRHAGE		3	0	2

PRIMEDICA REDFIELD STUDY NUMBER 132-007

SUMMARY OF HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

SEX: FEMALE

INCIDENCE OF MICROSCOPIC FINDINGS

GROUP:		1	4
NUMBER OF ANIMALS:		10	10
		#	#
ESOPHAGUS	# EX	10	10
MUSCULAR TUNIC- DEGENERATION		0	3
HARDERIAN GLAND	# EX	10	10
SUBACUTE INFLAMMATION		0	1
KIDNEYS	# EX	10	10
MINERALIZATION		8	10
TUBULAR DEGENERATION		1	2
LIVER	# EX	10	10
SUBACUTE INFLAMMATION		9	7
LUNGS WITH BRONCHI	# EX	10	10
INFLAMMATION		2	2
LYMPH NODES, MESENTERIC	# EX	10	10
HISTIOCYTOSIS		1	0
PANCREAS	# EX	10	10
SUBACUTE INFLAMMATION		1	0
PITUITARY GLAND	# EX	10	10
PARS NERVOSA- ECTOPIC EPITHELIAL REST		0	1
THYMUS	# EX	10	10
HEMORRHAGE		1	2
UTERUS	# EX	10	10
HORNS- DILATED		5	3

PRIMEDICA REDFIELD STUDY NUMBER 132-007

SUMMARY OF HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Terminal sacrifice

SEX: MALE

INCIDENCE OF MICROSCOPIC FINDINGS

GROUP:	1	4
NUMBER OF ANIMALS:	5	5
	#	#
EPIDIDYIMIDES	# EX 5	5
GRANULOMA(S)	0	1
KIDNEYS	# EX 5	5
HYDRONEPHROSIS	0	1
CYST(S)	1	0
TUBULAR DEGENERATION	1	1
LIVER	# EX 5	5
SUBACUTE INFLAMMATION	4	5
NECROSIS	0	1
LUNGS WITH BRONCHI	# EX 5	5
INFLAMMATION	0	1
TESTES	# EX 5	5
TUBULAR DEGENERATION	0	1
THYMUS	# EX 5	5
HEMORRHAGE	2	0

PRIMEDICA REDFIELD STUDY NUMBER 132-007

SUMMARY OF HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Terminal sacrifice

SEX: FEMALE

INCIDENCE OF MICROSCOPIC FINDINGS

GROUP:	1	4
NUMBER OF ANIMALS:	5	5
	#	#
HARDERIAN GLAND	# EX 5	5
SUBACUTE INFLAMMATION	1	0
KIDNEYS	# EX 5	5
HYDRONEPHROSIS	0	1
MINERALIZATION	2	3
TUBULAR DEGENERATION	0	1
LIVER	# EX 5	5
SUBACUTE INFLAMMATION	5	4
LYMPH NODES, MESENTERIC	# EX 5	5
HEMORRHAGE	1	0
UTERUS	# EX 5	5
HORNS- DILATED	1	2

PRIMEDICA REDFIELD STUDY NUMBER 132-007

III. Individual Animal Histologic Findings

 INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

GROUP: 1M

SEX: MALE

ANIMAL ID:	7569	7571	7573	7575
ADRENAL GLANDS	N	N	N	N
AORTA	N	N	N	N
BONE MARROW (STERNUM)	N	N	N	N
BRAIN	N	N	N	N
EPIDIDYIMIDES	N	N	N	N
ESOPHAGUS	N	N	N	N
EYES WITH OPTIC NERVE	N	N	N	N
FEMUR W/ ARTIC SURFACE	N	N	N	N
HARDERIAN GLAND	N	N	N	N
HEART	-	N	N	N
CARDIOMYOPATHY	1	-	-	-
KIDNEYS	N	-	-	N
HYDRONEPHROSIS	-	1L	-	-
CORTEX- SUBACUTE INFLAMMATION	-	-	<1>1	-
LACRIMAL GLAND	N	N	N	N
LG INTESTINE, CECUM	N	N	N	N
LG INTESTINE, COLON	N	N	N	N
LG INTESTINE, RECTUM	-	N	N	-
MUSCULAR TUNIC- PERIVASCULAR INFLAMMATION	2	-	-	-
SUBMUCOSA- PERIVASCULAR INFLAMMATION	-	-	-	1

 See Reports Code Table for Symbol Definitions
 PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

GROUP: 1M

SEX: MALE

ANIMAL ID:	7569	7571	7573	7575
LIVER	-	-	-	-
SUBACUTE INFLAMMATION	<1>	<1>	<1>	<1>
LUNGS WITH BRONCHI	N	-	-	N
ALVEOLI- EOSINOPHILIC CRYSTALS	-	(2)	-	-
HEMORRHAGE	-	(3)	-	-
INFLAMMATION	-	<2>	(1)	-
LYMPH NODES, MANDIBULAR	N	N	N	N
LYMPH NODES, MESENTERIC	N	N	N	N
MAMMARY GLAND	N	N	N	N
PANCREAS	N	N	N	-
SUBACUTE INFLAMMATION	-	-	-	(1)
PARATHYROID	N	N	N	U
PITUITARY GLAND	N	N	N	N
PROSTATE GLAND	N	N	N	N
SALIVARY GLAND, MANDIB	N	N	N	N
SCIATIC NERVE	N	N	N	N
SEMINAL VESICLES	N	N	N	N
SKELETAL MUSCLE	N	N	N	N
SM INTESTINE, DUODENUM	N	N	N	N
SM INTESTINE, ILEUM	N	N	N	N
SM INTESTINE, JEJUNUM	N	N	N	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

GROUP: 1M

SEX: MALE

ANIMAL ID:	7569	7571	7573	7575
SPINAL CORD, CERVICAL	N	N	N	N
SPINAL CORD, LUMBAR	N	N	N	N
SPINAL CORD, THORACIC	N	N	N	N
SPLEEN	N	N	N	N
STOMACH, FORESTOMACH	N	N	N	N
STOMACH, GLANDULAR	N	N	N	N
TESTES	N	N	N	N
THYMUS	N	N	N	N
THYROID	N	N	N	N
TONGUE	N	N	N	N
TRACHEA	N	N	N	N
URINARY BLADDER	N	N	N	N
ZYMBALS GLAND	N	N	N	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

 INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

GROUP: 1M

SEX: MALE

ANIMAL ID:	7577	7579	7581	7583
ADRENAL GLANDS	N	N	N	N
AORTA	N	N	N	N
BONE MARROW (STERNUM)	N	N	N	N
BRAIN	N	N	N	N
EPIDIDYMIDES	N	N	N	N
ESOPHAGUS	N	N	N	N
EYES WITH OPTIC NERVE	N	N	N	N
FEMUR W/ ARTIC SURFACE	N	N	N	N
HARDERIAN GLAND	N	N	N	N
HEART	N	N	-	N
CARDIOMYOPATHY	-	-	1	-
KIDNEYS	-	N	N	N
HYDRONEPHROSIS	1L	-	-	-
LACRIMAL GLAND	N	N	N	N
LG INTESTINE, CECUM	N	N	N	N
LG INTESTINE, COLON	N	N	N	N
LG INTESTINE, RECTUM	N	N	N	N
LIVER	-	-	-	-
SUBACUTE INFLAMMATION	<1>	<2>	<1>	<1>
LUNGS WITH BRONCHI	N	N	N	N

 See Reports Code Table for Symbol Definitions
 PRIMEDICA REDFIELD STUDY NUMBER 132-007

 INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

GROUP: 1M

SEX: MALE

ANIMAL ID:	7577	7579	7581	7583
LYMPH NODES, MANDIBULAR HEMORRHAGE	N -	N -	N -	- 1
LYMPH NODES, MESENTERIC	N	N	N	N
MAMMARY GLAND	N	N	N	N
PANCREAS	N	N	N	N
PARATHYROID	N	N	U	N
PITUITARY GLAND	N	N	N	N
PROSTATE GLAND	N	N	N	N
SALIVARY GLAND, MANDIB	N	N	N	N
SCIATIC NERVE	N	N	N	N
SEMINAL VESICLES	N	N	N	N
SKELETAL MUSCLE	N	N	N	N
SM INTESTINE, DUODENUM	N	N	N	N
SM INTESTINE, ILEUM	N	N	N	N
SM INTESTINE, JEJUNUM	N	N	N	N
SPINAL CORD, CERVICAL	N	N	N	N
SPINAL CORD, LUMBAR	N	N	N	N
SPINAL CORD, THORACIC	N	N	N	N
SPLEEN	N	N	N	N

 See Reports Code Table for Symbol Definitions
 PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

GROUP: 1M

SEX: MALE

ANIMAL ID:	7577	7579	7581	7583
STOMACH, FORESTOMACH	N	N	N	N
STOMACH, GLANDULAR	N	N	N	N
TESTES	N	N	N	N
THYMUS	N	N	N	-
HEMORRHAGE	-	-	-	1
THYROID	N	N	N	N
TONGUE	N	N	N	N
TRACHEA	N	N	N	N
URINARY BLADDER	N	N	N	N
ZYMBALS GLAND	N	N	N	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

GROUP: 1M

SEX: MALE

ANIMAL ID:	7585	7587
ADRENAL GLANDS	N	N
AORTA	N	N
BONE MARROW (STERNUM)	N	N
BRAIN	N	N
EPIDIDYIMIDES	N	N
ESOPHAGUS	N	N
EYES WITH OPTIC NERVE	N	N
FEMUR W/ ARTIC SURFACE	N	N
HARDERIAN GLAND	N	N
HEART	N	N
KIDNEYS	-	N
CYST(S)	1L	-
LACRIMAL GLAND	N	N
LG INTESTINE, CECUM	N	N
LG INTESTINE, COLON	N	N
LG INTESTINE, RECTUM	N	N
LIVER	-	-
SUBACUTE INFLAMMATION	<2>	<1>
LUNGS WITH BRONCHI	-	N
INFLAMMATION	(2)	-

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

GROUP: 1M

SEX: MALE

ANIMAL ID:	7585	7587
LYMPH NODES, MANDIBULAR	N	N
LYMPH NODES, MESENTERIC	N	N
MAMMARY GLAND	N	N
PANCREAS	N	N
PARATHYROID	N	N
PITUITARY GLAND	N	N
PROSTATE GLAND	N	N
SALIVARY GLAND, MANDIB	N	N
SCIATIC NERVE	N	N
SEMINAL VESICLES	N	N
SKELETAL MUSCLE	N	N
SM INTESTINE, DUODENUM	N	N
SM INTESTINE, ILEUM	N	N
SM INTESTINE, JEJUNUM	N	N
SPINAL CORD, CERVICAL	N	N
SPINAL CORD, LUMBAR	N	N
SPINAL CORD, THORACIC	N	N
SPLEEN	N	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

GROUP: 1M

SEX: MALE

ANIMAL ID:	7585	7587
STOMACH, FORESTOMACH	N	N
STOMACH, GLANDULAR	N	N
TESTES	N	N
THYMUS	-	-
HEMORRHAGE	1	1
THYROID	N	N
TONGUE	N	N
TRACHEA	N	N
URINARY BLADDER	N	N
ZYMBALS GLAND	N	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

GROUP: 2M

SEX: MALE

ANIMAL ID:

7607

TESTES

-

TUBULAR DEGENERATION

3L

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

GROUP: 4M

SEX: MALE

ANIMAL ID:	7639	7641	7643	7645
ADRENAL GLANDS	N	N	N	N
AORTA	N	N	N	N
BONE MARROW (STERNUM)	N	N	N	N
BRAIN	N	N	N	N
EPIDIDYMIDES	N	N	N	N
ESOPHAGUS	-	N	N	N
MUSCULAR TUNIC- DEGENERATION	(2)	-	-	-
EYES WITH OPTIC NERVE	N	N	N	N
FEMUR W/ ARTIC SURFACE	N	N	N	N
HARDERIAN GLAND	N	N	N	N
HEART	N	N	N	N
KIDNEYS	N	N	N	N
LACRIMAL GLAND	N	-	N	N
LYMPHOCYTE INFILTRATION	-	(1)I	-	-
LG INTESTINE, CECUM	N	N	N	N
LG INTESTINE, COLON	N	N	N	N
LG INTESTINE, RECTUM	N	N	N	N
LIVER	-	-	-	N
SUBACUTE INFLAMMATION	<1>	<2>	<2>	-
LUNGS WITH BRONCHI	N	N	N	-

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

GROUP: 4M

SEX: MALE

ANIMAL ID:	7639	7641	7643	7645
INFLAMMATION	-	-	-	<2>
LYMPH NODES, MANDIBULAR	N	N	N	N
LYMPH NODES, MESENTERIC	N	N	N	N
MAMMARY GLAND	N	N	N	N
PANCREAS	N	N	N	N
PARATHYROID	U	N	U	U
PITUITARY GLAND	N	N	N	N
PROSTATE GLAND	N	N	N	N
SALIVARY GLAND, MANDIB	N	N	N	N
SCIATIC NERVE	N	N	N	N
SEMINAL VESICLES	N	N	N	N
SKELETAL MUSCLE	N	N	N	N
SM INTESTINE, DUODENUM	N	N	N	N
SM INTESTINE, ILEUM	N	N	N	N
SM INTESTINE, JEJUNUM	N	N	N	N
SPINAL CORD, CERVICAL	N	N	N	N
SPINAL CORD, LUMBAR	N	N	N	N
SPINAL CORD, THORACIC	N	N	N	N

See Reports Code Table for Symbol Definitions

PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

GROUP: 4M

SEX: MALE

ANIMAL ID:	7639	7641	7643	7645
SPLEEN	N	N	N	N
STOMACH, FORESTOMACH	N	N	N	N
STOMACH, GLANDULAR	N	N	N	N
TESTES	N	N	N	N
THYMUS	N	-	-	N
HEMORRHAGE	-	1	2	-
THYROID	N	N	N	N
TONGUE	N	N	N	N
TRACHEA	N	N	N	N
URINARY BLADDER	N	N	N	N
ZYMBALS GLAND	N	N	N	N

See Reports Code Table for Symbol Definitions

PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

GROUP: 4M

SEX: MALE

ANIMAL ID:	7647	7649	7651	7653
ADRENAL GLANDS	N	N	N	N
AORTA	N	N	N	N
BONE MARROW (STERNUM)	N	N	N	N
BRAIN	N	N	N	N
EPIDIDYMIDES	N	N	N	N
ESOPHAGUS	N	N	N	N
EYES WITH OPTIC NERVE	N	N	N	N
FEMUR W/ ARTIC SURFACE	N	N	N	N
HARDERIAN GLAND	N	N	N	N
HEART	N	-	N	N
CARDIOMYOPATHY	-	1	-	-
KIDNEYS	-	N	N	N
HYDRONEPHROSIS	1L	-	-	-
LACRIMAL GLAND	N	N	N	N
LG INTESTINE, CECUM	N	N	N	N
LG INTESTINE, COLON	N	N	N	N
LG INTESTINE, RECTUM	N	N	N	N
LIVER	-	N	-	-
SUBACUTE INFLAMMATION	<1>	-	<1>	<1>
LUNGS WITH BRONCHI	N	N	N	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

GROUP: 4M

SEX: MALE

ANIMAL ID:	7647	7649	7651	7653
LYMPH NODES, MANDIBULAR	N	N	N	N
LYMPH NODES, MESENTERIC	N	N	N	N
MAMMARY GLAND	N	N	N	N
PANCREAS	N	N	N	N
PARATHYROID	N	N	U	N
PITUITARY GLAND	N	N	N	N
PROSTATE GLAND	N	N	N	N
SALIVARY GLAND, MANDIB	N	N	N	N
SCIATIC NERVE	N	N	N	N
SEMINAL VESICLES	N	N	N	N
SKELETAL MUSCLE	N	N	N	N
SM INTESTINE, DUODENUM	N	N	N	N
SM INTESTINE, ILEUM	N	N	N	N
SM INTESTINE, JEJUNUM	N	N	N	N
SPINAL CORD, CERVICAL	N	N	N	N
SPINAL CORD, LUMBAR	N	N	N	N
SPINAL CORD, THORACIC	N	N	N	N
SPLEEN	N	N	N	N

See Reports Code Table for Symbol Definitions

PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

GROUP: 4M

SEX: MALE

ANIMAL ID:	7647	7649	7651	7653
STOMACH, FORESTOMACH	N	N	N	N
STOMACH, GLANDULAR	N	N	N	N
TESTES	N	N	N	N
THYMUS	N	N	N	N
THYROID	N	N	N	N
TONGUE	N	N	N	N
TRACHEA	N	N	N	N
URINARY BLADDER	N	N	N	N
ZYMBALS GLAND	N	N	N	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

GROUP: 4M

SEX: MALE

ANIMAL ID:	7655	7657
ADRENAL GLANDS	N	N
AORTA	N	N
BONE MARROW (STERNUM)	N	N
BRAIN	N	N
EPIDIDYIMIDES	N	N
ESOPHAGUS	N	N
EYES WITH OPTIC NERVE	N	N
FEMUR W/ ARTIC SURFACE	N	N
HARDERIAN GLAND	N	N
HEART	N	N
KIDNEYS	N	N
LACRIMAL GLAND	N	N
LG INTESTINE, CECUM	N	N
LG INTESTINE, COLON	N	N
LG INTESTINE, RECTUM	N	N
LIVER	-	N
SUBACUTE INFLAMMATION	<1>	-
LUNGS WITH BRONCHI	N	N
LYMPH NODES, MANDIBULAR	N	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

GROUP: 4M

SEX: MALE

ANIMAL ID:	7655	7657
LYMPH NODES, MESENTERIC	N	-
HEMORRHAGE	-	2
MAMMARY GLAND	N	N
PANCREAS	N	N
PARATHYROID	N	N
PITUITARY GLAND	N	N
PROSTATE GLAND	N	N
SALIVARY GLAND, MANDIB	N	N
SCIATIC NERVE	N	N
SEMINAL VESICLES	N	N
SKELETAL MUSCLE	N	N
SM INTESTINE, DUODENUM	N	N
SM INTESTINE, ILEUM	N	N
SM INTESTINE, JEJUNUM	N	N
SPINAL CORD, CERVICAL	N	N
SPINAL CORD, LUMBAR	N	N
SPINAL CORD, THORACIC	N	N
SPLEEN	N	N
STOMACH, FORESTOMACH	N	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

GROUP: 4M

SEX: MALE

ANIMAL ID:	7655	7657
STOMACH, GLANDULAR	N	N
TESTES	N	N
THYMUS	N	N
THYROID	N	N
TONGUE	N	N
TRACHEA	N	N
URINARY BLADDER	N	N
ZYMBALS GLAND	N	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

GROUP: 1F

SEX: FEMALE

ANIMAL ID:	7570	7572	7574	7576
ADRENAL GLANDS	N	N	N	N
AORTA	N	N	N	N
BONE MARROW (STERNUM)	N	N	N	N
BRAIN	N	N	N	N
CERVIX	N	N	N	N
ESOPHAGUS	N	N	N	N
EYES WITH OPTIC NERVE	N	N	N	N
FEMUR W/ ARTIC SURFACE	N	N	N	N
HARDERIAN GLAND	N	N	N	N
HEART	N	N	N	N
KIDNEYS	N	N	-	-
MINERALIZATION	-	-	<2>L	<1>I
LACRIMAL GLAND	N	N	N	N
LG INTESTINE, CECUM	N	N	N	N
LG INTESTINE, COLON	N	N	N	N
LG INTESTINE, RECTUM	N	N	N	N
LIVER	-	-	-	-
SUBACUTE INFLAMMATION	<1>	<1>	<1>	<1>
LUNGS WITH BRONCHI	N	-	-	N
INFLAMMATION	-	<2>	(1)	-

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

 INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

GROUP: 1F

SEX: FEMALE

ANIMAL ID:	7570	7572	7574	7576
LYMPH NODES, MANDIBULAR	N	N	N	N
LYMPH NODES, MESENTERIC	N	N	N	N
MAMMARY GLAND	N	N	N	N
OVARIES	N	N	N	N
OVIDUCTS	N	N	N	N
PANCREAS	N	N	-	N
SUBACUTE INFLAMMATION	-	-	(1)	-
PARATHYROID	N	N	N	N
PITUITARY GLAND	N	N	N	N
SALIVARY GLAND, MANDIB	N	N	N	N
SCIATIC NERVE	N	N	N	N
SKELETAL MUSCLE	N	N	N	N
SM INTESTINE, DUODENUM	N	N	N	N
SM INTESTINE, ILEUM	N	N	N	N
SM INTESTINE, JEJUNUM	N	N	N	N
SPINAL CORD, CERVICAL	N	N	N	N
SPINAL CORD, LUMBAR	N	N	N	N
SPINAL CORD, THORACIC	N	N	N	N
SPLEEN	N	N	N	N

 See Reports Code Table for Symbol Definitions
 PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

GROUP: 1F

SEX: FEMALE

ANIMAL ID:	7570	7572	7574	7576
STOMACH, FORESTOMACH	N	N	N	N
STOMACH, GLANDULAR	N	N	N	N
THYMUS	N	N	-	N
HEMORRHAGE	-	-	1	-
THYROID	N	N	N	N
TONGUE	N	N	N	N
TRACHEA	N	N	N	N
URINARY BLADDER	N	N	N	N
UTERUS	N	-	-	N
HORNS- DILATED	-	1I	2L	-
VAGINA	N	N	N	N
ZYMBALS GLAND	N	N	N	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

GROUP: 1F

SEX: FEMALE

ANIMAL ID:	7578	7580	7582	7584
ADRENAL GLANDS	N	N	N	N
AORTA	N	N	N	N
BONE MARROW (STERNUM)	N	N	N	N
BRAIN	N	N	N	N
CERVIX	N	N	N	N
ESOPHAGUS	N	N	N	N
EYES WITH OPTIC NERVE	N	N	N	N
FEMUR W/ ARTIC SURFACE	N	N	N	N
HARDERIAN GLAND	N	N	N	N
HEART	N	N	N	N
KIDNEYS	-	-	-	-
MINERALIZATION	<2>I	<2>I	<1>I	<1>I
LACRIMAL GLAND	N	N	N	N
LG INTESTINE, CECUM	N	N	N	N
LG INTESTINE, COLON	N	N	N	N
LG INTESTINE, RECTUM	N	N	N	N
LIVER	-	-	-	-
SUBACUTE INFLAMMATION	<1>	<1>	<2>	<1>
LUNGS WITH BRONCHI	N	N	N	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

GROUP: 1F

SEX: FEMALE

ANIMAL ID:	7578	7580	7582	7584
LYMPH NODES, MANDIBULAR	N	N	N	N
LYMPH NODES, MESENTERIC	N	N	N	N
MAMMARY GLAND	N	N	N	N
OVARIES	N	N	N	N
OVIDUCTS	N	N	N	N
PANCREAS	N	N	N	N
PARATHYROID	N	N	U	U
PITUITARY GLAND	N	N	N	N
SALIVARY GLAND, MANDIB	N	N	N	N
SCIATIC NERVE	N	N	N	N
SKELETAL MUSCLE	N	N	N	N
SM INTESTINE, DUODENUM	N	N	N	N
SM INTESTINE, ILEUM	N	N	N	N
SM INTESTINE, JEJUNUM	N	N	N	N
SPINAL CORD, CERVICAL	N	N	N	N
SPINAL CORD, LUMBAR	N	N	N	N
SPINAL CORD, THORACIC	N	N	N	N
SPLEEN	N	N	N	N

See Reports Code Table for Symbol Definitions

PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

GROUP: 1F

SEX: FEMALE

ANIMAL ID:	7578	7580	7582	7584
STOMACH, FORESTOMACH	N	N	N	N
STOMACH, GLANDULAR	N	N	N	N
THYMUS	N	N	N	N
THYROID	N	N	N	N
TONGUE	N	N	N	N
TRACHEA	N	N	N	N
URINARY BLADDER	N	N	N	N
UTERUS	-	N	N	N
HORNS- DILATED	3I	-	-	-
VAGINA	N	N	N	N
ZYMBALS GLAND	N	N	N	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

GROUP: 1F

SEX: FEMALE

ANIMAL ID:	7586	7588
ADRENAL GLANDS	N	N
AORTA	N	N
BONE MARROW (STERNUM)	N	N
BRAIN	N	N
CERVIX	U	N
ESOPHAGUS	N	N
EYES WITH OPTIC NERVE	N	N
FEMUR W/ ARTIC SURFACE	N	N
HARDERIAN GLAND	N	N
HEART	N	N
KIDNEYS	-	-
MINERALIZATION	<2>I	<2>I
TUBULAR DEGENERATION	1I	-
LACRIMAL GLAND	N	N
LG INTESTINE, CECUM	N	N
LG INTESTINE, COLON	N	N
LG INTESTINE, RECTUM	N	N
LIVER	N	-
SUBACUTE INFLAMMATION	-	<1>
LUNGS WITH BRONCHI	N	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

GROUP: 1F

SEX: FEMALE

ANIMAL ID:	7586	7588
LYMPH NODES, MANDIBULAR	N	N
LYMPH NODES, MESENTERIC	-	N
HISTIOCYTOSIS	3	-
MAMMARY GLAND	N	N
OVARIES	N	N
OVIDUCTS	N	N
PANCREAS	N	N
PARATHYROID	U	N
PITUITARY GLAND	N	N
SALIVARY GLAND, MANDIB	N	N
SCIATIC NERVE	N	N
SKELETAL MUSCLE	N	N
SM INTESTINE, DUODENUM	N	N
SM INTESTINE, ILEUM	N	N
SM INTESTINE, JEJUNUM	N	N
SPINAL CORD, CERVICAL	N	N
SPINAL CORD, LUMBAR	N	N
SPINAL CORD, THORACIC	N	N
SPLEEN	N	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

GROUP: 1F

SEX: FEMALE

ANIMAL ID:	7586	7588
STOMACH, FORESTOMACH	N	N
STOMACH, GLANDULAR	N	N
THYMUS	N	N
THYROID	N	N
TONGUE	N	N
TRACHEA	N	N
URINARY BLADDER	N	N
UTERUS	-	-
HORNS- DILATED	2I	2I
VAGINA	N	N
ZYMBALS GLAND	N	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

GROUP: 4F

SEX: FEMALE

ANIMAL ID:	7640	7642	7644	7646
ADRENAL GLANDS	N	N	N	N
AORTA	N	N	N	N
BONE MARROW (STERNUM)	N	N	N	N
BRAIN	N	N	N	N
CERVIX	N	N	N	N
ESOPHAGUS	N	-	N	N
MUSCULAR TUNIC- DEGENERATION	-	(1)	-	-
EYES WITH OPTIC NERVE	N	N	N	N
FEMUR W/ ARTIC SURFACE	N	N	N	N
HARDERIAN GLAND	N	N	-	N
SUBACUTE INFLAMMATION	-	-	(1)L	-
HEART	N	N	N	N
KIDNEYS	-	-	-	-
MINERALIZATION	<2>I	<2>I	<2>I	<1>I
TUBULAR DEGENERATION	3L	-	3L	-
LACRIMAL GLAND	N	N	N	N
LG INTESTINE, CECUM	N	N	N	N
LG INTESTINE, COLON	N	N	N	N
LG INTESTINE, RECTUM	N	N	N	N
LIVER	-	-	N	-
SUBACUTE INFLAMMATION	<1>	<1>	-	<1>

See Reports Code Table for Symbol Definitions

PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

GROUP: 4F

SEX: FEMALE

ANIMAL ID:	7640	7642	7644	7646
LUNGS WITH BRONCHI INFLAMMATION	- (1)	N -	N -	N -
LYMPH NODES, MANDIBULAR	N	N	N	N
LYMPH NODES, MESENTERIC	N	N	N	N
MAMMARY GLAND	N	N	N	N
OVARIES	N	N	N	N
OVIDUCTS	N	N	N	N
PANCREAS	N	N	N	N
PARATHYROID	N	N	U	U
PITUITARY GLAND	N	N	N	N
SALIVARY GLAND, MANDIB	N	N	N	N
SCIATIC NERVE	N	N	N	N
SKELETAL MUSCLE	N	N	N	N
SM INTESTINE, DUODENUM	N	N	N	N
SM INTESTINE, ILEUM	N	N	N	N
SM INTESTINE, JEJUNUM	N	N	N	N
SPINAL CORD, CERVICAL	N	N	N	N
SPINAL CORD, LUMBAR	N	N	N	N
SPINAL CORD, THORACIC	N	N	N	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

GROUP: 4F

SEX: FEMALE

ANIMAL ID:	7640	7642	7644	7646
SPLEEN	N	N	N	N
STOMACH, FORESTOMACH	N	N	N	N
STOMACH, GLANDULAR	N	N	N	N
THYMUS	N	N	N	N
THYROID	N	N	N	N
TONGUE	N	N	N	N
TRACHEA	N	N	N	N
URINARY BLADDER	N	N	N	N
UTERUS	-	N	N	N
HORNS- DILATED	2I	-	-	-
VAGINA	N	N	N	N
ZYMBALS GLAND	N	N	N	N

See Reports Code Table for Symbol Definitions

PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

GROUP: 4F

SEX: FEMALE

ANIMAL ID:	7648	7650	7652	7654
ADRENAL GLANDS	N	N	N	N
AORTA	N	N	N	N
BONE MARROW (STERNUM)	N	N	N	N
BRAIN	N	N	N	N
CERVIX	N	N	N	N
ESOPHAGUS	-	N	-	N
MUSCULAR TUNIC- DEGENERATION	(2)	-	(1)	-
EYES WITH OPTIC NERVE	N	N	N	N
FEMUR W/ ARTIC SURFACE	N	N	N	N
HARDERIAN GLAND	N	N	N	N
HEART	N	N	N	N
KIDNEYS	-	-	-	-
MINERALIZATION	<2>I	<2>I	<2>I	<2>
LACRIMAL GLAND	N	N	N	N
LG INTESTINE, CECUM	N	N	N	N
LG INTESTINE, COLON	N	N	N	N
LG INTESTINE, RECTUM	N	N	N	N
LIVER	N	-	N	-
SUBACUTE INFLAMMATION	-	<2>	-	<1>
LUNGS WITH BRONCHI	N	N	N	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

GROUP: 4F

SEX: FEMALE

ANIMAL ID:	7648	7650	7652	7654
LYMPH NODES, MANDIBULAR	N	N	N	N
LYMPH NODES, MESENTERIC	N	N	N	N
MAMMARY GLAND	N	N	N	N
OVARIES	N	N	N	N
OVIDUCTS	N	N	N	N
PANCREAS	N	N	N	N
THYROID	U	U	N	N
PITUITARY GLAND	N	-	N	N
PARS NERVOSA- ECTOPIC EPITHELIAL REST	-	P	-	-
SALIVARY GLAND, MANDIB	N	N	N	N
SCIATIC NERVE	N	N	N	N
SKELETAL MUSCLE	N	N	N	N
SM INTESTINE, DUODENUM	N	N	N	N
SM INTESTINE, ILEUM	N	N	N	N
SM INTESTINE, JEJUNUM	N	N	N	N
SPINAL CORD, CERVICAL	N	N	N	N
SPINAL CORD, LUMBAR	N	N	N	N
SPINAL CORD, THORACIC	N	N	N	N
SPLEEN	N	N	N	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

GROUP: 4F

SEX: FEMALE

ANIMAL ID:	7648	7650	7652	7654
STOMACH, FORESTOMACH	N	N	N	N
STOMACH, GLANDULAR	N	N	N	N
THYMUS	N	N	-	N
HEMORRHAGE	-	-	1	-
THYROID	N	N	N	N
TONGUE	N	N	N	N
TRACHEA	N	N	N	N
URINARY BLADDER	N	N	N	N
UTERUS	N	N	-	-
HORNS- DILATED	-	-	21	21
VAGINA	N	N	N	N
ZYMBALS GLAND	N	N	N	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

GROUP: 4F

SEX: FEMALE

ANIMAL ID:	7656	7658
ADRENAL GLANDS	N	N
AORTA	N	N
BONE MARROW (STERNUM)	N	N
BRAIN	N	N
CERVIX	N	N
ESOPHAGUS	N	N
EYES WITH OPTIC NERVE	N	N
FEMUR W/ ARTIC SURFACE	N	N
HARDERIAN GLAND	N	N
HEART	N	N
KIDNEYS	-	-
MINERALIZATION	<2>I	<2>I
LACRIMAL GLAND	N	N
LG INTESTINE, CECUM	N	N
LG INTESTINE, COLON	N	N
LG INTESTINE, RECTUM	N	N
LIVER	-	-
SUBACUTE INFLAMMATION	<1>	<1>
LUNGS WITH BRONCHI	N	-
INFLAMMATION	-	<1>

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

GROUP: 4F

SEX: FEMALE

ANIMAL ID:	7656	7658
LYMPH NODES, MANDIBULAR	N	N
LYMPH NODES, MESENTERIC	N	N
MAMMARY GLAND	N	N
OVARIES	N	N
OVIDUCTS	N	N
PANCREAS	N	N
PARATHYROID	N	N
PITUITARY GLAND	N	N
THYROID GLAND, MANDIB	N	N
SCIATIC NERVE	N	N
SKELETAL MUSCLE	N	N
SM INTESTINE, DUODENUM	N	N
SM INTESTINE, ILEUM	N	N
SM INTESTINE, JEJUNUM	N	N
SPINAL CORD, CERVICAL	N	N
SPINAL CORD, LUMBAR	N	N
SPINAL CORD, THORACIC	N	N
SPLEEN	N	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Interim sacrifice

GROUP: 4F

SEX: FEMALE

ANIMAL ID:	7656	7658
STOMACH, FORESTOMACH	N	N
STOMACH, GLANDULAR	N	N
THYMUS	N	-
HEMORRHAGE	-	1
THYROID	N	N
TONGUE	N	N
TRACHEA	N	N
URINARY BLADDER	N	N
UTERUS	N	N
VAGINA	N	N
ZYMBALS GLAND	N	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Terminal sacrifice

GROUP: 1M

SEX: MALE

ANIMAL ID:	7589	7591	7593	7595
ADRENAL GLANDS	N	N	N	N
AORTA	N	N	N	N
BONE MARROW (STERNUM)	N	N	N	N
BRAIN	N	N	N	N
EPIDIDYIMIDES	N	N	N	N
ESOPHAGUS	N	N	N	N
EYES WITH OPTIC NERVE	N	N	N	N
FEMUR W/ ARTIC SURFACE	N	N	N	N
HARDERIAN GLAND	N	N	N	N
HEART	N	N	N	N
KIDNEYS	N	-	N	-
CYST(S)	-	2L	-	-
TUBULAR DEGENERATION	-	-	-	(1)L
LACRIMAL GLAND	N	N	N	N
LG INTESTINE, CECUM	N	N	N	N
LG INTESTINE, COLON	N	N	N	N
LG INTESTINE, RECTUM	N	N	N	N
LIVER	-	-	-	N
SUBACUTE INFLAMMATION	<2>	<1>	<2>	-

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Terminal sacrifice

GROUP: 1M

SEX: MALE

ANIMAL ID:	7589	7591	7593	7595
LUNGS WITH BRONCHI	N	N	N	N
LYMPH NODES, MANDIBULAR	N	N	N	N
LYMPH NODES, MESENTERIC	N	N	N	N
MAMMARY GLAND	N	N	N	N
PANCREAS	N	N	N	N
PARATHYROID	N	U	N	N
PITUITARY GLAND	N	N	N	N
PROSTATE GLAND	N	N	N	N
SALIVARY GLAND, MANDIB	N	N	N	N
SCIATIC NERVE	N	N	N	N
SEMINAL VESICLES	N	N	N	N
SKELETAL MUSCLE	N	N	N	N
SM INTESTINE, DUODENUM	N	N	N	N
SM INTESTINE, ILEUM	N	N	N	N
SM INTESTINE, JEJUNUM	N	N	N	N
SPINAL CORD, CERVICAL	N	N	N	N
SPINAL CORD, LUMBAR	N	N	N	N
SPINAL CORD, THORACIC	N	N	N	N

See Reports Code Table for Symbol Definitions

PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Terminal sacrifice

GROUP: 1M

SEX: MALE

ANIMAL ID:	7589	7591	7593	7595
SPLEEN	N	N	N	N
STOMACH, FORESTOMACH	N	N	N	N
STOMACH, GLANDULAR	N	N	N	N
TESTES	N	N	N	N
THYMUS	-	-	N	N
HEMORRHAGE	1	1	-	-
THYROID	N	N	N	N
TONGUE	N	N	N	N
TRACHEA	N	N	N	N
URY BLADDER	N	N	N	N
ZYMBALS GLAND	N	N	N	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Terminal sacrifice

GROUP: 1M

SEX: MALE

ANIMAL ID:	7597
ADRENAL GLANDS	N
AORTA	N
BONE MARROW (STERNUM)	N
BRAIN	N
EPIDIDYMIDES	N
ESOPHAGUS	N
ES WITH OPTIC NERVE	N
FEMUR W/ ARTIC SURFACE	N
HARDERIAN GLAND	N
HEART	N
KIDNEYS	N
LACRIMAL GLAND	N
LG INTESTINE, CECUM	N
LG INTESTINE, COLON	N
LG INTESTINE, RECTUM	N
LIVER	-
SUBACUTE INFLAMMATION	<1>
LUNGS WITH BRONCHI	N
LYMPH NODES, MANDIBULAR	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Terminal sacrifice

GROUP: 1M

SEX: MALE

ANIMAL ID:	7597
LYMPH NODES, MESENTERIC	N
MAMMARY GLAND	N
PANCREAS	N
PARATHYROID	N
PITUITARY GLAND	N
PROSTATE GLAND	N
SALIVARY GLAND, MANDIB	N
SCIATIC NERVE	N
SEMIPL VESICLES	N
SKIN MUSCLE	N
SM INTESTINE, DUODENUM	N
SM INTESTINE, ILEUM	N
SM INTESTINE, JEJUNUM	N
SPINAL CORD, CERVICAL	N
SPINAL CORD, LUMBAR	N
SPINAL CORD, THORACIC	N
SPLEEN	N
STOMACH, FORESTOMACH	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Terminal sacrifice

GROUP: 1M

SEX: MALE

ANIMAL ID:	7597
STOMACH, GLANDULAR	N
TESTES	N
THYMUS	N
THYROID	N
TONGUE	N
TRACHEA	N
URINARY BLADDER	N
ZYMBALS GLAND	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

 INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Terminal sacrifice

GROUP: 4M

SEX: MALE

ANIMAL ID:	7659	7661	7663	7665
ADRENAL GLANDS	N	N	N	N
AORTA	N	N	N	N
BONE MARROW (STERNUM)	N	N	N	N
BRAIN	N	N	N	N
EPIDIDYMIDES	N	-	N	N
GRANULOMA(S)	-	2L	-	-
ESOPHAGUS	N	N	N	N
EYES WITH OPTIC NERVE	N	N	N	N
FEMUR W/ ARTIC SURFACE	N	N	N	N
HARDERIAN GLAND	N	N	N	N
HEART	N	N	N	N
KIDNEYS	-	N	N	-
HYDRONEPHROSIS	-	-	-	1L
TUBULAR DEGENERATION	1L	-	-	-
LACRIMAL GLAND	N	N	N	N
LG INTESTINE, CECUM	N	N	N	N
LG INTESTINE, COLON	N	N	N	N
LG INTESTINE, RECTUM	N	N	N	N
LIVER	-	-	-	-
SUBACUTE INFLAMMATION	<2>	<1>	<2>	<1>
NECROSIS	-	-	<2>	-

 See Reports Code Table for Symbol Definitions
 PRIMEDICA REDFIELD STUDY NUMBER 132-007

 INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Terminal sacrifice

GROUP: 4M

SEX: MALE

ANIMAL ID:	7659	7661	7663	7665
LUNGS WITH BRONCHI INFLAMMATION	N -	N -	- (1)	N -
LYMPH NODES, MANDIBULAR	N	N	N	N
LYMPH NODES, MESENTERIC	N	N	N	N
MAMMARY GLAND	N	N	N	N
PANCREAS	N	N	N	N
PARATHYROID	N	N	U	N
PITUITARY GLAND	N	N	N	N
PROSTATE GLAND	N	N	N	N
SALIVARY GLAND, MANDIB	N	N	N	N
SCIATIC NERVE	N	N	N	N
SEMINAL VESICLES	N	N	N	N
SKELETAL MUSCLE	N	N	N	N
SM INTESTINE, DUODENUM	N	N	N	N
SM INTESTINE, ILEUM	N	N	N	N
SM INTESTINE, JEJUNUM	N	N	N	N
SPINAL CORD, CERVICAL	N	N	N	N
SPINAL CORD, LUMBAR	N	N	N	N
SPINAL CORD, THORACIC	N	N	N	N

 See Reports Code Table for Symbol Definitions
 PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Terminal sacrifice

GROUP: 4M

SEX: MALE

ANIMAL ID:	7659	7661	7663	7665
SPLEEN	N	N	N	N
STOMACH, FORESTOMACH	N	N	N	N
STOMACH, GLANDULAR	N	N	N	N
TESTES	N	-	N	N
TUBULAR DEGENERATION	-	3L	-	-
THYMUS	N	N	N	N
THYROID	N	N	N	N
TONGUE	N	N	N	N
TRACHEA	N	N	N	N
URINARY BLADDER	N	N	N	N
ZYMBALS GLAND	N	N	N	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Terminal sacrifice

GROUP: 4M

SEX: MALE

ANIMAL ID:	7667
ADRENAL GLANDS	N
AORTA	N
BONE MARROW (STERNUM)	N
BRAIN	N
EPIDIDYMIDES	N
ESOPHAGUS	N
EYES WITH OPTIC NERVE	N
FEMUR W/ ARTIC SURFACE	N
HARDERIAN GLAND	N
HEART	N
KIDNEYS	N
LACRIMAL GLAND	N
LG INTESTINE, CECUM	N
LG INTESTINE, COLON	N
LG INTESTINE, RECTUM	N
LIVER	-
SUBACUTE INFLAMMATION	<1>
LUNGS WITH BRONCHI	N
LYMPH NODES, MANDIBULAR	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Terminal sacrifice

GROUP: 4M

SEX: MALE

ANIMAL ID:	7667
LYMPH NODES, MESENTERIC	N
MAMMARY GLAND	N
PANCREAS	N
PARATHYROID	N
PITUITARY GLAND	N
PROSTATE GLAND	N
SALIVARY GLAND, MANDIB	N
SCIATIC NERVE	N
SEMINAL VESICLES	N
SKELETAL MUSCLE	N
SM INTESTINE, DUODENUM	N
SM INTESTINE, ILEUM	N
SM INTESTINE, JEJUNUM	N
SPINAL CORD, CERVICAL	N
SPINAL CORD, LUMBAR	N
SPINAL CORD, THORACIC	N
SPLEEN	N
STOMACH, FORESTOMACH	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Terminal sacrifice

GROUP: 4M

SEX: MALE

ANIMAL ID:	7667
STOMACH, GLANDULAR	N
TESTES	N
THYMUS	N
THYROID	N
TONGUE	N
TRACHEA	N
URINARY BLADDER	N
ZYMBALS GLAND	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

 INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Terminal sacrifice

GROUP: 1F

SEX: FEMALE

ANIMAL ID:	7590	7592	7594	7596
ADRENAL GLANDS	N	N	N	N
AORTA	N	N	N	N
BONE MARROW (STERNUM)	N	N	N	N
BRAIN	N	N	N	N
CERVIX	N	N	N	N
ESOPHAGUS	N	N	N	N
EYES WITH OPTIC NERVE	N	N	N	N
FEMUR W/ ARTIC SURFACE	N	N	N	N
HARDERIAN GLAND	-	N	N	N
SUBACUTE INFLAMMATION	(2)L	-	-	-
HEART	N	N	N	N
KIDNEYS	-	-	N	N
MINERALIZATION	2I	2I	-	-
LACRIMAL GLAND	N	N	N	N
LG INTESTINE, CECUM	N	N	N	N
LG INTESTINE, COLON	N	N	N	N
LG INTESTINE, RECTUM	N	N	N	N
LIVER	-	-	-	-
SUBACUTE INFLAMMATION	<1>	<1>	<1>	<1>
LUNGS WITH BRONCHI	N	N	N	N

 See Reports Code Table for Symbol Definitions
 PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Terminal sacrifice

GROUP: 1F

SEX: FEMALE

ANIMAL ID:	7590	7592	7594	7596
LYMPH NODES, MANDIBULAR	N	N	N	N
LYMPH NODES, MESENTERIC	N	N	-	N
HEMORRHAGE	-	-	1	-
MAMMARY GLAND	N	U	N	N
OVARIES	N	N	N	N
OVIDUCTS	N	N	N	N
PANCREAS	N	N	N	N
PARATHYROID	N	N	N	U
PITUITARY GLAND	N	N	N	N
SALIVARY GLAND, MANDIB	N	N	N	N
SCIATIC NERVE	N	N	N	N
SKELETAL MUSCLE	N	N	N	N
SM INTESTINE, DUODENUM	N	N	N	N
SM INTESTINE, ILEUM	N	N	N	N
SM INTESTINE, JEJUNUM	N	N	N	N
SPINAL CORD, CERVICAL	N	N	N	N
SPINAL CORD, LUMBAR	N	N	N	N
SPINAL CORD, THORACIC	N	N	N	N
SPLEEN	N	N	N	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Terminal sacrifice

GROUP: 1F

SEX: FEMALE

ANIMAL ID:	7590	7592	7594	7596
STOMACH, FORESTOMACH	N	N	N	N
STOMACH, GLANDULAR	N	N	N	N
THYMUS	N	N	N	N
THYROID	N	N	N	N
TONGUE	N	N	N	N
TRACHEA	N	N	N	N
URINARY BLADDER	N	N	N	N
UTERUS	N	N	-	N
HORNS- DILATED	-	-	21	-
VAGINA	N	N	N	N
ZYMBALS GLAND	N	N	N	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Terminal sacrifice

GROUP: 1F

SEX: FEMALE

ANIMAL ID:	7598
ADRENAL GLANDS	N
AORTA	N
BONE MARROW (STERNUM)	N
BRAIN	N
CERVIX	N
ESOPHAGUS	N
EYES WITH OPTIC NERVE	N
FEMUR W/ ARTIC SURFACE	N
HARDERIAN GLAND	N
HEART	N
KIDNEYS	N
LACRIMAL GLAND	N
LG INTESTINE, CECUM	N
LG INTESTINE, COLON	N
LG INTESTINE, RECTUM	N
LIVER	-
SUBACUTE INFLAMMATION	<1>
LUNGS WITH BRONCHI	N
LYMPH NODES, MANDIBULAR	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Terminal sacrifice

GROUP: 1F

SEX: FEMALE

ANIMAL ID:	7598
LYMPH NODES, MESENTERIC	N
MAMMARY GLAND	N
OVARIES	N
OVIDUCTS	N
PANCREAS	N
PARATHYROID	U
PIEUTARY GLAND	N
SALIVARY GLAND, MANDIB	N
SCIATIC NERVE	N
SKELETAL MUSCLE	N
SM INTESTINE, DUODENUM	N
SM INTESTINE, ILEUM	N
SM INTESTINE, JEJUNUM	N
SPINAL CORD, CERVICAL	N
SPINAL CORD, LUMBAR	N
SPINAL CORD, THORACIC	N
SPLEEN	N
STOMACH, FORESTOMACH	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Terminal sacrifice

GROUP: 1F

SEX: FEMALE

ANIMAL ID:	7598
STOMACH, GLANDULAR	N
THYMUS	N
THYROID	N
TONGUE	N
TRACHEA	N
URINARY BLADDER	N
UTERUS	N
VAGINA	N
ZYMBALS GLAND	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Terminal sacrifice

GROUP: 4F

SEX: FEMALE

ANIMAL ID:	7660	7662	7664	7666
ADRENAL GLANDS	N	N	N	N
AORTA	N	N	N	N
BONE MARROW (STERNUM)	N	N	N	N
BRAIN	N	N	N	N
CERVIX	N	N	N	N
ESOPHAGUS	N	N	N	N
EYES WITH OPTIC NERVE	N	N	N	N
FEMUR W/ ARTIC SURFACE	N	N	N	N
HARDERIAN GLAND	N	N	N	N
HEART	N	N	N	N
KIDNEYS	-	N	N	-
HYDRONEPHROSIS	-	-	-	1I
MINERALIZATION	2I	-	-	2I
TUBULAR DEGENERATION	-	-	-	3I
LACRIMAL GLAND	N	N	N	N
LG INTESTINE, CECUM	N	N	N	N
LG INTESTINE, COLON	N	N	N	N
LG INTESTINE, RECTUM	N	N	N	N
LIVER	-	N	-	-
SUBACUTE INFLAMMATION	<1>	-	<1>	<1>

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Terminal sacrifice

GROUP: 4F

SEX: FEMALE

ANIMAL ID:	7660	7662	7664	7666
LUNGS WITH BRONCHI	N	N	N	N
LYMPH NODES, MANDIBULAR	N	N	N	N
LYMPH NODES, MESENTERIC	N	N	N	N
MAMMARY GLAND	N	N	N	N
OVARIES	N	N	N	N
OVIDUCTS	N	N	N	N
PANCREAS	N	N	N	N
PARATHYROID	N	U	N	N
PITUITARY GLAND	N	N	N	N
SALIVARY GLAND, MANDIB	N	N	N	N
SCIATIC NERVE	N	N	N	N
SKELETAL MUSCLE	N	N	N	N
SM INTESTINE, DUODENUM	N	N	N	N
SM INTESTINE, ILEUM	N	N	N	N
SM INTESTINE, JEJUNUM	N	N	N	N
SPINAL CORD, CERVICAL	N	N	N	N
SPINAL CORD, LUMBAR	N	N	N	N
SPINAL CORD, THORACIC	N	N	N	N

See Reports Code Table for Symbol Definitions

PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Terminal sacrifice

GROUP: 4F

SEX: FEMALE

ANIMAL ID:	7660	7662	7664	7666
SPLEEN	N	N	N	N
STOMACH, FORESTOMACH	N	N	N	N
STOMACH, GLANDULAR	N	N	N	N
THYMUS	N	N	N	N
THYROID	N	N	N	N
TONGUE	N	N	N	N
TRACHEA	N	N	N	N
URINARY BLADDER	N	N	N	N
UTERUS	N	-	N	-
HORNS- DILATED	-	3I	-	2I
	N	N	N	N
ZYMBALS GLAND	N	N	N	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Terminal sacrifice

GROUP: 4F

SEX: FEMALE

ANIMAL ID:	7668
ADRENAL GLANDS	N
AORTA	N
BONE MARROW (STERNUM)	N
BRAIN	N
CERVIX	N
ESOPHAGUS	N
EYES WITH OPTIC NERVE	N
EUR W/ ARTIC SURFACE	N
HARDERIAN GLAND	N
HEART	N
KIDNEYS	-
MINERALIZATION	11
LACRIMAL GLAND	N
LG INTESTINE, CECUM	N
LG INTESTINE, COLON	N
LG INTESTINE, RECTUM	N
LIVER	-
SUBACUTE INFLAMMATION	<2>
LUNGS WITH BRONCHI	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Terminal sacrifice

GROUP: 4F

SEX: FEMALE

ANIMAL ID:	7668
LYMPH NODES, MANDIBULAR	N
LYMPH NODES, MESENTERIC	N
MAMMARY GLAND	N
OVARIES	N
OVIDUCTS	N
PANCREAS	N
PARATHYROID	N
PITUITARY GLAND	N
SALIVARY GLAND, MANDIB	N
SCIATIC NERVE	N
SKELETAL MUSCLE	N
SM INTESTINE, DUODENUM	N
SM INTESTINE, ILEUM	N
SM INTESTINE, JEJUNUM	N
SPINAL CORD, CERVICAL	N
SPINAL CORD, LUMBAR	N
SPINAL CORD, THORACIC	N
SPLEEN	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

INDIVIDUAL ANIMAL HISTOLOGIC FINDINGS

DRUG: T-7485

FATE: Terminal sacrifice

GROUP: 4F

SEX: FEMALE

ANIMAL ID:	7668
STOMACH, FORESTOMACH	N
STOMACH, GLANDULAR	N
THYMUS	N
THYROID	N
TONGUE	N
TRACHEA	N
URINARY BLADDER	N
UTERUS	N
VAGINA	N
ZYMBALS GLAND	N

See Reports Code Table for Symbol Definitions
PRIMEDICA REDFIELD STUDY NUMBER 132-007

IV. Gross & Microscopic Correlation of Findings

GROSS & MICROSCOPIC CORRELATION OF FINDINGS

DRUG: T-7485

SEX: MALE

GROUP: 1:

No Gross Observations for any animal in this group

PRIMEDICA REDFIELD STUDY NUMBER 132-007

GROSS & MICROSCOPIC CORRELATION OF FINDINGS

DRUG: T-7485

SEX: MALE

GROUP: 2:

Animal ID: 7607

Pathologist: JMP

Animal Fate: Interim sacrifice

Reference to Necropsy Record:

TESTES - RIGHT, SMALL

Related Histopathology:

TESTES - TUBULAR DEGENERATION

PRIMEDICA REDFIELD STUDY NUMBER 132-007

GROSS & MICROSCOPIC CORRELATION OF FINDINGS

DRUG: T-7485

SEX: MALE

GROUP: 4:

No Gross Observations for any animal in this group

PRIMEDICA REDFIELD STUDY NUMBER 132-007

GROSS & MICROSCOPIC CORRELATION OF FINDINGS

DRUG: T-7485

SEX: FEMALE

GROUP: 1:

No Gross Observations for any animal in this group

PRIMEDICA REDFIELD STUDY NUMBER 132-007

GROSS & MICROSCOPIC CORRELATION OF FINDINGS

DRUG: T-7485

SEX: FEMALE

GROUP: 4:

No Gross Observations for any animal in this group

PRIMEDICA REDFIELD STUDY NUMBER 132-007

GROSS & MICROSCOPIC CORRELATION OF FINDINGS

DRUG: T-7485

SEX: MALE

GROUP: 1:

No Gross Observations for any animal in this group

PRIMEDICA REDFIELD STUDY NUMBER 132-007

GROSS & MICROSCOPIC CORRELATION OF FINDINGS

DRUG: T-7485

SEX: MALE

GROUP: 4:

No Gross Observations for any animal in this group

PRIMEDICA REDFIELD STUDY NUMBER 132-007

GROSS & MICROSCOPIC CORRELATION OF FINDINGS

DRUG: T-7485

SEX: FEMALE

GROUP: 1:

No Gross Observations for any animal in this group

PRIMEDICA REDFIELD STUDY NUMBER 132-007

GROSS & MICROSCOPIC CORRELATION OF FINDINGS

DRUG: T-7485

SEX: FEMALE

GROUP: 4:

No Gross Observations for any animal in this group

PRIMEDICA REDFIELD STUDY NUMBER 132-007

V. Comment Report

COMMENT REPORT

DRUG: T-7485

SEX: MALE

GROUP: 1:

Animal ID: 7575

Pathologist: JMP

Animal Fate: Interim sacrifice

TISSUE COMMENTS:

ADRENAL GLANDS - ADRENAL MEDULLAS NOT AVAILABLE FOR EVALUATION

Animal ID: 7577

Pathologist: JMP

Animal Fate: Interim sacrifice

TISSUE COMMENTS:

THYROID - SCANT SECTION AVAILABLE FOR EVALUATION

PARATHYROID - SCANT SECTION AVAILABLE FOR EVALUATION

PRIMEDICA REDFIELD STUDY NUMBER 132-007

COMMENT REPORT

DRUG: T-7485

SEX: MALE

GROUP: 2:

No Comments for any animal in this group

PRIMEDICA REDFIELD STUDY NUMBER 132-007

COMMENT REPORT

DRUG: T-7485

SEX: MALE

GROUP: 4:

Animal ID: 7639

Pathologist: JMP

Animal Fate: Interim sacrifice

TISSUE COMMENTS:

LYMPH NODES, MANDIBULAR - SCANT SECTION AVAILABLE FOR EVALUATION

Animal ID: 7643

Pathologist: JMP

Animal Fate: Interim sacrifice

TISSUE COMMENTS:

THYROID - SCANT SECTION AVAILABLE FOR EVALUATION

Animal ID: 7649

Pathologist: JMP

Animal Fate: Interim sacrifice

TISSUE COMMENTS:

MAMMARY GLAND - SCANT SECTION AVAILABLE FOR EVALUATION

Animal ID: 7659

Pathologist: JMP

Animal Fate: Terminal sacrifice

TISSUE COMMENTS:

ZYMBA'S GLAND - SCANT SECTION AVAILABLE FOR EVALUATION

Animal ID: 7665

Pathologist: JMP

Animal Fate: Terminal sacrifice

TISSUE COMMENTS:

ADRENAL GLANDS - ADRENAL MEDULLAS NOT AVAILABLE FOR EVALUATION

PRIMEDICA REDFIELD STUDY NUMBER 132-007

COMMENT REPORT

DRUG: T-7485

SEX: FEMALE

GROUP: 1:

Animal ID: 7578

Pathologist: JMP

Animal Fate: Interim sacrifice

TISSUE COMMENTS:

OVARIES - ONE OVARY AVAILABLE FOR EVALUATION

Animal ID: 7588

Pathologist: JMP

Animal Fate: Interim sacrifice

TISSUE COMMENTS:

EYES WITH OPTIC NERVE - OPTIC NERVES NOT AVAILABLE FOR EVALUATION

PRIMEDICA REDFIELD STUDY NUMBER 132-007

COMMENT REPORT

DRUG: T-7485

SEX: FEMALE

GROUP: 4;

Animal ID: 7646

Pathologist: JMP

Animal Fate: Interim sacrifice

TISSUE COMMENTS:

ESOPHAGUS - PARTIAL SECTION AVAILABLE FOR EVALUATION

Animal ID: 7660

Pathologist: JMP

Animal Fate: Terminal sacrifice

TISSUE COMMENTS:

EYES WITH OPTIC NERVE - ONE EYE AVAILABLE FOR EVALUATION

PRIMEDICA REDFIELD STUDY NUMBER 132-007

VI. Quality Assurance Statement

**Pathology Report****A 28-Day Oral (Gavage) Toxicity Study of T-7485
in Sprague-Dawley Rats**

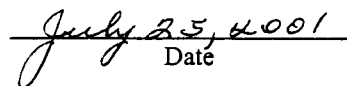
Primedica Redfield Protocol Number: 132-007

QUALITY ASSURANCE STATEMENT

This histopathology project has been inspected and audited by the PAI Quality Assurance Unit (QAU) as required by the Good Laboratory Practice (GLP) regulations promulgated by the Organization for Economic Cooperation and Development (OECD). The pathology report is an accurate reflection of the recorded data. The following table is a record of the inspections/audits performed and reported by the QAU.

<u>Date of Inspection</u>	<u>Phase Inspected</u>	<u>Date Findings Reported to PAI Management/Study Pathologist</u>
10/10/00	Tissue Trimming	10/10/00
11/21/00	Individual Animal Data	11/21/00
11/21/00	Draft Pathology Report	11/21/00
06/29/01	Final Pathology Report	06/29/01
07/25/01	Amended Final Pathology Report	07/25/01


Doraine Dundee
Quality Assurance Specialist


Date

APPENDIX 4
INDIVIDUAL CLINICAL OBSERVATIONS

PROTOCOL 132-007: A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

APPENDIX 4: CLINICAL OBSERVATIONS - INDIVIDUAL - MALE RATS

DOSE GROUP 1 0 (VEHICLE) MG/KG/DAY

RAT #	DESCRIPTION
7569	NO ADVERSE FINDINGS
7571	NO ADVERSE FINDINGS
7573	NO ADVERSE FINDINGS
7575	NO ADVERSE FINDINGS
7577	NO ADVERSE FINDINGS
7579	NO ADVERSE FINDINGS
7581	SD(8) LOCALIZED ALOPECIA, LIMBS
	SD(22) LOCALIZED ALOPECIA, LIMBS
	SD(28- 29) LOCALIZED ALOPECIA, LIMBS
7583	NO ADVERSE FINDINGS
7585	NO ADVERSE FINDINGS
7587	NO ADVERSE FINDINGS
7589	NO ADVERSE FINDINGS
7591	NO ADVERSE FINDINGS
7593	NO ADVERSE FINDINGS
7595	NO ADVERSE FINDINGS
7597	NO ADVERSE FINDINGS

DOSE GROUP 2 100 MG/KG/DAY

RAT #	DESCRIPTION
7599	NO ADVERSE FINDINGS
7601	NO ADVERSE FINDINGS
7603	NO ADVERSE FINDINGS
7605	NO ADVERSE FINDINGS
7607	NO ADVERSE FINDINGS
7609	NO ADVERSE FINDINGS
7611	NO ADVERSE FINDINGS
7613	NO ADVERSE FINDINGS
7615	NO ADVERSE FINDINGS
7617	NO ADVERSE FINDINGS

SD = STUDY DAY

Animals with NO ADVERSE FINDINGS were normal until their scheduled sacrifice.

PROTOCOL 132-007: A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

APPENDIX 4: CLINICAL OBSERVATIONS - INDIVIDUAL - MALE RATS

DOSE GROUP 3		300 MG/KG/DAY
RAT #		DESCRIPTION
7619		NO ADVERSE FINDINGS
7621		NO ADVERSE FINDINGS
7623		NO ADVERSE FINDINGS
7625		NO ADVERSE FINDINGS
7627		NO ADVERSE FINDINGS
7629	SD(22)	LOCALIZED ALOPECIA, LIMBS
	SD(28- 29)	LOCALIZED ALOPECIA, LIMBS
7631		NO ADVERSE FINDINGS
7633		NO ADVERSE FINDINGS
7635		NO ADVERSE FINDINGS
7637		NO ADVERSE FINDINGS
DOSE GROUP 4		900 MG/KG/DAY
RAT #		DESCRIPTION
7639	SD(8)	SOFT OR LIQUID FECES
7641		NO ADVERSE FINDINGS
7643		NO ADVERSE FINDINGS
7645		NO ADVERSE FINDINGS
7647		NO ADVERSE FINDINGS
7649		NO ADVERSE FINDINGS
7651		NO ADVERSE FINDINGS
7653		NO ADVERSE FINDINGS
7655		NO ADVERSE FINDINGS
7657		NO ADVERSE FINDINGS
7659	SD(44)	LOCALIZED ALOPECIA, LIMBS
7661	SD(28)	URINE-STAINED ABDOMINAL FUR
7663		NO ADVERSE FINDINGS
7665	SD(36)	LOCALIZED ALOPECIA, LIMBS
	SD(43- 44)	LOCALIZED ALOPECIA, LIMBS
7667		NO ADVERSE FINDINGS

SD = STUDY DAY

Animals with NO ADVERSE FINDINGS were normal until their scheduled sacrifice.

PROTOCOL 132-007: A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

APPENDIX 4: CLINICAL OBSERVATIONS - INDIVIDUAL - FEMALE RATS

DOSE GROUP 1		0 (VEHICLE) MG/KG/DAY
RAT #		DESCRIPTION
7570	SD(15)	LOCALIZED ALOPECIA, LIMBS
	SD(22)	LOCALIZED ALOPECIA, LIMBS
	SD(28- 29)	LOCALIZED ALOPECIA, LIMBS
7572		NO ADVERSE FINDINGS
7574		NO ADVERSE FINDINGS
7576		NO ADVERSE FINDINGS
7578		NO ADVERSE FINDINGS
7580		NO ADVERSE FINDINGS
7582		NO ADVERSE FINDINGS
7584		NO ADVERSE FINDINGS
7586		NO ADVERSE FINDINGS
7588		NO ADVERSE FINDINGS
7590		NO ADVERSE FINDINGS
7592		NO ADVERSE FINDINGS
7594	SD(43)	LOCALIZED ALOPECIA, LIMBS
7596		NO ADVERSE FINDINGS
7598		NO ADVERSE FINDINGS
DOSE GROUP 2		100 MG/KG/DAY
RAT #		DESCRIPTION
7600		NO ADVERSE FINDINGS
7602	SD(8)	LOCALIZED ALOPECIA, BACK
	SD(8)	SCABBED AREA, BACK
	SD(15)	LOCALIZED ALOPECIA, BACK
7604		NO ADVERSE FINDINGS
7606		NO ADVERSE FINDINGS
7608		NO ADVERSE FINDINGS
7610		NO ADVERSE FINDINGS
7612	SD(8)	LOCALIZED ALOPECIA, LIMBS
	SD(8)	LOCALIZED ALOPECIA, UNDERSIDE
	SD(15)	LOCALIZED ALOPECIA, LIMBS
	SD(15)	LOCALIZED ALOPECIA, UNDERSIDE
	SD(22)	LOCALIZED ALOPECIA, LIMBS
	SD(22)	LOCALIZED ALOPECIA, UNDERSIDE
	SD(28- 29)	LOCALIZED ALOPECIA, LIMBS
	SD(28- 29)	LOCALIZED ALOPECIA, UNDERSIDE

SD = STUDY DAY

Animals with NO ADVERSE FINDINGS were normal until their scheduled sacrifice.

PROTOCOL 132-007: A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

APPENDIX 4: CLINICAL OBSERVATIONS - INDIVIDUAL - FEMALE RATS

DOSE GROUP 2		100 MG/KG/DAY
RAT #	DESCRIPTION	
7614	SD(8)	LOCALIZED ALOPECIA, LIMBS
	SD(8)	LOCALIZED ALOPECIA, UNDERSIDE
	SD(15)	LOCALIZED ALOPECIA, UNDERSIDE
	SD(22)	LOCALIZED ALOPECIA, UNDERSIDE
	SD(28- 29)	LOCALIZED ALOPECIA, UNDERSIDE
7616	NO ADVERSE FINDINGS	
7618	NO ADVERSE FINDINGS	
DOSE GROUP 3		300 MG/KG/DAY
RAT #	DESCRIPTION	
7620	NO ADVERSE FINDINGS	
7622	NO ADVERSE FINDINGS	
7624	SD(8)	LOCALIZED ALOPECIA, LIMBS
	SD(15)	LOCALIZED ALOPECIA, LIMBS
	SD(22)	LOCALIZED ALOPECIA, LIMBS
	SD(28- 29)	LOCALIZED ALOPECIA, LIMBS
7626	NO ADVERSE FINDINGS	
7628	NO ADVERSE FINDINGS	
7630	SD(8)	LOCALIZED ALOPECIA, NECK
	SD(8)	SCABBED AREA, NECK
	SD(15)	LOCALIZED ALOPECIA, NECK
	SD(15)	SCABBED AREA, NECK
	SD(22)	LOCALIZED ALOPECIA, NECK
	SD(22)	SCABBED AREA, NECK
	SD(28- 29)	LOCALIZED ALOPECIA, NECK
	SD(28- 29)	SCABBED AREA, NECK
7632	NO ADVERSE FINDINGS	
7634	SD(22)	LOCALIZED ALOPECIA, LIMBS
	SD(28- 29)	LOCALIZED ALOPECIA, LIMBS
7636	NO ADVERSE FINDINGS	
7638	NO ADVERSE FINDINGS	

SD = STUDY DAY

Animals with NO ADVERSE FINDINGS were normal until their scheduled sacrifice.

PROTOCOL 132-007: A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

APPENDIX 4: CLINICAL OBSERVATIONS - INDIVIDUAL - FEMALE RATS

DOSE GROUP 4		900 MG/KG/DAY
RAT #		DESCRIPTION
7640	SD(8)	LOCALIZED ALOPECIA, UNDERSIDE
7642		NO ADVERSE FINDINGS
7644	SD(8)	LOCALIZED ALOPECIA, LIMBS
	SD(15)	LOCALIZED ALOPECIA, LIMBS
	SD(22)	LOCALIZED ALOPECIA, LIMBS
	SD(28- 29)	LOCALIZED ALOPECIA, LIMBS
7646		NO ADVERSE FINDINGS
7648		NO ADVERSE FINDINGS
7650		NO ADVERSE FINDINGS
7652		NO ADVERSE FINDINGS
7654		NO ADVERSE FINDINGS
7656	SD(8)	LOCALIZED ALOPECIA, LIMBS
	SD(15)	LOCALIZED ALOPECIA, LIMBS
	SD(22)	LOCALIZED ALOPECIA, LIMBS
	SD(28- 29)	LOCALIZED ALOPECIA, LIMBS
7658		NO ADVERSE FINDINGS
7660	SD(43)	LOCALIZED ALOPECIA, LIMBS
7662		NO ADVERSE FINDINGS
7664	SD(22)	LOCALIZED ALOPECIA, LIMBS
	SD(28)	LOCALIZED ALOPECIA, LIMBS
	SD(36)	LOCALIZED ALOPECIA, LIMBS
	SD(42- 43)	LOCALIZED ALOPECIA, LIMBS
7666		NO ADVERSE FINDINGS
7668		NO ADVERSE FINDINGS

SD = STUDY DAY

Animals with NO ADVERSE FINDINGS were normal until their scheduled sacrifice.

APPENDIX 5
INDIVIDUAL MOTOR ACTIVITY DATA

PROTOCOL 132-007: A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

APPENDIX 5: MOTOR ACTIVITY - INDIVIDUAL - MALE RATS

DOSE GROUP 1	0 (VEHICLE) MG/KG/DAY										
RAT #	7569	7571	7573	7575	7577	7579	7581	7583	7585	7587	7589
NUMBER OF MOVEMENTS											
BLOCK 1	154	155	160	156	172	179	165	159	133	154	147
BLOCK 2	153	129	114	137	150	160	180	146	148	159	148
BLOCK 3	172	141	105	166	162	131	157	124	132	144	157
BLOCK 4	44	113	112	64	147	104	164	111	149	123	161
BLOCK 5	21	71	24	11	59	6	158	78	126	21	147
BLOCK 6	5	5	2	16	15	10	166	2	111	82	175
TOTAL	549	614	517	550	705	590	990	620	799	683	935
TIME (SECONDS) SPENT IN MOVEMENT											
BLOCK 1	259	255	264	255	294	337	296	275	299	355	372
BLOCK 2	191	184	146	194	254	249	319	218	295	282	314
BLOCK 3	164	219	129	258	276	176	263	166	200	248	234
BLOCK 4	26	117	114	95	211	99	237	152	210	191	247
BLOCK 5	11	62	17	9	61	4	186	79	193	24	196
BLOCK 6	1	3	1	14	6	3	172	0	159	78	274
TOTAL	652	840	671	825	1102	868	1473	890	1356	1178	1637

TOTAL = SUM OF BLOCKS; EACH BLOCK CONSISTS OF A 10 MINUTE PERIOD.

PROTOCOL 132-007: A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

APPENDIX 5: MOTOR ACTIVITY - INDIVIDUAL - MALE RATS

DOSE GROUP 1		0 (VEHICLE) MG/KG/DAY			
RAT #		7591	7593	7595	7597
NUMBER OF MOVEMENTS					
BLOCK 1		149	143	123	141
BLOCK 2		129	146	135	164
BLOCK 3		133	152	137	145
BLOCK 4		138	142	111	122
BLOCK 5		134	151	120	150
BLOCK 6		160	131	120	71
TOTAL		843	865	746	793
TIME (SECONDS) SPENT IN MOVEMENT					
BLOCK 1		292	416	313	345
BLOCK 2		267	349	312	311
BLOCK 3		244	296	371	237
BLOCK 4		240	266	215	215
BLOCK 5		184	263	249	222
BLOCK 6		232	181	185	89
TOTAL		1459	1771	1645	1419

TOTAL = SUM OF BLOCKS; EACH BLOCK CONSISTS OF A 10 MINUTE PERIOD.

PROTOCOL 132-007: A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

APPENDIX 5: MOTOR ACTIVITY - INDIVIDUAL - MALE RATS

DOSE GROUP 2		100 MG/KG/DAY									
RAT #		7599	7601	7603	7605	7607	7609	7611	7613	7615	7617
NUMBER OF MOVEMENTS											
BLOCK	1	167	136	150	159	145	180	141	158	151	153
BLOCK	2	143	137	152	139	136	143	132	142	117	151
BLOCK	3	72	54	132	131	129	138	114	76	104	128
BLOCK	4	68	45	127	108	63	145	113	7	126	151
BLOCK	5	0	0	139	3	18	147	35	10	98	129
BLOCK	6	8	0	65	1	6	169	0	4	134	125
TOTAL		458	372	765	541	497	922	535	397	730	837
TIME (SECONDS) SPENT IN MOVEMENT											
BLOCK	1	288	340	241	236	324	320	305	320	338	355
BLOCK	2	250	219	195	178	307	276	256	320	234	309
BLOCK	3	70	54	211	134	218	299	144	112	174	255
BLOCK	4	63	51	213	121	54	287	164	3	184	235
BLOCK	5	0	0	167	1	9	258	51	2	134	118
BLOCK	6	3	0	65	0	0	243	0	1	204	166
TOTAL		674	664	1092	670	912	1683	920	758	1268	1438

TOTAL = SUM OF BLOCKS; EACH BLOCK CONSISTS OF A 10 MINUTE PERIOD.

PROTOCOL 132-007: A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

APPENDIX 5: MOTOR ACTIVITY - INDIVIDUAL - MALE RATS

DOSE GROUP 3 300 MG/KG/DAY										
RAT #	7619	7621	7623	7625	7627	7629	7631	7633	7635	7637
NUMBER OF MOVEMENTS										
BLOCK 1	154	152	166	159	161	164	148	146	163	166
BLOCK 2	159	135	137	147	164	152	138	169	184	175
BLOCK 3	100	88	143	127	169	146	134	145	145	149
BLOCK 4	78	95	97	102	168	108	139	135	62	79
BLOCK 5	54	51	41	100	127	111	123	6	1	1
BLOCK 6	25	5	0	37	91	64	11	9	16	9
TOTAL	570	526	584	672	880	745	693	610	571	579
TIME (SECONDS) SPENT IN MOVEMENT										
BLOCK 1	300	320	247	261	408	258	289	326	333	336
BLOCK 2	295	189	215	284	363	192	236	291	250	297
BLOCK 3	173	116	180	224	264	186	172	250	196	221
BLOCK 4	126	156	162	129	212	117	188	160	41	139
BLOCK 5	43	79	26	149	90	97	131	3	0	0
BLOCK 6	20	1	0	40	83	63	11	5	15	7
TOTAL	957	861	830	1087	1420	913	1027	1035	835	1000

TOTAL = SUM OF BLOCKS; EACH BLOCK CONSISTS OF A 10 MINUTE PERIOD.

PROTOCOL 132-007: A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

APPENDIX 5: MOTOR ACTIVITY - INDIVIDUAL - MALE RATS

DOSE GROUP 4		900 MG/KG/DAY										
RAT #		7639	7641	7643	7645	7647	7649	7651	7653	7655	7657	7659
NUMBER OF MOVEMENTS												
BLOCK	1	160	147	149	158	142	134	151	160	159	159	152
BLOCK	2	160	149	177	146	131	139	136	142	144	163	165
BLOCK	3	4	138	133	98	114	112	133	139	139	167	150
BLOCK	4	41	131	58	22	108	111	176	9	85	175	145
BLOCK	5	3	62	2	0	136	136	104	1	2	142	153
BLOCK	6	11	4	0	21	15	129	12	0	103	21	129
TOTAL		379	631	519	445	646	761	712	451	632	827	894
TIME (SECONDS) SPENT IN MOVEMENT												
BLOCK	1	280	292	226	256	345	317	293	292	326	387	356
BLOCK	2	170	226	251	186	241	260	226	271	299	309	322
BLOCK	3	3	236	101	87	156	198	166	158	160	249	321
BLOCK	4	41	193	52	15	141	160	214	2	115	281	214
BLOCK	5	0	76	0	0	188	226	132	0	0	203	206
BLOCK	6	4	1	0	12	14	198	5	0	132	20	196
TOTAL		498	1024	630	556	1085	1359	1036	723	1032	1449	1615

TOTAL = SUM OF BLOCKS; EACH BLOCK CONSISTS OF A 10 MINUTE PERIOD.

PROTOCOL 132-007: A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

APPENDIX 5: MOTOR ACTIVITY - INDIVIDUAL - MALE RATS

DOSE GROUP 4 900 MG/KG/DAY

RAT #	7661	7663	7665	7667
-------	------	------	------	------

NUMBER OF MOVEMENTS

BLOCK 1	146	168	150	165
BLOCK 2	137	155	156	185
BLOCK 3	151	156	132	155
BLOCK 4	126	146	143	110
BLOCK 5	130	99	150	116
BLOCK 6	126	2	169	72
TOTAL	816	726	900	803

TIME (SECONDS) SPENT IN MOVEMENT

BLOCK 1	307	296	417	308
BLOCK 2	269	260	387	250
BLOCK 3	313	266	383	244
BLOCK 4	219	187	316	134
BLOCK 5	195	109	234	129
BLOCK 6	192	2	294	59
TOTAL	1495	1120	2031	1124

TOTAL = SUM OF BLOCKS; EACH BLOCK CONSISTS OF A 10 MINUTE PERIOD.

PROTOCOL 132-007: A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

APPENDIX 5: MOTOR ACTIVITY - INDIVIDUAL - FEMALE RATS

DOSE GROUP 1		0 (VEHICLE) MG/KG/DAY										
RAT #		7570	7572	7574	7576	7578	7580	7582	7584	7586	7588	7590
NUMBER OF MOVEMENTS												
BLOCK	1	169	134	137	147	139	120	147	154	144	164	156
BLOCK	2	179	146	147	119	160	144	136	156	136	138	138
BLOCK	3	159	155	149	128	115	121	134	141	140	142	141
BLOCK	4	164	130	130	111	122	112	124	134	81	112	125
BLOCK	5	148	132	151	68	74	117	116	92	14	114	94
BLOCK	6	102	105	113	69	102	23	69	3	4	115	69
TOTAL		921	802	827	642	712	637	726	680	519	785	723
TIME (SECONDS) SPENT IN MOVEMENT												
BLOCK	1	329	259	321	304	380	373	276	278	286	366	293
BLOCK	2	354	266	335	216	309	283	281	245	203	261	265
BLOCK	3	239	244	287	192	203	225	190	200	235	227	298
BLOCK	4	241	192	282	162	147	165	208	177	133	204	194
BLOCK	5	187	192	222	73	81	136	170	87	11	131	127
BLOCK	6	68	95	140	64	98	30	74	0	1	112	58
TOTAL		1418	1248	1587	1011	1218	1212	1199	987	869	1301	1235

TOTAL = SUM OF BLOCKS; EACH BLOCK CONSISTS OF A 10 MINUTE PERIOD.

PROTOCOL 132-007: A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

APPENDIX 5: MOTOR ACTIVITY - INDIVIDUAL - FEMALE RATS

DOSE GROUP 1		0 (VEHICLE) MG/KG/DAY			
RAT #		7592	7594	7596	7598
NUMBER OF MOVEMENTS					
BLOCK 1		172	153	159	157
BLOCK 2		148	144	129	144
BLOCK 3		158	137	113	142
BLOCK 4		140	128	72	135
BLOCK 5		143	129	17	150
BLOCK 6		160	152	0	120
TOTAL		921	843	490	848
TIME (SECONDS) SPENT IN MOVEMENT					
BLOCK 1		296	342	319	277
BLOCK 2		290	303	188	234
BLOCK 3		314	364	160	163
BLOCK 4		180	298	98	134
BLOCK 5		170	311	14	177
BLOCK 6		225	283	0	107
TOTAL		1475	1901	779	1092

TOTAL = SUM OF BLOCKS; EACH BLOCK CONSISTS OF A 10 MINUTE PERIOD.

PROTOCOL 132-007: A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

APPENDIX 5: MOTOR ACTIVITY - INDIVIDUAL - FEMALE RATS

DOSE GROUP 2		100 MG/KG/DAY									

RAT #		7600	7602	7604	7606	7608	7610	7612	7614	7616	7618

NUMBER OF MOVEMENTS											
BLOCK	1	150	156	148	122	155	160	148	168	141	172
BLOCK	2	137	163	169	121	160	168	144	140	120	151
BLOCK	3	143	170	137	91	162	128	150	120	113	159
BLOCK	4	75	147	103	114	196	150	125	88	120	131
BLOCK	5	30	152	45	64	95	102	121	109	36	153
BLOCK	6	85	145	37	120	135	49	74	85	15	17
TOTAL		620	933	639	632	903	757	762	710	545	783
TIME (SECONDS) SPENT IN MOVEMENT											
BLOCK	1	325	396	332	249	351	319	278	271	261	349
BLOCK	2	237	362	310	211	282	267	255	246	185	344
BLOCK	3	188	348	212	128	293	157	248	184	175	323
BLOCK	4	81	259	133	168	243	138	218	118	155	224
BLOCK	5	26	265	51	59	133	105	178	141	24	191
BLOCK	6	97	218	32	153	195	40	79	122	3	8
TOTAL		954	1848	1070	968	1497	1026	1256	1082	803	1439

TOTAL = SUM OF BLOCKS; EACH BLOCK CONSISTS OF A 10 MINUTE PERIOD.

PROTOCOL 132-007: A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

APPENDIX 5: MOTOR ACTIVITY - INDIVIDUAL - FEMALE RATS

DOSE GROUP 3 300 MG/KG/DAY										
RAT #	7620	7622	7624	7626	7628	7630	7632	7634	7636	7638
NUMBER OF MOVEMENTS										
BLOCK 1	146	139	155	136	127	147	141	157	163	172
BLOCK 2	147	137	162	124	168	158	142	124	173	151
BLOCK 3	133	109	135	139	140	119	76	80	163	88
BLOCK 4	127	68	125	129	144	75	98	119	126	37
BLOCK 5	90	73	81	96	113	104	66	118	87	35
BLOCK 6	0	78	84	106	2	83	122	112	23	4
TOTAL	643	604	742	730	694	686	645	710	735	487
TIME (SECONDS) SPENT IN MOVEMENT										
BLOCK 1	315	296	237	356	442	320	256	290	287	260
BLOCK 2	274	246	167	250	346	271	208	191	234	215
BLOCK 3	183	180	111	239	293	186	100	97	191	123
BLOCK 4	191	94	140	210	181	98	136	145	138	31
BLOCK 5	113	75	71	109	144	106	100	119	95	22
BLOCK 6	0	107	77	137	0	85	146	122	14	1
TOTAL	1076	998	803	1301	1406	1066	946	964	959	652

TOTAL = SUM OF BLOCKS; EACH BLOCK CONSISTS OF A 10 MINUTE PERIOD.

PROTOCOL 132-007: A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

APPENDIX 5: MOTOR ACTIVITY - INDIVIDUAL - FEMALE RATS

DOSE GROUP 4 900 MG/KG/DAY											
RAT #	7640	7642	7644	7646	7648	7650	7652	7654	7656	7658	7660
NUMBER OF MOVEMENTS											
BLOCK 1	141	164	157	167	124	158	140	155	151	150	174
BLOCK 2	145	148	146	142	119	155	154	162	160	137	148
BLOCK 3	37	101	160	144	131	137	158	120	120	152	142
BLOCK 4	6	98	148	94	112	131	150	119	135	149	99
BLOCK 5	7	53	177	83	101	145	130	102	119	77	105
BLOCK 6	0	10	153	132	71	127	114	109	94	8	62
TOTAL	336	574	941	762	658	853	846	767	779	673	730
TIME (SECONDS) SPENT IN MOVEMENT											
BLOCK 1	279	282	385	315	342	334	298	376	378	388	338
BLOCK 2	212	261	364	230	323	324	247	316	318	326	211
BLOCK 3	32	127	326	177	270	249	244	169	210	333	225
BLOCK 4	0	124	264	94	208	181	212	141	198	252	136
BLOCK 5	0	47	268	71	119	226	185	120	207	121	126
BLOCK 6	0	5	249	111	119	167	129	131	99	3	66
TOTAL	523	846	1856	998	1381	1481	1315	1253	1410	1423	1102

TOTAL = SUM OF BLOCKS; EACH BLOCK CONSISTS OF A 10 MINUTE PERIOD.

PROTOCOL 132-007: A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

APPENDIX 5: MOTOR ACTIVITY - INDIVIDUAL - FEMALE RATS

DOSE GROUP 4 900 MG/KG/DAY

RAT #	7662	7664	7666	7668
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NUMBER OF MOVEMENTS

BLOCK 1	153	153	171	150
BLOCK 2	122	123	154	153
BLOCK 3	134	126	155	177
BLOCK 4	58	121	157	170
BLOCK 5	1	116	159	158
BLOCK 6	9	92	163	165
TOTAL	477	731	959	973

TIME (SECONDS) SPENT IN MOVEMENT

BLOCK 1	363	367	341	308
BLOCK 2	335	283	369	255
BLOCK 3	282	271	285	310
BLOCK 4	69	173	280	299
BLOCK 5	0	133	236	225
BLOCK 6	8	100	233	215
TOTAL	1057	1327	1744	1612

TOTAL = SUM OF BLOCKS; EACH BLOCK CONSISTS OF A 10 MINUTE PERIOD.

APPENDIX 6
NEUROLOGICAL FUNCTION EXAMINATION RESULTS

APPENDIX 6

PERIPHERAL NEUROPATHY FUNCTIONAL EXAMS FOR WEEK 4 - 132-007

MALES

Group 1	Tail Flick Latency	Forelimb Grip	Hindlimb Grip	Rotorod Latency	Foot Splay
Animal	(Time/Second)	(Grams)	(Grams)	(Seconds)	(Centimeters)
7569	4.4	368.5	500.0	6.6	8.0
7571	2.9	920.0	537.0	6.6	7.2
7573	3.2	601.5	613.5	6.8	6.6
7575	4.6	577.5	793.0	6.8	7.8
7577	3.2	811.5	683.0	7.6	7.8
7579	4.3	650.0	773.5	7.8	7.0
7581	2.6	611.0	847.5	5.4	8.6
7583	4.0	702.5	762.5	3.0	8.0
7585	3.0	554.0	731.0	1.2	7.5
7587	4.3	538.0	620.0	1.4	7.0
7589	4.0	652.5	648.0	1.2	7.8
7591	4.2	808.5	830.5	2.6	7.0
7593	3.5	599.5	638.0	5.4	6.8
7595	3.6	612.0	719.0	3.0	9.0
7597	2.2	692.5	809.5	4.8	8.5
Mean	3.6	646.6	700.4	4.7	7.6
S.D.	0.7	131.6	106.0	2.4	0.7

MALES

Group 2	Tail Flick Latency	Forelimb Grip	Hindlimb Grip	Rotorod Latency	Foot Splay
Animal	(Time/Second)	(Grams)	(Grams)	(Seconds)	(Centimeters)
7599	1.2	713.0	685.0	1.8	8.8
7601	2.6	784.5	861.5	1.6	6.6
7603	3.1	623.5	792.0	1.8	7.2
7605	3.0	832.5	897.0	1.4	5.8
7607	2.5	603.0	698.5	3.2	8.8
7609	3.6	504.0	574.0	2.0	6.8
7611	2.3	772.0	871.5	2.8	7.3
7613	2.2	937.0	881.0	2.0	7.4
7615	2.8	660.5	838.0	4.8	6.8
7617	2.3	698.0	733.0	2.0	4.9
Mean	2.6**	712.8	783.2*	2.3	7.0
S.D.	0.6	124.6	106.8	1.0	1.2

* = Significantly different from Group 1 at $p < 0.05$.** = Significantly different from Group 1 at $p < 0.01$.

APPENDIX 6

PERIPHERAL NEUROPATHY FUNCTIONAL EXAMS FOR WEEK 4 - 132-007

MALES

Group 3	Tail Flick Latency	Forelimb Grip	Hindlimb Grip	Rotorod Latency	Foot Splay
Animal	(Time/Second)	(Grams)	(Grams)	(Seconds)	(Centimeters)
7619	3.4	714.5	708.0	3.0	5.1
7621	3.0	571.0	693.0	2.2	6.3
7623	4.7	722.0	790.5	1.6	5.3
7625	2.6	593.0	716.0	1.4	6.4
7627	1.8	600.0	803.0	2.2	5.0
7629	2.6	595.5	727.5	2.0	5.2
7631	1.8	583.0	810.0	2.4	7.3
7633	4.2	612.0	954.5	2.4	7.3
7635	1.8	664.0	814.5	2.2	7.5
7637	2.4	714.5	807.0	2.4	9.1
Mean	2.8*	637.0	782.4*	2.2*	6.5*
S.D.	1.0	60.5	77.1	0.4	1.4

MALES

Group 4	Tail Flick Latency	Forelimb Grip	Hindlimb Grip	Rotorod Latency	Foot Splay
Animal	(Time/Second)	(Grams)	(Grams)	(Seconds)	(Centimeters)
7639	3.4	580.0	744.0	3.2	8.2
7641	2.4	700.0	760.5	4.0	8.2
7643	2.4	646.0	835.5	2.4	7.2
7645	3.4	785.0	828.5	2.0	5.2
7647	3.8	650.0	730.0	1.4	7.2
7649	3.1	576.5	805.5	1.8	5.5
7651	2.6	665.0	788.0	2.4	5.3
7653	2.5	705.0	945.0	1.4	6.8
7655	1.9	669.5	845.5	1.6	6.6
7657	3.3	562.0	780.5	2.0	7.2
7659	3.9	603.5	718.0	3.4	8.0
7661	2.0	680.0	730.0	2.0	5.5
7663	2.1	715.5	758.0	2.2	6.0
7665	1.8	685.0	747.5	1.6	6.3
7667	1.9	594.5	725.0	1.4	7.2
Mean	2.7**	654.5	782.8*	2.2*	6.7*
S.D.	0.7	62.0	61.3	0.8	1.0

* = Significantly different from Group 1 at $p < 0.05$.** = Significantly different from Group 1 at $p < 0.01$.

APPENDIX 6

PERIPHERAL NEUROPATHY FUNCTIONAL EXAMS FOR WEEK 4 - 132-007

FEMALES

Group 1	Tail Flick Latency	Forelimb Grip	Hindlimb Grip	Rotorod Latency	Foot Splay
Animal	(Time/Second)	(Grams)	(Grams)	(Seconds)	(Centimeters)
7570	1.5	361.0	266.5	2.0	5.4
7572	2.6	501.5	236.5	2.0	4.8
7574	1.0	488.0	289.5	0.4	8.2
7576	2.5	556.0	419.5	2.6	9.4
7578	1.7	406.5	343.0	1.0	9.7
7580	1.8	257.0	272.0	0.6	5.9
7582	1.4	257.0	309.5	0.6	7.0
7584	1.1	202.0	256.0	0.4	5.7
7586	2.7	208.5	321.0	1.6	7.4
7588	2.2	401.5	307.0	0.0	5.8
7590	2.1	608.5	432.5	0.6	4.2
7592	3.0	438.5	353.5	1.4	3.8
7594	2.2	439.0	335.5	0.6	5.2
7596	3.0	433.5	232.5	0.8	6.0
7598	3.6	274.5	285.0	0.2	8.5
Mean	2.2	388.9	310.6	1.0	6.5
S.D.	0.8	126.0	59.4	0.8	1.8

FEMALES

Group 2	Tail Flick Latency	Forelimb Grip	Hindlimb Grip	Rotorod Latency	Foot Splay
Animal	(Time/Second)	(Grams)	(Grams)	(Seconds)	(Centimeters)
7600	2.5	156.0	234.0	1.4	6.9
7602	1.4	293.5	256.5	1.0	6.7
7604	2.7	190.5	265.0	1.6	6.1
7606	1.6	187.5	334.5	2.2	7.6
7608	2.1	459.0	334.5	2.2	6.2
7610	0.5	561.5	330.0	0.2	5.8
7612	1.2	319.0	289.0	5.4	4.8
7614	2.8	410.0	314.0	2.2	5.8
7616	1.4	393.0	279.0	8.8	9.2
7618	1.8	285.0	240.0	1.6	5.8
Mean	1.8	325.5	287.7	2.7	6.5
S.D.	0.7	130.8	38.9	2.5	1.2

APPENDIX 6

PERIPHERAL NEUROPATHY FUNCTIONAL EXAMS FOR WEEK 4 - 132-007

FEMALES

Group 3	Tail Flick Latency	Forelimb Grip	Hindlimb Grip	Rotorod Latency	Foot Splay
Animal	(Time/Second)	(Grams)	(Grams)	(Seconds)	(Centimeters)
7620	1.4	413.5	361.5	5.6	7.0
7622	1.6	348.0	422.0	7.0	8.4
7624	1.0	300.0	377.0	1.2	6.0
7626	1.6	317.0	300.0	2.6	7.6
7628	2.0	283.5	244.0	3.0	7.2
7630	2.6	779.5	863.5	0.6	6.4
7632	2.6	473.0	222.0	7.8	11.2
7634	2.5	763.0	837.5	3.2	3.6
7636	3.0	621.5	332.5	2.6	4.4
7638	1.6	751.0	767.5	1.4	4.2
Mean	2.0	505.0	472.8	3.5**	6.6
S.D.	0.7	204.5	249.8	2.5	2.3

FEMALES

Group 4	Tail Flick Latency	Forelimb Grip	Hindlimb Grip	Rotorod Latency	Foot Splay
Animal	(Time/Second)	(Grams)	(Grams)	(Seconds)	(Centimeters)
7640	3.0	506.0	206.0	2.2	5.6
7642	1.8	375.0	573.5	3.4	5.1
7644	1.0	224.0	222.5	4.4	7.6
7646	1.9	580.0	650.5	2.6	8.3
7648	2.1	532.5	207.5	6.4	6.3
7650	2.3	655.0	746.0	11.0	5.1
7652	1.2	251.0	199.5	3.6	7.2
7654	2.4	671.0	754.5	2.4	4.2
7656	0.6	329.5	255.0	1.4	6.2
7658	2.4	705.5	616.0	2.6	5.0
7660	2.0	581.0	695.5	4.2	4.8
7662	1.2	249.0	237.0	3.2	9.5
7664	1.8	614.5	799.5	1.6	5.0
7666	1.4	498.5	759.5	1.8	7.8
7668	1.8	413.0	307.0	2.6	5.5
Mean	1.8	479.0	482.0	3.6**	6.2
S.D.	0.6	162.5	248.3	2.4	1.5

** = Significantly different from Group 1 at $p < 0.01$.

APPENDIX 6

AUDIO/VISUAL EXAMS - 132-007

Group 1	MALES	
ANIMAL	AUDIO	VISUAL
7569	Response observed	Response observed
7571	Response observed	Response observed
7573	Response observed	Response observed
7575	Response observed	Response observed
7577	Response observed	Response observed
7579	Response observed	Response observed
7581	Response observed	Response observed
7583	Response observed	Response observed
7585	Response observed	Response observed
7587	Response observed	Response observed
7589	Response observed	Response observed
7591	Response observed	Response observed
7593	Response observed	Response observed
7595	Response observed	Response observed
7597	Response observed	Response observed

Group 2	MALES	
ANIMAL	AUDIO	VISUAL
7599	Response observed	Response observed
7601	Response observed	Response observed
7603	Response observed	Response observed
7605	Response observed	Response observed
7607	Response observed	Response observed
7609	Response observed	Response observed
7611	Response observed	Response observed
7613	Response observed	Response observed
7615	Response observed	Response observed
7617	Response observed	Response observed

APPENDIX 6

AUDIO/VISUAL EXAMS - 132-007

Group 3	MALES	
	AUDIO	VISUAL
ANIMAL		
7619	Response observed	Response observed
7621	Response observed	Response observed
7623	Response observed	Response observed
7625	Response observed	Response observed
7627	Response observed	Response observed
7629	Response observed	Response observed
7631	Response observed	Response observed
7633	Response observed	Response observed
7635	Response observed	Response observed
7637	Response observed	Response observed

Group 4	MALES	
	AUDIO	VISUAL
ANIMAL		
7569	Response observed	Response observed
7571	Response observed	Response observed
7573	Response observed	Response observed
7575	Response observed	Response observed
7577	Response observed	Response observed
7579	Response observed	Response observed
7581	Response observed	Response observed
7583	Response observed	Response observed
7585	Response observed	Response observed
7587	Response observed	Response observed
7589	Response observed	Response observed
7591	Response observed	Response observed
7593	Response observed	Response observed
7595	Response observed	Response observed
7597	Response observed	Response observed

APPENDIX 6

AUDIO/VISUAL EXAMS - 132-007

Group 1	FEMALES	
ANIMAL	AUDIO	VISUAL
7570	Response observed	Response observed
7572	Response observed	Response observed
7574	Response observed	Response observed
7576	Response observed	Response observed
7578	Response observed	Response observed
7580	Response observed	Response observed
7582	Response observed	Response observed
7584	Response observed	Response observed
7586	Response observed	Response observed
7588	Response observed	Response observed
7590	Response observed	Response observed
7592	Response observed	Response observed
7594	Response observed	Response observed
7596	Response observed	Response observed
7598	Response observed	Response observed

Group 2	FEMALES	
ANIMAL	AUDIO	VISUAL
7600	Response observed	Response observed
7602	Response observed	Response observed
7604	Response observed	Response observed
7606	Response observed	Response observed
7608	Response observed	Response observed
7610	Response observed	Response observed
7612	Response observed	Response observed
7614	Response observed	Response observed
7616	Response observed	Response observed
7618	Response observed	Response observed

APPENDIX 6

AUDIO/VISUAL EXAMS - 132-007

Group 3	FEMALES	
ANIMAL	AUDIO	VISUAL
7620	Response observed	Response observed
7622	Response observed	Response observed
7624	Response observed	Response observed
7626	Response observed	Response observed
7628	Response observed	Response observed
7630	Response observed	Response observed
7632	Response observed	Response observed
7634	Response observed	Response observed
7636	Response observed	Response observed
7638	Response observed	Response observed

Group 4	FEMALES	
ANIMAL	AUDIO	VISUAL
7640	Response observed	Response observed
7642	Response observed	Response observed
7644	Response observed	Response observed
7646	Response observed	Response observed
7648	Response observed	Response observed
7650	Response observed	Response observed
7652	Response observed	Response observed
7654	Response observed	Response observed
7656	Response observed	Response observed
7658	Response observed	Response observed
7660	Response observed	Response observed
7662	Response observed	Response observed
7664	Response observed	Response observed
7666	Response observed	Response observed
7668	Response observed	Response observed

**APPENDIX 7
INDIVIDUAL BODY WEIGHTS**

PROTOCOL 132-007: A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

APPENDIX 7: BODY WEIGHTS - INDIVIDUAL - MALE RATS

SD	1	8	15	22	28	36	43
RAT #	DOSE GROUP 1		0 (VEHICLE) MG/KG/DAY				
7569	216.	257.	290.	314.	315.	a	
7571	253.	305.	352.	380.	381.	a	
7573	228.	278.	329.	364.	376.	a	
7575	233.	287.	338.	373.	380.	a	
7577	219.	260.	294.	330.	340.	a	
7579	241.	282.	318.	346.	364.	a	
7581	228.	279.	328.	364.	377.	a	
7583	230.	280.	318.	343.	356.	a	
7585	217.	265.	313.	350.	363.	a	
7587	240.	306.	357.	400.	418.	a	
7589	224.	283.	323.	360.	375.	407.	432.
7591	238.	291.	341.	379.	397.	425.	461.
7593	225.	274.	321.	371.	394.	427.	458.
7595	234.	277.	320.	356.	379.	414.	425.
7597	241.	307.	355.	391.	396.	432.	472.
SD	1	8	15	22	28	36	43
RAT #	DOSE GROUP 2		100 MG/KG/DAY				
7599	216.	270.	310.	351.	361.	a	
7601	242.	289.	330.	356.	365.	a	
7603	231.	278.	313.	351.	364.	a	
7605	232.	285.	320.	350.	362.	a	
7607	222.	275.	322.	367.	377.	a	
7609	245.	302.	347.	384.	402.	a	
7611	229.	281.	330.	370.	387.	a	
7613	239.	294.	348.	390.	411.	a	
7615	213.	256.	292.	326.	335.	a	
7617	242.	287.	332.	365.	386.	a	

SD = STUDY DAY

All weights were reported in grams (G).

a = Scheduled sacrifice.

PROTOCOL 132-007: A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

APPENDIX 7: BODY WEIGHTS - INDIVIDUAL - MALE RATS

	SD	1	8	15	22	28	36	43
RAT #	DOSE GROUP 3	300 MG/KG/DAY						
7619	209.	245.	265.	291.	301.	a		
7621	249.	294.	332.	365.	374.	a		
7623	232.	280.	317.	339.	339.	a		
7625	230.	277.	314.	349.	359.	a		
7627	217.	266.	307.	331.	351.	a		
7629	247.	306.	352.	394.	412.	a		
7631	222.	287.	335.	373.	383.	a		
7633	238.	292.	324.	358.	366.	a		
7635	215.	255.	278.	301.	313.	a		
7637	249.	301.	351.	394.	412.	a		
	SD	1	8	15	22	28	36	43
RAT #	DOSE GROUP 4	900 MG/KG/DAY						
7639	219.	252.	291.	303.	299.	a		
7641	251.	284.	320.	347.	351.	a		
7643	232.	280.	317.	344.	316.	a		
7645	225.	267.	291.	321.	328.	a		
7647	222.	276.	321.	348.	355.	a		
7649	251.	306.	352.	386.	398.	a		
7651	234.	291.	341.	378.	396.	a		
7653	236.	290.	320.	355.	358.	a		
7655	227.	273.	318.	351.	363.	a		
7657	234.	282.	341.	376.	401.	a		
7659	218.	264.	296.	330.	332.	365.	387.	
7661	233.	275.	316.	344.	351.	387.	412.	
7663	228.	283.	335.	374.	391.	423.	460.	
7665	245.	301.	350.	382.	384.	413.	444.	
7667	220.	264.	313.	339.	347.	377.	404.	

SD = STUDY DAY

All weights were reported in grams (G).

a = Scheduled sacrifice.

PROTOCOL 132-007: A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

APPENDIX 7: BODY WEIGHTS - INDIVIDUAL - FEMALE RATS

	SD	1	8	15	22	28	36	42
RAT #	DOSE GROUP 1	0 (VEHICLE) MG/KG/DAY						
7570	178.	202.	221.	225.	233.	a		
7572	212.	236.	248.	258.	273.	a		
7574	196.	226.	248.	261.	262.	a		
7576	192.	204.	210.	223.	229.	a		
7578	178.	203.	220.	231.	233.	a		
7580	203.	218.	237.	241.	249.	a		
7582	199.	214.	226.	240.	238.	a		
7584	193.	213.	219.	244.	243.	a		
7586	188.	204.	198.	222.	215.	a		
7588	204.	228.	244.	252.	255.	a		
7590	203.	229.	246.	252.	260.	284.	277.	
7592	194.	210.	228.	234.	239.	249.	266.	
7594	188.	211.	217.	238.	238.	248.	258.	
7596	195.	218.	236.	244.	231.	253.	258.	
7598	192.	203.	214.	227.	219.	240.	241.	
	SD	1	8	15	22	28	36	42
RAT #	DOSE GROUP 2	100 MG/KG/DAY						
7600	182.	202.	216.	225.	226.	a		
7602	205.	203.	229.	235.	238.	a		
7604	194.	212.	236.	246.	245.	a		
7606	202.	221.	236.	241.	256.	a		
7608	184.	204.	208.	223.	226.	a		
7610	206.	221.	230.	247.	241.	a		
7612	194.	213.	229.	230.	231.	a		
7614	201.	222.	238.	239.	232.	a		
7616	193.	203.	216.	227.	223.	a		
7618	199.	216.	232.	237.	244.	a		

SD = STUDY DAY

All weights were reported in grams (G).

a = Scheduled sacrifice.

PROTOCOL 132-007: A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

APPENDIX 7: BODY WEIGHTS - INDIVIDUAL - FEMALE RATS

	SD	1	8	15	22	28	36	42
RAT #	DOSE GROUP 3		300 MG/KG/DAY					
7620	178.	208.	220.	236.	230.	a		
7622	210.	226.	235.	254.	249.	a		
7624	197.	226.	242.	261.	243.	a		
7626	191.	209.	227.	242.	234.	a		
7628	185.	208.	225.	235.	239.	a		
7630	208.	235.	246.	269.	271.	a		
7632	193.	215.	238.	238.	243.	a		
7634	201.	211.	234.	234.	236.	a		
7636	190.	206.	211.	221.	223.	a		
7638	202.	227.	244.	264.	256.	a		
	SD	1	8	15	22	28	36	42
RAT #	DOSE GROUP 4		900 MG/KG/DAY					
7640	183.	198.	220.	230.	213.	a		
7642	212.	236.	252.	264.	260.	a		
7644	197.	223.	239.	261.	256.	a		
7646	193.	221.	234.	251.	253.	a		
7648	193.	218.	237.	254.	243.	a		
7650	207.	210.	223.	242.	237.	a		
7652	198.	224.	239.	249.	252.	a		
7654	198.	216.	235.	245.	249.	a		
7656	191.	203.	217.	223.	223.	a		
7658	206.	224.	233.	238.	237.	a		
7660	191.	214.	227.	241.	240.	250.	255.	
7662	196.	222.	234.	246.	242.	258.	263.	
7664	195.	216.	230.	230.	242.	259.	259.	
7666	204.	221.	228.	251.	248.	253.	265.	
7668	193.	210.	226.	230.	242.	258.	255.	

SD = STUDY DAY

All weights were reported in grams (G).

a = Scheduled sacrifice.

APPENDIX 8
INDIVIDUAL FEED CONSUMPTION

PROTOCOL 132-007: A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

APPENDIX 8: FEED CONSUMPTION - INDIVIDUAL - MALE RATS

SD 1 - 8 8 - 15 15 - 22 22 - 28 28 - 36 36 - 43						
RAT #	DOSE GROUP 1		0 (VEHICLE) MG/KG/DAY			
7569	160.	162.	166.	136.	a	
7571	197.	195.	196.	167.	a	
7573	181.	184.	197.	168.	a	
7575	192.	197.	195.	169.	a	
7577	177.	175.	192.	168.	a	
7579	197.	191.	196.	176.	a	
7581	198.	210.	214.	184.	a	
7583	198.	196.	195.	172.	a	
7585	173.	182.	186.	174.	a	
7587	218.	225.	236.	197.	a	
7589	191.	195.	206.	185.	249.	240.
7591	192.	195.	198.	181.	241.	227.
7593	196.	199.	219.	198.	258.	247.
7595	181.	182.	193.	173.	231.	220.
7597	219.	230.	220.	196.	270.	260.
SD 1 - 8 8 - 15 15 - 22 22 - 28 28 - 36 36 - 43						
RAT #	DOSE GROUP 2		100 MG/KG/DAY			
7599	195.	207.	216.	187.	a	
7601	196.	193.	187.	173.	a	
7603	182.	188.	195.	174.	a	
7605	184.	184.	180.	159.	a	
7607	195.	208.	222.	190.	a	
7609	207.	209.	219.	202.	a	
7611	194.	206.	227.	204.	a	
7613	212.	220.	234.	212.	a	
7615	170.	171.	182.	158.	a	
7617	185.	197.	208.	189.	a	

SD = STUDY DAY

All weights were reported in grams (G).

a = Scheduled sacrifice.

PROTOCOL 132-007: A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

APPENDIX 8: FEED CONSUMPTION - INDIVIDUAL - MALE RATS

SD 1 - 8 - 15 - 22 - 28 - 36 - 43									
RAT #	DOSE GROUP 3				300 MG/KG/DAY				
7619	163.	159.	168.	148.					a
7621	195.	192.	203.	176.					a
7623	173.	173.	169.	141.					a
7625	182.	187.	196.	167.					a
7627	184.	186.	196.	177.					a
7629	206.	208.	227.	204.					a
7631	209.	208.	227.	187.					a
7633	210.	201.	209.	192.					a
7635	168.	157.	163.	145.					a
7637	200.	204.	209.	184.					a
SD 1 - 8 - 15 - 22 - 28 - 36 - 43									
RAT #	DOSE GROUP 4				900 MG/KG/DAY				
7639	178.	184.	182.	286.					a
7641	194.	188.	195.	173.					a
7643	213.	210.	215.	153.					a
7645	172.	160.	176.	b					a
7647	190.	199.	203.	181.					a
7649	220.	232.	222.	198.					a
7651	213.	229.	236.	219.					a
7653	190.	194.	225.	193.					a
7655	192.	199.	208.	188.					a
7657	200.	214.	230.	212.					a
7659	183.	184.	191.	167.					208.
7661	177.	179.	188.	164.					204.
7663	201.	219.	226.	206.					251.
7665	210.	217.	223.	196.					241.
7667	176.	182.	196.	165.					203.

SD = STUDY DAY

All weights were reported in grams (G).

a = Scheduled sacrifice.

b = Spilled feed.

PROTOCOL 132-007: A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

APPENDIX 8: FEED CONSUMPTION - INDIVIDUAL - FEMALE RATS

SD 1 - 8 - 15 - 22 - 28 - 36 - 42												
RAT #	DOSE GROUP 1				0 (VEHICLE) MG/KG/DAY							
7570	133.	140.	139.	130.	a							
7572	151.	155.	167.	143.	a							
7574	150.	158.	161.	150.	a							
7576	144.	156.	161.	127.	a							
7578	138.	138.	139.	136.	a							
7580	157.	157.	161.	145.	a							
7582	139.	134.	141.	122.	a							
7584	148.	146.	154.	122.	a							
7586	136.	117.	108.	115.	a							
7588	169.	167.	164.	135.	a							
7590	161.	160.	159.	150.	193.	151.						
7592	140.	145.	151.	134.	176.	155.						
7594	143.	139.	158.	126.	175.	148.						
7596	166.	161.	156.	133.	185.	143.						
7598	129.	124.	132.	154.	91.	123.						
SD 1 - 8 - 15 - 22 - 28 - 36 - 42												
RAT #	DOSE GROUP 2				100 MG/KG/DAY							
7600	130.	135.	141.	121.	a							
7602	142.	153.	156.	127.	a							
7604	142.	147.	156.	137.	a							
7606	154.	157.	172.	153.	a							
7608	129.	127.	143.	120.	a							
7610	147.	142.	148.	122.	a							
7612	144.	151.	148.	136.	a							
7614	150.	153.	145.	122.	a							
7616	141.	140.	138.	113.	a							
7618	157.	170.	171.	158.	a							

SD = STUDY DAY

All weights were reported in grams (G).

a = Scheduled sacrifice.

PROTOCOL 132-007: A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

APPENDIX 8: FEED CONSUMPTION - INDIVIDUAL - FEMALE RATS

SD 1 - 8 - 15 - 22 - 28 - 36 - 42												
RAT #	DOSE GROUP 3 300 MG/KG/DAY											
7620	145.	138.	146.	125.								a
7622	156.	150.	162.	133.								a
7624	153.	144.	156.	115.								a
7626	137.	139.	144.	120.								a
7628	145.	151.	154.	141.								a
7630	160.	156.	169.	153.								a
7632	151.	152.	150.	136.								a
7634	151.	152.	149.	120.								a
7636	141.	132.	142.	113.								a
7638	164.	174.	185.	146.								a
SD 1 - 8 - 15 - 22 - 28 - 36 - 42												
RAT #	DOSE GROUP 4 900 MG/KG/DAY											
7640	144.	148.	141.	114.								a
7642	146.	153.	155.	121.								a
7644	155.	166.	176.	142.								a
7646	152.	149.	156.	134.								a
7648	156.	151.	159.	141.								a
7650	145.	158.	170.	138.								a
7652	168.	164.	165.	150.								a
7654	140.	145.	148.	139.								a
7656	140.	151.	152.	136.								a
7658	150.	144.	131.	114.								a
7660	152.	150.	151.	137.								134.
7662	147.	144.	149.	125.								138.
7664	152.	156.	161.	146.								134.
7666	161.	162.	172.	128.								157.
7668	149.	159.	157.	139.								148.

SD = STUDY DAY

All weights were reported in grams (G).

a = Scheduled sacrifice.

**APPENDIX 9
INDIVIDUAL HEMATOLOGY DATA**

KEY TO HEMATOLOGY TABLES

<u>ABBREVIATION</u>	<u>TERMINOLOGY</u>	<u>UNITS</u>
WBC	White Blood Cells (Leukocytes)	$10^3/\text{cu mm}$
RBC	Red Blood Cells (Erythrocytes)	$10^6/\text{cu mm}$
HGB	Hemoglobin	g/dL
HCT	Hematocrit (Packed Cell Volume)	%
MCV	Mean Corpuscular Volume	fL or cu micron
MCH	Mean Corpuscular Hemoglobin	pg or picograms
MCHC	Mean Corpuscular Hemoglobin Concentration	%
PLT	Platelets	$10^3/\text{cu mm}$
NRBC	Nucleated Red Blood Cell Count	
Lymphocyte	Lymphocytes	$10^3/\text{cu mm}$
Segmented	Segmented Neutrophils	$10^3/\text{cu mm}$
Eosinophil	Eosinophils	$10^3/\text{cu mm}$
Abnormal L	Abnormal Lymphocytes	$10^3/\text{cu mm}$
APTT	Activated Partial Thromboplastin Time	seconds
PT	Prothrombin time	seconds
Other	Other Cells	$10^3/\text{cu mm}$
ABS	Absolute	
CNT	Count	

APPENDIX 9

Study Report for Hematology

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: MALE

Animal ID	WBC THSN/CU MM	RBC MILL/CU MM	HGB GRAMS/DL	HCT %	MCV CU MICRONS	MCH PICO GRAMS	MCHC %	PLT THSN/CU MM
GROUP: 1-M								
7569	e	e	e	e	e	e	e	e
7571	e	e	e	e	e	e	e	e
7573	e	e	e	e	e	e	e	e
7575	e	e	e	e	e	e	e	e
7577	e	e	e	e	e	e	e	e
7579	e	e	e	e	e	e	e	e
7581	e	e	e	e	e	e	e	e
7583	e	e	e	e	e	e	e	e
7585	e	e	e	e	e	e	e	e
7587	e	e	e	e	e	e	e	e
7589	13.0	7.08	14.5	38.6	54.5	20.5	37.6	1421
7591	19.2	7.10	15.4	41.0	57.8	21.7	37.6	1134
7593	14.2	6.79	15.2	39.9	58.7	22.4	38.1	1234
7595	8.3	7.65	16.0	43.7	57.1	20.9	36.6	1188
7597	12.2	6.74	14.3	37.6	55.8	21.2	38.0	1304
MEAN	13.4	7.07	15.1	40.2	56.8	21.3	37.6	1256
SD	3.93	0.362	0.69	2.36	1.66	0.74	0.59	111.3
N	5	5	5	5	5	5	5	5

e - Terminal Sacrifice

LABCAT HE4.41c

03-NOV-2000

APPENDIX 9

Study Report for Hematology

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: MALE

Animal ID	WBC THSN/CU MM	RBC MILL/CU MM	HGB GRAMS/DL	HCT %	MCV CU MICRONS	MCH PICO GRAMS	MCHC %	PLT THSN/CU MM
GROUP: 4-M								
7639	e	e	e	e	e	e	e	e
7641	e	e	e	e	e	e	e	e
7643	e	e	e	e	e	e	e	e
7645	e	e	e	e	e	e	e	e
7647	e	e	e	e	e	e	e	e
7649	e	e	e	e	e	e	e	e
7651	e	e	e	e	e	e	e	e
7653	e	e	e	e	e	e	e	e
7655	e	e	e	e	e	e	e	e
7657	e	e	e	e	e	e	e	e
7659	11.5	7.19	15.9	42.5	59.1	22.1	37.4	1088
7661	9.5	7.94	16.2	44.4	55.9	20.4	36.5	1180
7663	7.0	7.48	15.9	42.6	57.0	21.3	37.3	1161
7665	12.6	6.71	14.0	37.2	55.5	20.9	37.6	1061
7667	16.8	7.07	15.1	40.3	57.0	21.4	37.5	1098
MEAN	11.5	7.28	15.4	41.4	56.9	21.2	37.3	1118
SD	3.66	0.462	0.89	2.76	1.40	0.63	0.44	50.6
N	5	5	5	5	5	5	5	5

e - Terminal Sacrifice

LABCAT HE4.41c

03-NOV-2000

APPENDIX 9

Study Report for Hematology

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: MALE

Animal ID	PT seconds	APTT seconds	NRBC COUNT	Lymphocyte THSN/CU MM	Segmented THSN/CU MM	Bands THSN/CU MM	Monocytes THSN/CU MM	Eosinophil THSN/CU MM
GROUP: 1-M								
7569	e	e	e	e	e	e	e	e
7571	e	e	e	e	e	e	e	e
7573	e	e	e	e	e	e	e	e
7575	e	e	e	e	e	e	e	e
7577	e	e	e	e	e	e	e	e
7579	e	e	e	e	e	e	e	e
7581	e	e	e	e	e	e	e	e
7583	e	e	e	e	e	e	e	e
7585	e	e	e	e	e	e	e	e
7587	e	e	e	e	e	e	e	e
7589	12.7	20.0	0	12.0	0.9	0.0	0.0	0.1
7591	12.5	14.0	0	18.2	1.0	0.0	0.0	0.0
7593	12.6	20.2	0	12.1	2.0	0.0	0.0	0.1
7595	12.4	18.4	0	6.9	1.3	0.0	0.0	0.1
7597	12.6	15.6	0	10.7	1.3	0.0	0.1	0.0
MEAN	12.6	17.6	0	12.0	1.3	0.0	0.0	0.1
SD	0.11	2.74	0.0	4.07	0.43	0.00	0.04	0.05
N	5	5	5	5	5	5	5	5

e - Terminal Sacrifice

LABCAT HE4.41c

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APPENDIX 9

Study Report for Hematology

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: MALE

Animal ID	PT seconds	APTT seconds	NRBC COUNT	Lymphocyte THSN/CU MM	Segmented THSN/CU MM	Bands THSN/CU MM	Monocytes THSN/CU MM	Eosinophil THSN/CU MM
GROUP: 4-M								
7639	e	e	e	e	e	e	e	e
7641	e	e	e	e	e	e	e	e
7643	e	e	e	e	e	e	e	e
7645	e	e	e	e	e	e	e	e
7647	e	e	e	e	e	e	e	e
7649	e	e	e	e	e	e	e	e
7651	e	e	e	e	e	e	e	e
7653	e	e	e	e	e	e	e	e
7655	e	e	e	e	e	e	e	e
7657	e	e	e	e	e	e	e	e
7659	13.4	19.6	0	10.2	1.3	0.0	0.0	0.0
7661	13.4	21.4	0	8.7	0.7	0.0	0.0	0.1
7663	13.4	27.8	0	6.2	0.7	0.0	0.1	0.0
7665	13.6	20.5	0	10.7	1.6	0.0	0.3	0.0
7667	13.3	22.1	0	14.8	1.8	0.0	0.2	0.0
MEAN	13.4	22.3	0	10.1	1.2	0.0	0.1	0.0
SD	0.11	3.23	0.0	3.15	0.51	0.00	0.13	0.04
N	5	5	5	5	5	5	5	5

e - Terminal Sacrifice

LABCAT HE4.41c

03-NOV-2000

APPENDIX 9

Study Report for Hematology

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: MALE

Animal ID	Basophils THSN/CU MM	Abnormal L THSN/CU MM	Other THSN/CU MM
GROUP: 1-M			
7569	e	e	e
7571	e	e	e
7573	e	e	e
7575	e	e	e
7577	e	e	e
7579	e	e	e
7581	e	e	e
7583	e	e	e
7585	e	e	e
7587	e	e	e
7589	0.0	0.0	0.0
7591	0.0	0.0	0.0
7593	0.0	0.0	0.0
7595	0.0	0.0	0.0
7597	0.0	0.0	0.0
MEAN	0.0	0.0	0.0
SD	0.00	0.00	0.00
N	5	5	5

e - Terminal Sacrifice

LABCAT HE4.41c

03-NOV-2000

APPENDIX 9

Study Report for Hematology

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: MALE

Animal ID	Basophils THSN/CU MM	Abnormal L THSN/CU MM	Other THSN/CU MM
GROUP: 4-M			
7639	e	e	e
7641	e	e	e
7643	e	e	e
7645	e	e	e
7647	e	e	e
7649	e	e	e
7651	e	e	e
7653	e	e	e
7655	e	e	e
7657	e	e	e
7659	0.0	0.0	0.0
7661	0.0	0.0	0.0
7663	0.0	0.0	0.0
7665	0.0	0.0	0.0
7667	0.0	0.0	0.0
MEAN	0.0	0.0	0.0
SD	0.00	0.00	0.00
N	5	5	5

e - Terminal Sacrifice

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APPENDIX 9

Study Report for Hematology

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: TERMINALSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: MALE

Animal ID	WBC THSN/CU MM	RBC MILL/CU MM	HGB GRAMS/DL	HCT %	MCV CU MICRONS	MCH PICO GRAMS	MCHC %	PLT THSN/CU MM
GROUP: 1-M								
7569	7.5	7.16	15.5	42.4	59.2	21.6	36.6	1057
7571	5.4	7.14	15.6	41.6	58.2	21.8	37.5	1093
7573	10.7	7.71	16.6	45.5	59.0	21.5	36.5	1303
7575	20.6	7.37	16.5	48.6	66.0	22.4	34.0	1234
7577	7.6	7.69	16.3	43.9	57.1	21.2	37.1	1011
7579	12.8	6.29	15.0	40.0	63.6	23.8	37.5	1027
7581	12.5	7.62	17.3	47.2	61.9	22.7	36.7	1242
7583	7.9	6.82	16.4	42.6	62.5	24.0	38.5	1458
7585	8.1	5.98	13.2	36.2	60.5	22.1	36.5	1275
7587	6.9	5.33	12.5	32.6	61.1	23.5	38.3	1044
7589	--	--	--	--	--	--	--	--
7591	--	--	--	--	--	--	--	--
7593	--	--	--	--	--	--	--	--
7595	--	--	--	--	--	--	--	--
7597	--	--	--	--	--	--	--	--
MEAN	10.0	6.91	15.5	42.1	60.9	22.5	36.9	1174
SD	4.44	0.805	1.54	4.87	2.69	1.01	1.25	149.5
N	10	10	10	10	10	10	10	10
GROUP: 2-M								
7599	10.8	7.44	16.6	45.2	60.8	22.3	36.7	1014
7601	11.6	7.23	15.7	43.2	59.8	21.7	36.3	1262
7603	13.9	6.70	15.2	41.4	61.8	22.7	36.7	1185
7605	17.5	7.94	16.0	46.4	58.4	20.2	34.5	1291
7607	14.3	7.06	16.3	44.4	62.9	23.1	36.7	1199
7609	11.8	6.69	15.5	41.9	62.7	23.2	37.0	1266
7611	8.3	6.46	15.4	40.2	62.3	23.8	38.3	1409
7613	11.1	6.44	15.0	39.5	61.3	23.3	38.0	1308
7615	7.7	7.30	16.4	44.2	60.5	22.5	37.1	1261
7617	14.6	6.98	15.5	41.7	59.8	22.2	37.2	1223
MEAN	12.2	7.02	15.8	42.8	61.0	22.5	36.8	1242
SD	2.99	0.473	0.54	2.24	1.45	1.02	1.03	101.9
N	10	10	10	10	10	10	10	10

(--) - Data Unavailable

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Study Report for Hematology

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: TERMINALSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: MALE

Animal ID	WBC THSN/CU MM	RBC MILL/CU MM	HGB GRAMS/DL	HCT %	MCV CU MICRONS	MCH PICO GRAMS	MCHC %	PLT THSN/CU MM
GROUP: 3-M								
7619	9.0	7.01	15.4	40.8	58.2	22.0	37.7	1019
7621	10.0	6.70	15.1	41.0	61.2	22.5	36.8	1033
7623	8.6	7.66	16.6	44.4	58.0	21.7	37.4	1380
7625	10.9	6.85	15.4	41.3	60.3	22.5	37.3	1200
7627	14.2	6.91	14.9	40.0	57.9	21.6	37.3	1051
7629	9.1	6.82	15.9	43.2	63.4	23.3	36.8	1180
7631	14.4	6.40	15.6	41.2	64.4	24.4	37.9	1155
7633	14.5	6.70	15.7	41.8	62.4	23.4	37.6	1103
7635	7.0	7.09	15.7	41.1	58.0	22.1	38.2	1063
7637	6.6	6.85	15.5	41.6	60.7	22.6	37.3	1022
MEAN	10.4	6.90	15.6	41.6	60.5	22.6	37.4	1121
SD	2.99	0.328	0.46	1.27	2.41	0.87	0.44	112.8
N	10	10	10	10	10	10	10	10
GROUP: 4-M								
7639	10.0	7.34	15.9	42.8	58.3	21.7	37.1	1118
7641	12.3	6.43	14.6	38.8	60.4	22.7	37.6	981
7643	8.2	7.47	15.6	42.6	57.0	20.9	36.6	915
7645	11.5	6.81	15.6	40.9	60.0	22.9	38.1	1069
7647	6.8	7.05	15.8	42.2	59.8	22.4	37.4	847
7649	7.8	6.58	14.9	38.1	57.9	22.6	39.1	1269
7651	9.7	6.92	15.4	40.6	58.7	22.3	37.9	867
7653	7.9	5.56	13.0	34.5	62.1	23.4	37.7	853
7655	12.0	6.59	15.9	42.1	63.9	24.1	37.8	1119
7657	9.1	5.77	13.4	35.3	61.2	23.2	38.0	977
7659	--	--	--	--	--	--	--	--
7661	--	--	--	--	--	--	--	--
7663	--	--	--	--	--	--	--	--
7665	--	--	--	--	--	--	--	--
7667	--	--	--	--	--	--	--	--
MEAN	9.5	6.65	15.0	39.8	59.9	22.6	37.7	1002
SD	1.91	0.617	1.05	3.02	2.09	0.89	0.66	139.8
N	10	10	10	10	10	10	10	10

(--) - Data Unavailable

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APPENDIX 9

Study Report for Hematology

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: TERMINAL

STUDY ID: 28-DAY ORAL DOSE/RAT							SEX: MALE	
STUDY NO: 132-007								
Animal ID	PT seconds	APTT seconds	NRBC COUNT	Lymphocyte THSN/CU MM	Segmented THSN/CU MM	Bands THSN/CU MM	Monocytes THSN/CU MM	Eosinophil THSN/CU MM
GROUP: 1-M								
7569	15.2	22.3	0	7.1	0.4	0.0	0.0	0.1
7571	14.3	15.8	0	5.0	0.3	0.0	0.0	0.1
7573	15.0	29.4	0	10.3	0.2	0.0	0.2	0.0
7575	14.2	27.2	0	18.5	1.6	0.0	0.0	0.4
7577	16.5	40.4	0	7.1	0.5	0.0	0.0	0.0
7579	14.3	19.1	0	11.8	0.9	0.0	0.1	0.0
7581	15.3	36.0	0	11.4	1.1	0.0	0.0	0.0
7583	13.7	25.0	0	7.2	0.4	0.1	0.0	0.2
7585	14.0	24.5	0	7.3	0.7	0.0	0.1	0.0
7587	13.2	19.7	1	6.4	0.4	0.0	0.0	0.1
7589	--	--	--	--	--	--	--	--
7591	--	--	--	--	--	--	--	--
7593	--	--	--	--	--	--	--	--
7595	--	--	--	--	--	--	--	--
7597	--	--	--	--	--	--	--	--
MEAN	14.6	25.9	0	9.2	0.6	0.0	0.0	0.1
SD	0.95	7.66	0.3	3.96	0.44	0.03	0.07	0.13
N	10	10	10	10	10	10	10	10
GROUP: 2-M								
7599	CL	CL	0	9.5	1.2	0.0	0.0	0.1
7601	15.2	25.7	0	9.6	1.9	0.0	0.0	0.1
7603	15.6	27.9	0	11.8	2.1	0.0	0.0	0.0
7605	16.4	28.2	0	15.6	1.8	0.0	0.0	0.0
7607	15.5	30.8	0	12.9	1.4	0.0	0.0	0.0
7609	15.0	29.6	0	9.8	1.9	0.0	0.0	0.1
7611	15.2	26.2	0	6.6	1.6	0.0	0.0	0.1
7613	14.5	24.5	0	9.8	1.3	0.0	0.0	0.0
7615	15.8	27.4	0	7.1	0.5	0.0	0.0	0.1
7617	14.1	21.6	0	12.3	2.0	0.0	0.0	0.3
MEAN	15.3	26.9	0	10.5	1.6	0.0	0.0	0.1
SD	0.69	2.77	0.0	2.71	0.49	0.00	0.00	0.09
N	9	9	10	10	10	10	10	10

(--) - Data Unavailable

CL - Clotted

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Study Report for Hematology

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: TERMINALSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: MALE

Animal ID	PT seconds	APTT seconds	NRBC COUNT	Lymphocyte THSN/CU MM	Segmented THSN/CU MM	Bands THSN/CU MM	Monocytes THSN/CU MM	Eosinophil THSN/CU MM
GROUP: 3-M								
7619	14.6	26.7	0	8.1	0.9	0.0	0.0	0.0
7621	14.6	20.0	0	9.5	0.5	0.0	0.0	0.0
7623	14.4	15.9	0	8.0	0.6	0.0	0.0	0.0
7625	13.6	20.1	0	9.8	1.1	0.0	0.0	0.0
7627	13.3	26.3	0	12.1	1.8	0.0	0.0	0.3
7629	15.3	27.9	0	6.5	2.6	0.0	0.0	0.0
7631	14.8	23.4	0	12.7	1.6	0.0	0.0	0.1
7633	14.8	20.8	0	13.9	0.3	0.0	0.1	0.1
7635	14.3	24.4	0	6.5	0.5	0.0	0.0	0.0
7637	15.1	23.2	0	6.1	0.4	0.0	0.0	0.1
MEAN	14.5	22.9	0	9.3	1.0	0.0	0.0	0.1
SD	0.62	3.70	0.0	2.79	0.75	0.00	0.03	0.10
N	10	10	10	10	10	10	10	10
GROUP: 4-M								
7639	14.7	32.1	0	8.5	1.5	0.0	0.0	0.0
7641	13.3	29.7	0	11.2	0.9	0.0	0.2	0.0
7643	14.6	19.8	0	7.8	0.4	0.0	0.0	0.0
7645	14.0	20.5	0	9.8	1.4	0.0	0.3	0.0
7647	16.5	31.6	0	5.8	0.7	0.0	0.1	0.1
7649	14.6	25.3	0	6.9	0.8	0.0	0.1	0.0
7651	CL	CL	0	8.7	0.7	0.0	0.1	0.2
7653	14.1	22.5	0	6.6	1.1	0.0	0.2	0.0
7655	14.3	25.6	0	11.4	0.5	0.0	0.1	0.0
7657	15.1	19.1	0	8.0	0.8	0.0	0.2	0.1
7659	--	--	--	--	--	--	--	--
7661	--	--	--	--	--	--	--	--
7663	--	--	--	--	--	--	--	--
7665	--	--	--	--	--	--	--	--
7667	--	--	--	--	--	--	--	--
MEAN	14.6	25.1	0	8.5	0.9	0.0	0.1	0.0
SD	0.88	5.06	0.0	1.87	0.36	0.00	0.09	0.07
N	9	9	10	10	10	10	10	10

(--) - Data Unavailable

CL - Clotted

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Study Report for Hematology

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: TERMINALSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: MALE

Animal ID	Basophils THSN/CU MM	Abnormal L THSN/CU MM	Other THSN/CU MM
GROUP: 1-M			
7569	0.0	0.0	0.0
7571	0.0	0.0	0.0
7573	0.0	0.0	0.0
7575	0.0	0.0	0.0
7577	0.0	0.0	0.0
7579	0.0	0.0	0.0
7581	0.0	0.0	0.0
7583	0.0	0.0	0.0
7585	0.0	0.0	0.0
7587	0.0	0.0	0.0
7589	--	--	--
7591	--	--	--
7593	--	--	--
7595	--	--	--
7597	--	--	--
MEAN	0.0	0.0	0.0
SD	0.00	0.00	0.00
N	10	10	10
GROUP: 2-M			
7599	0.0	0.0	0.0
7601	0.0	0.0	0.0
7603	0.0	0.0	0.0
7605	0.0	0.2	0.0
7607	0.0	0.0	0.0
7609	0.0	0.0	0.0
7611	0.0	0.0	0.0
7613	0.0	0.0	0.0
7615	0.0	0.0	0.0
7617	0.0	0.0	0.0
MEAN	0.0	0.0	0.0
SD	0.00	0.06	0.00
N	10	10	10

(--) - Data Unavailable

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Study Report for Hematology

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: TERMINALSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: MALE

Animal ID	Basophils THSN/CU MM	Abnormal L THSN/CU MM	Other THSN/CU MM
GROUP: 3-M			
7619	0.0	0.0	0.0
7621	0.0	0.0	0.0
7623	0.0	0.0	0.0
7625	0.0	0.0	0.0
7627	0.0	0.0	0.0
7629	0.0	0.0	0.0
7631	0.0	0.0	0.0
7633	0.0	0.0	0.0
7635	0.0	0.0	0.0
7637	0.0	0.0	0.0
MEAN	0.0	0.0	0.0
SD	0.00	0.00	0.00
N	10	10	10
GROUP: 4-M			
7639	0.0	0.0	0.0
7641	0.0	0.0	0.0
7643	0.0	0.0	0.0
7645	0.0	0.0	0.0
7647	0.0	0.0	0.0
7649	0.0	0.0	0.0
7651	0.0	0.0	0.0
7653	0.0	0.0	0.0
7655	0.0	0.0	0.0
7657	0.0	0.0	0.0
7659	--	--	--
7661	--	--	--
7663	--	--	--
7665	--	--	--
7667	--	--	--
MEAN	0.0	0.0	0.0
SD	0.00	0.00	0.00
N	10	10	10

(--) - Data Unavailable

LABCAT HE4.41c

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APPENDIX 9

Study Report for Hematology

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: MALE

Animal ID	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	PLT
	THSN/CU MM	MILL/CU MM	GRAMS/DL	%	CU MICRONS	PICO GRAMS	%	THSN/CU MM
GROUP: 1-M								
7569	e	e	e	e	e	e	e	e
7571	e	e	e	e	e	e	e	e
7573	e	e	e	e	e	e	e	e
7575	e	e	e	e	e	e	e	e
7577	e	e	e	e	e	e	e	e
7579	e	e	e	e	e	e	e	e
7581	e	e	e	e	e	e	e	e
7583	e	e	e	e	e	e	e	e
7585	e	e	e	e	e	e	e	e
7587	e	e	e	e	e	e	e	e
7589	13.0	7.08	14.5	38.6	54.5	20.5	37.6	1421
7591	19.2	7.10	15.4	41.0	57.8	21.7	37.6	1134
7593	14.2	6.79	15.2	39.9	58.7	22.4	38.1	1234
7595	8.3	7.65	16.0	43.7	57.1	20.9	36.6	1188
7597	12.2	6.74	14.3	37.6	55.8	21.2	38.0	1304
MEAN	13.4	7.07	15.1	40.2	56.8	21.3	37.6	1256
SD	3.93	0.362	0.69	2.36	1.66	0.74	0.59	111.3
N	5	5	5	5	5	5	5	5

e - Terminal Sacrifice

LABCAT HE4.41c

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Study Report for Hematology

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: MALE

Animal ID	WBC THSN/CU MM	RBC MILL/CU MM	HGB GRAMS/DL	HCT %	MCV CU MICRONS	MCH PICO GRAMS	MCHC %	PLT THSN/CU MM
GROUP: 4-M								
7639	e	e	e	e	e	e	e	e
7641	e	e	e	e	e	e	e	e
7643	e	e	e	e	e	e	e	e
7645	e	e	e	e	e	e	e	e
7647	e	e	e	e	e	e	e	e
7649	e	e	e	e	e	e	e	e
7651	e	e	e	e	e	e	e	e
7653	e	e	e	e	e	e	e	e
7655	e	e	e	e	e	e	e	e
7657	e	e	e	e	e	e	e	e
7659	11.5	7.19	15.9	42.5	59.1	22.1	37.4	1088
7661	9.5	7.94	16.2	44.4	55.9	20.4	36.5	1180
7663	7.0	7.48	15.9	42.6	57.0	21.3	37.3	1161
7665	12.6	6.71	14.0	37.2	55.5	20.9	37.6	1061
7667	16.8	7.07	15.1	40.3	57.0	21.4	37.5	1098
MEAN	11.5	7.28	15.4	41.4	56.9	21.2	37.3	1118
SD	3.66	0.462	0.89	2.76	1.40	0.63	0.44	50.6
N	5	5	5	5	5	5	5	5

e - Terminal Sacrifice

LABCAT HE4.41c

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Study Report for Hematology

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: MALE

Animal ID	PT seconds	APTT seconds	NRBC COUNT	Lymphocyte THSN/CU MM	Segmented THSN/CU MM	Bands THSN/CU MM	Monocytes THSN/CU MM	Eosinophil THSN/CU MM
GROUP: 1-M								
7569	e	e	e	e	e	e	e	e
7571	e	e	e	e	e	e	e	e
7573	e	e	e	e	e	e	e	e
7575	e	e	e	e	e	e	e	e
7577	e	e	e	e	e	e	e	e
7579	e	e	e	e	e	e	e	e
7581	e	e	e	e	e	e	e	e
7583	e	e	e	e	e	e	e	e
7585	e	e	e	e	e	e	e	e
7587	e	e	e	e	e	e	e	e
7589	12.7	20.0	0	12.0	0.9	0.0	0.0	0.1
7591	12.5	14.0	0	18.2	1.0	0.0	0.0	0.0
7593	12.6	20.2	0	12.1	2.0	0.0	0.0	0.1
7595	12.4	18.4	0	6.9	1.3	0.0	0.0	0.1
7597	12.6	15.6	0	10.7	1.3	0.0	0.1	0.0
MEAN	12.6	17.6	0	12.0	1.3	0.0	0.0	0.1
SD	0.11	2.74	0.0	4.07	0.43	0.00	0.04	0.05
N	5	5	5	5	5	5	5	5

e - Terminal Sacrifice

LABCAT HE4.41c

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Study Report for Hematology

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: RECOVERY

STUDY ID: 28-DAY ORAL DOSE/RAT								SEX: MALE
STUDY NO: 132-007								
Animal ID	PT seconds	APTT seconds	NRBC COUNT	Lymphocyte THSN/CU MM	Segmented THSN/CU MM	Bands THSN/CU MM	Monocytes THSN/CU MM	Eosinophil THSN/CU MM
GROUP: 4-M								
7639	e	e	e	e	e	e	e	e
7641	e	e	e	e	e	e	e	e
7643	e	e	e	e	e	e	e	e
7645	e	e	e	e	e	e	e	e
7647	e	e	e	e	e	e	e	e
7649	e	e	e	e	e	e	e	e
7651	e	e	e	e	e	e	e	e
7653	e	e	e	e	e	e	e	e
7655	e	e	e	e	e	e	e	e
7657	e	e	e	e	e	e	e	e
7659	13.4	19.6	0	10.2	1.3	0.0	0.0	0.0
7661	13.4	21.4	0	8.7	0.7	0.0	0.0	0.1
7663	13.4	27.8	0	6.2	0.7	0.0	0.1	0.0
7665	13.6	20.5	0	10.7	1.6	0.0	0.3	0.0
7667	13.3	22.1	0	14.8	1.8	0.0	0.2	0.0
MEAN	13.4	22.3	0	10.1	1.2	0.0	0.1	0.0
SD	0.11	3.23	0.0	3.15	0.51	0.00	0.13	0.04
N	5	5	5	5	5	5	5	5

e - Terminal Sacrifice

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APPENDIX 9

Study Report for Hematology

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: MALE

Animal ID	Basophils THSN/CU MM	Abnormal L THSN/CU MM	Other THSN/CU MM
GROUP: 1-M			
7569	e	e	e
7571	e	e	e
7573	e	e	e
7575	e	e	e
7577	e	e	e
7579	e	e	e
7581	e	e	e
7583	e	e	e
7585	e	e	e
7587	e	e	e
7589	0.0	0.0	0.0
7591	0.0	0.0	0.0
7593	0.0	0.0	0.0
7595	0.0	0.0	0.0
7597	0.0	0.0	0.0
MEAN	0.0	0.0	0.0
SD	0.00	0.00	0.00
N	5	5	5

e - Terminal Sacrifice

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Study Report for Hematology

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: MALE

Animal ID	Basophils	Abnormal L	Other
	THSN/CU MM	THSN/CU MM	THSN/CU MM
GROUP: 4-M			
7639	e	e	e
7641	e	e	e
7643	e	e	e
7645	e	e	e
7647	e	e	e
7649	e	e	e
7651	e	e	e
7653	e	e	e
7655	e	e	e
7657	e	e	e
7659	0.0	0.0	0.0
7661	0.0	0.0	0.0
7663	0.0	0.0	0.0
7665	0.0	0.0	0.0
7667	0.0	0.0	0.0
MEAN	0.0	0.0	0.0
SD	0.00	0.00	0.00
N	5	5	5

e - Terminal Sacrifice

LABCAT HE4.41c

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Study Report for Hematology

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

Animal ID	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	PLT
	THSN/CU MM	MILL/CU MM	GRAMS/DL	%	CU MICRONS	PICO GRAMS	%	THSN/CU MM
GROUP: 1-F								
7570	e	e	e	e	e	e	e	e
7572	e	e	e	e	e	e	e	e
7574	e	e	e	e	e	e	e	e
7576	e	e	e	e	e	e	e	e
7578	e	e	e	e	e	e	e	e
7580	e	e	e	e	e	e	e	e
7582	e	e	e	e	e	e	e	e
7584	e	e	e	e	e	e	e	e
7586	e	e	e	e	e	e	e	e
7588	e	e	e	e	e	e	e	e
7590	10.1	6.79	15.1	41.4	60.9	22.2	36.5	1350
7592	10.0	7.46	15.0	41.6	55.7	20.1	36.1	1349
7594	7.1	7.33	14.9	41.6	56.8	20.3	35.8	1106
7596	12.8	7.41	16.3	44.7	60.3	22.0	36.5	1330
7598	8.7	6.74	14.4	39.0	57.9	21.4	36.9	1059
MEAN	9.7	7.15	15.1	41.7	58.3	21.2	36.4	1239
SD	2.10	0.351	0.70	2.02	2.23	0.96	0.42	143.9
N	5	5	5	5	5	5	5	5

e - Terminal Sacrifice

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Study Report for Hematology

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

Animal ID	WBC THSN/CU MM	RBC MILL/CU MM	HGB GRAMS/DL	HCT %	MCV CU MICRONS	MCH PICO GRAMS	MCHC %	PLT THSN/CU MM
GROUP: 4-F								
7640	e	e	e	e	e	e	e	e
7642	e	e	e	e	e	e	e	e
7644	e	e	e	e	e	e	e	e
7646	e	e	e	e	e	e	e	e
7648	e	e	e	e	e	e	e	e
7650	e	e	e	e	e	e	e	e
7652	e	e	e	e	e	e	e	e
7654	e	e	e	e	e	e	e	e
7656	e	e	e	e	e	e	e	e
7658	e	e	e	e	e	e	e	e
7660	6.0	7.50	17.0	46.1	61.5	22.7	36.9	968
7662	5.4	6.08	14.2	37.5	61.6	23.4	37.9	801
7664	16.1	6.88	15.1	40.6	59.0	21.9	37.2	967
7666	6.9	7.15	14.7	40.5	56.6	20.6	36.3	1212
7668	8.5	6.86	13.8	38.4	56.0	20.1	35.9	1024
MEAN	8.6	6.89	15.0	40.6	58.9	21.7	36.8	994
SD	4.36	0.524	1.24	3.34	2.63	1.39	0.78	147.5
N	5	5	5	5	5	5	5	5

e - Terminal Sacrifice

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Study Report for Hematology

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

Animal ID	PT seconds	APTT seconds	NRBC COUNT	Lymphocyte THSN/CU MM	Segmented THSN/CU MM	Bands THSN/CU MM	Monocytes THSN/CU MM	Eosinophil THSN/CU MM
GROUP: 1-F								
7570	e	e	e	e	e	e	e	e
7572	e	e	e	e	e	e	e	e
7574	e	e	e	e	e	e	e	e
7576	e	e	e	e	e	e	e	e
7578	e	e	e	e	e	e	e	e
7580	e	e	e	e	e	e	e	e
7582	e	e	e	e	e	e	e	e
7584	e	e	e	e	e	e	e	e
7586	e	e	e	e	e	e	e	e
7588	e	e	e	e	e	e	e	e
7590	12.4	17.8	0	9.5	0.6	0.0	0.0	0.0
7592	13.0	19.9	0	8.7	1.2	0.0	0.1	0.0
7594	12.1	18.1	0	6.5	0.6	0.0	0.0	0.0
7596	11.8	18.6	0	11.8	1.0	0.0	0.0	0.0
7598	12.2	18.3	0	7.9	0.8	0.0	0.0	0.0
MEAN	12.3	18.5	0	8.9	0.8	0.0	0.0	0.0
SD	0.45	0.81	0.0	1.97	0.26	0.00	0.04	0.00
N	5	5	5	5	5	5	5	5

e - Terminal Sacrifice

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Study Report for Hematology

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

Animal ID	PT seconds	APTT seconds	NRBC COUNT	Lymphocyte THSN/CU MM	Segmented THSN/CU MM	Bands THSN/CU MM	Monocytes THSN/CU MM	Eosinophil THSN/CU MM
GROUP: 4-F								
7640	e	e	e	e	e	e	e	e
7642	e	e	e	e	e	e	e	e
7644	e	e	e	e	e	e	e	e
7646	e	e	e	e	e	e	e	e
7648	e	e	e	e	e	e	e	e
7650	e	e	e	e	e	e	e	e
7652	e	e	e	e	e	e	e	e
7654	e	e	e	e	e	e	e	e
7656	e	e	e	e	e	e	e	e
7658	e	e	e	e	e	e	e	e
7660	12.7	21.0	0	5.6	0.3	0.0	0.1	0.0
7662	13.2	23.6	0	4.6	0.8	0.0	0.0	0.0
7664	12.9	19.6	0	14.8	1.1	0.0	0.2	0.0
7666	12.7	19.8	0	5.2	1.7	0.0	0.0	0.0
7668	12.8	21.2	0	7.5	1.0	0.0	0.0	0.0
MEAN	12.9	21.0	0	7.5	1.0	0.0	0.1	0.0
SD	0.21	1.60	0.0	4.20	0.51	0.00	0.09	0.00
N	5	5	5	5	5	5	5	5

e - Terminal Sacrifice

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Study Report for Hematology

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

Animal ID	Basophils THSN/CU MM	Abnormal L THSN/CU MM	Other THSN/CU MM
GROUP: 1-F			
7570	e	e	e
7572	e	e	e
7574	e	e	e
7576	e	e	e
7578	e	e	e
7580	e	e	e
7582	e	e	e
7584	e	e	e
7586	e	e	e
7588	e	e	e
7590	0.0	0.0	0.0
7592	0.0	0.0	0.0
7594	0.0	0.0	0.0
7596	0.0	0.0	0.0
7598	0.0	0.0	0.0
MEAN	0.0	0.0	0.0
SD	0.00	0.00	0.00
N	5	5	5

e - Terminal Sacrifice

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Study Report for Hematology

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

Animal ID	Basophils THSN/CU MM	Abnormal L THSN/CU MM	Other THSN/CU MM
GROUP: 4-F			
7640	e	e	e
7642	e	e	e
7644	e	e	e
7646	e	e	e
7648	e	e	e
7650	e	e	e
7652	e	e	e
7654	e	e	e
7656	e	e	e
7658	e	e	e
7660	0.0	0.0	0.0
7662	0.0	0.0	0.0
7664	0.0	0.0	0.0
7666	0.0	0.0	0.0
7668	0.0	0.0	0.0
MEAN	0.0	0.0	0.0
SD	0.00	0.00	0.00
N	5	5	5

e - Terminal Sacrifice

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Study Report for Hematology

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: TERMINAL

STUDY ID: 28-DAY ORAL DOSE/RAT								SEX: FEMALE
STUDY NO: 132-007								
Animal ID	WBC THSN/CU MM	RBC MILL/CU MM	HGB GRAMS/DL	HCT %	MCV CU MICRONS	MCH PICO GRAMS	MCHC %	PLT THSN/CU MM
GROUP: 1-F								
7570	8.8	6.63	15.4	41.3	62.3	23.2	37.3	1119
7572	9.9	6.49	14.9	40.1	61.8	23.0	37.2	1044
7574	3.4	6.27	15.1	41.3	65.9	24.1	36.6	1080
7576	7.1	7.34	16.0	44.1	60.1	21.8	36.3	1107
7578	5.1	6.91	15.4	42.2	61.1	22.3	36.5	1016
7580	15.2	6.47	15.3	41.5	64.1	23.6	36.9	1044
7582	10.2	6.60	15.1	40.0	60.6	22.9	37.8	1231
7584	14.9	6.74	15.6	41.6	61.7	23.1	37.5	922
7586	14.0	6.74	15.6	41.0	60.8	23.1	38.0	1172
7588	3.9	6.76	15.2	41.1	60.8	22.5	37.0	1163
7590	--	--	--	--	--	--	--	--
7592	--	--	--	--	--	--	--	--
7594	--	--	--	--	--	--	--	--
7596	--	--	--	--	--	--	--	--
7598	--	--	--	--	--	--	--	--
MEAN	9.2	6.70	15.4	41.4	61.9	23.0	37.1	1090
SD	4.42	0.290	0.32	1.15	1.80	0.65	0.56	88.9
N	10	10	10	10	10	10	10	10
GROUP: 2-F								
7600	10.9	7.00	15.4	42.7	61.0	22.0	36.1	746
7602	8.7	6.41	15.1	41.2	64.3	23.6	36.7	829
7604	8.4	6.41	14.5	39.7	61.9	22.6	36.5	1760
7606	7.2	7.16	15.7	43.1	60.2	21.9	36.4	1423
7608	8.2	6.59	15.2	41.0	62.2	23.1	37.1	1337
7610	17.3	7.19	15.4	42.5	59.1	21.4	36.2	1075
7612	11.3	7.53	16.6	45.8	60.8	22.0	36.2	1094
7614	CL	CL	CL	CL	CL	CL	CL	CL
7616	14.1	7.47	15.8	42.5	56.9	21.2	37.2	908
7618	14.6	6.22	14.4	37.8	60.7	23.2	38.1	1225
MEAN	11.2	6.89	15.3	41.8	60.8	22.3	36.7	1155
SD	3.47	0.490	0.67	2.26	2.06	0.84	0.65	320.3
N	9	9	9	9	9	9	9	9

(--)-- Data Unavailable

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Study Report for Hematology

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: TERMINALSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

Animal ID	WBC THSN/CU MM	RBC MILL/CU MM	HGB GRAMS/DL	HCT %	MCV CU MICRONS	MCH PICO GRAMS	MCHC %	PLT THSN/CU MM
GROUP: 3-F								
7620	7.6	6.93	15.1	42.1	60.8	21.8	35.9	1414
7622	3.9	6.55	15.4	42.4	64.8	23.5	36.3	768
7624	6.4	6.52	14.1	40.0	61.3	21.6	35.3	1164
7626	10.6	6.94	16.5	46.0	66.3	23.8	35.9	1030
7628	4.9	5.97	13.4	37.4	62.7	22.4	35.8	1095
7630	10.6	6.97	15.8	42.8	61.4	22.7	36.9	1439
7632	9.7	7.39	16.6	45.4	61.5	22.5	36.6	809
7634	5.4	6.28	14.6	38.7	61.7	23.2	37.7	1112
7636	3.3	7.25	15.7	42.2	58.2	21.7	37.2	1087
7638	11.4	6.61	15.6	41.6	62.9	23.6	37.5	1260
MEAN	7.4	6.74	15.3	41.9	62.2	22.7	36.5	1118
SD	3.02	0.437	1.01	2.68	2.22	0.82	0.80	221.2
N	10	10	10	10	10	10	10	10
GROUP: 4-F								
7640	4.6	6.93	16.2	43.8	63.2	23.4	37.0	1270
7642	11.8	6.51	15.3	42.6	65.4	23.5	35.9	1038
7644	3.1	6.37	14.7	40.1	63.0	23.1	36.7	1413
7646	9.1	6.42	15.1	40.1	62.4	23.5	37.7	1291
7648	9.4	7.17	15.9	44.4	61.9	22.2	35.8	1404
7650	9.2	6.37	14.3	38.0	59.6	22.4	37.6	1124
7652	6.9	6.65	14.6	39.0	58.7	22.0	37.4	1098
7654	10.1	6.52	14.4	39.0	59.8	22.1	36.9	947
7656	11.6	7.03	15.5	42.0	59.7	22.0	36.9	977
7658	11.7	6.67	15.7	41.8	62.7	23.5	37.6	1112
7660	--	--	--	--	--	--	--	--
7662	--	--	--	--	--	--	--	--
7664	--	--	--	--	--	--	--	--
7666	--	--	--	--	--	--	--	--
7668	--	--	--	--	--	--	--	--
MEAN	8.8	6.66	15.2	41.1	61.6	22.8	37.0	1167
SD	3.00	0.286	0.66	2.16	2.11	0.68	0.68	167.8
N	10	10	10	10	10	10	10	10

(--) - Data Unavailable

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Study Report for Hematology

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: TERMINALSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

Animal ID	PT seconds	APTT seconds	NRBC COUNT	Lymphocyte THSN/CU MM	Segmented THSN/CU MM	Bands THSN/CU MM	Monocytes THSN/CU MM	Eosinophil THSN/CU MM
GROUP: 1-F								
7570	--	--	0	7.7	0.6	0.0	0.4	0.2
7572	--	--	0	9.0	0.7	0.0	0.2	0.0
7574	14.8	39.0	0	3.0	0.4	0.0	0.0	0.0
7576	18.1	47.4	0	5.8	1.1	0.0	0.2	0.0
7578	12.6	25.3	0	4.5	0.4	0.0	0.1	0.1
7580	13.3	23.9	0	14.0	0.3	0.0	0.5	0.5
7582	--	--	0	9.5	0.5	0.0	0.1	0.1
7584	15.4	33.3	0	14.3	0.3	0.0	0.0	0.3
7586	13.3	27.9	0	12.2	1.5	0.0	0.3	0.0
7588	13.0	24.2	0	3.7	0.2	0.0	0.0	0.0
7590	--	--	--	--	--	--	--	--
7592	--	--	--	--	--	--	--	--
7594	--	--	--	--	--	--	--	--
7596	--	--	--	--	--	--	--	--
7598	--	--	--	--	--	--	--	--
MEAN	14.4	31.6	0	8.4	0.6	0.0	0.2	0.1
SD	1.93	8.89	0.0	4.16	0.41	0.00	0.18	0.17
N	7	7	10	10	10	10	10	10
GROUP: 2-F								
7600	13.8	30.9	0	9.9	0.8	0.0	0.1	0.1
7602	19.4	46.4	0	7.6	0.9	0.0	0.3	0.0
7604	13.6	30.9	0	7.6	0.5	0.0	0.2	0.1
7606	14.5	25.9	0	6.6	0.5	0.0	0.0	0.1
7608	13.3	20.6	0	7.9	0.3	0.0	0.0	0.0
7610	14.0	30.2	0	15.7	1.2	0.0	0.3	0.0
7612	17.2	34.5	0	10.1	1.0	0.0	0.1	0.1
7614	14.4	30.9	CL	--	--	--	--	--
7616	15.6	42.3	0	13.3	0.4	0.0	0.1	0.3
7618	13.3	25.4	0	12.6	1.5	0.1	0.1	0.3
MEAN	14.9	31.8	0	10.1	0.8	0.0	0.1	0.1
SD	1.98	7.72	0.0	3.11	0.40	0.03	0.11	0.12
N	10	10	9	9	9	9	9	9

(--) - Data Unavailable

CL - Clotted

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Study Report for Hematology

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: TERMINALSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

Animal ID	PT seconds	APTT seconds	NRBC COUNT	Lymphocyte THSN/CU MM	Segmented THSN/CU MM	Bands THSN/CU MM	Monocytes THSN/CU MM	Eosinophil THSN/CU MM
GROUP: 3-F								
7620	14.6	30.6	0	6.9	0.6	0.0	0.0	0.1
7622	14.1	27.9	0	3.4	0.4	0.0	0.0	0.0
7624	14.1	24.0	0	5.4	1.0	0.0	0.0	0.0
7626	17.5	39.0	0	9.6	0.8	0.0	0.0	0.1
7628	12.5	21.1	0	4.1	0.7	0.0	0.0	0.0
7630	14.9	27.9	0	8.1	2.3	0.0	0.0	0.1
7632	14.3	19.0	0	8.8	0.9	0.0	0.0	0.0
7634	14.9	32.4	0	5.0	0.3	0.0	0.1	0.0
7636	13.6	22.5	0	3.1	0.2	0.0	0.0	0.0
7638	13.9	24.0	0	10.1	1.3	0.0	0.0	0.0
MEAN	14.4	26.8	0	6.4	0.9	0.0	0.0	0.0
SD	1.28	6.01	0.0	2.60	0.61	0.00	0.03	0.05
N	10	10	10	10	10	10	10	10
GROUP: 4-F								
7640	14.3	26.6	0	4.4	0.2	0.0	0.0	0.0
7642	15.4	27.9	0	11.2	0.5	0.0	0.0	0.1
7644	14.1	28.5	0	2.5	0.5	0.0	0.0	0.0
7646	17.5	24.1	0	7.4	1.4	0.0	0.1	0.3
7648	17.3	39.8	0	8.4	0.9	0.0	0.0	0.1
7650	15.2	22.5	1	7.5	1.4	0.0	0.2	0.1
7652	13.9	22.5	0	5.6	1.2	0.0	0.0	0.0
7654	16.0	25.2	0	8.4	1.4	0.0	0.0	0.3
7656	18.9	48.7	0	10.9	0.3	0.0	0.3	0.0
7658	12.9	23.4	0	10.5	0.8	0.0	0.2	0.1
7660	--	--	--	--	--	--	--	--
7662	--	--	--	--	--	--	--	--
7664	--	--	--	--	--	--	--	--
7666	--	--	--	--	--	--	--	--
7668	--	--	--	--	--	--	--	--
MEAN	15.6	28.9	0	7.7	0.9	0.0	0.1	0.1
SD	1.88	8.60	0.3	2.86	0.47	0.00	0.11	0.12
N	10	10	10	10	10	10	10	10

(--) - Data Unavailable

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APPENDIX 9

Study Report for Hematology

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: TERMINALSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

Animal ID	Basophils THSN/CU MM	Abnormal L THSN/CU MM	Other THSN/CU MM
GROUP: 1-F			
7570	0.0	0.0	0.0
7572	0.0	0.0	0.0
7574	0.0	0.0	0.0
7576	0.0	0.0	0.0
7578	0.0	0.0	0.0
7580	0.0	0.0	0.0
7582	0.0	0.0	0.0
7584	0.0	0.0	0.0
7586	0.0	0.0	0.0
7588	0.0	0.0	0.0
7590	--	--	--
7592	--	--	--
7594	--	--	--
7596	--	--	--
7598	--	--	--
MEAN	0.0	0.0	0.0
SD	0.00	0.00	0.00
N	10	10	10
GROUP: 2-F			
7600	0.0	0.0	0.0
7602	0.0	0.0	0.0
7604	0.0	0.0	0.0
7606	0.0	0.0	0.0
7608	0.0	0.0	0.0
7610	0.0	0.0	0.0
7612	0.0	0.0	0.0
7614	--	--	--
7616	0.0	0.0	0.0
7618	0.0	0.0	0.0
MEAN	0.0	0.0	0.0
SD	0.00	0.00	0.00
N	9	9	9

(--) - Data Unavailable

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Study Report for Hematology

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: TERMINALSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

Animal ID	Basophils THSN/CU MM	Abnormal L THSN/CU MM	Other THSN/CU MM
GROUP: 3-F			
7620	0.0	0.0	0.0
7622	0.0	0.0	0.0
7624	0.0	0.0	0.0
7626	0.0	0.0	0.0
7628	0.0	0.0	0.0
7630	0.0	0.1	0.0
7632	0.0	0.0	0.0
7634	0.0	0.0	0.0
7636	0.0	0.0	0.0
7638	0.0	0.0	0.0
MEAN	0.0	0.0	0.0
SD	0.00	0.03	0.00
N	10	10	10
GROUP: 4-F			
7640	0.0	0.0	0.0
7642	0.0	0.0	0.0
7644	0.0	0.0	0.0
7646	0.0	0.0	0.0
7648	0.0	0.0	0.0
7650	0.0	0.0	0.0
7652	0.0	0.1	0.0
7654	0.0	0.0	0.0
7656	0.0	0.0	0.0
7658	0.0	0.0	0.0
7660	--	--	--
7662	--	--	--
7664	--	--	--
7666	--	--	--
7668	--	--	--
MEAN	0.0	0.0	0.0
SD	0.00	0.03	0.00
N	10	10	10

(--) - Data Unavailable

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Study Report for Hematology

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

Animal ID	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	PLT
	THSN/CU MM	MILL/CU MM	GRAMS/DL	%	CU MICRONS	PICO GRAMS	%	THSN/CU MM
GROUP: 1-F								
7570	e	e	e	e	e	e	e	e
7572	e	e	e	e	e	e	e	e
7574	e	e	e	e	e	e	e	e
7576	e	e	e	e	e	e	e	e
7578	e	e	e	e	e	e	e	e
7580	e	e	e	e	e	e	e	e
7582	e	e	e	e	e	e	e	e
7584	e	e	e	e	e	e	e	e
7586	e	e	e	e	e	e	e	e
7588	e	e	e	e	e	e	e	e
7590	10.1	6.79	15.1	41.4	60.9	22.2	36.5	1350
7592	10.0	7.46	15.0	41.6	55.7	20.1	36.1	1349
7594	7.1	7.33	14.9	41.6	56.8	20.3	35.8	1106
7596	12.8	7.41	16.3	44.7	60.3	22.0	36.5	1330
7598	8.7	6.74	14.4	39.0	57.9	21.4	36.9	1059
MEAN	9.7	7.15	15.1	41.7	58.3	21.2	36.4	1239
SD	2.10	0.351	0.70	2.02	2.23	0.96	0.42	143.9
N	5	5	5	5	5	5	5	5

e - Terminal Sacrifice

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Study Report for Hematology

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

Animal ID	WBC THSN/CU MM	RBC MILL/CU MM	HGB GRAMS/DL	HCT %	MCV CU MICRONS	MCH PICO GRAMS	MCHC %	PLT THSN/CU MM
GROUP: 4-F								
7640	e	e	e	e	e	e	e	e
7642	e	e	e	e	e	e	e	e
7644	e	e	e	e	e	e	e	e
7646	e	e	e	e	e	e	e	e
7648	e	e	e	e	e	e	e	e
7650	e	e	e	e	e	e	e	e
7652	e	e	e	e	e	e	e	e
7654	e	e	e	e	e	e	e	e
7656	e	e	e	e	e	e	e	e
7658	e	e	e	e	e	e	e	e
7660	6.0	7.50	17.0	46.1	61.5	22.7	36.9	968
7662	5.4	6.08	14.2	37.5	61.6	23.4	37.9	801
7664	16.1	6.88	15.1	40.6	59.0	21.9	37.2	967
7666	6.9	7.15	14.7	40.5	56.6	20.6	36.3	1212
7668	8.5	6.86	13.8	38.4	56.0	20.1	35.9	1024
MEAN	8.6	6.89	15.0	40.6	58.9	21.7	36.8	994
SD	4.36	0.524	1.24	3.34	2.63	1.39	0.78	147.5
N	5	5	5	5	5	5	5	5

e - Terminal Sacrifice

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Study Report for Hematology

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

Animal ID	PT seconds	APTT seconds	NRBC COUNT	Lymphocyte THSN/CU MM	Segmented THSN/CU MM	Bands THSN/CU MM	Monocytes THSN/CU MM	Eosinophil THSN/CU MM
GROUP: 1-F								
7570	e	e	e	e	e	e	e	e
7572	e	e	e	e	e	e	e	e
7574	e	e	e	e	e	e	e	e
7576	e	e	e	e	e	e	e	e
7578	e	e	e	e	e	e	e	e
7580	e	e	e	e	e	e	e	e
7582	e	e	e	e	e	e	e	e
7584	e	e	e	e	e	e	e	e
7586	e	e	e	e	e	e	e	e
7588	e	e	e	e	e	e	e	e
7590	12.4	17.8	0	9.5	0.6	0.0	0.0	0.0
7592	13.0	19.9	0	8.7	1.2	0.0	0.1	0.0
7594	12.1	18.1	0	6.5	0.6	0.0	0.0	0.0
7596	11.8	18.6	0	11.8	1.0	0.0	0.0	0.0
7598	12.2	18.3	0	7.9	0.8	0.0	0.0	0.0
MEAN	12.3	18.5	0	8.9	0.8	0.0	0.0	0.0
SD	0.45	0.81	0.0	1.97	0.26	0.00	0.04	0.00
N	5	5	5	5	5	5	5	5

e - Terminal Sacrifice

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Study Report for Hematology

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

Animal ID	PT seconds	APTT seconds	NRBC COUNT	Lymphocyte THSN/CU MM	Segmented THSN/CU MM	Bands THSN/CU MM	Monocytes THSN/CU MM	Eosinophil THSN/CU MM
GROUP: 4-F								
7640	e	e	e	e	e	e	e	e
7642	e	e	e	e	e	e	e	e
7644	e	e	e	e	e	e	e	e
7646	e	e	e	e	e	e	e	e
7648	e	e	e	e	e	e	e	e
7650	e	e	e	e	e	e	e	e
7652	e	e	e	e	e	e	e	e
7654	e	e	e	e	e	e	e	e
7656	e	e	e	e	e	e	e	e
7658	e	e	e	e	e	e	e	e
7660	12.7	21.0	0	5.6	0.3	0.0	0.1	0.0
7662	13.2	23.6	0	4.6	0.8	0.0	0.0	0.0
7664	12.9	19.6	0	14.8	1.1	0.0	0.2	0.0
7666	12.7	19.8	0	5.2	1.7	0.0	0.0	0.0
7668	12.8	21.2	0	7.5	1.0	0.0	0.0	0.0
MEAN	12.9	21.0	0	7.5	1.0	0.0	0.1	0.0
SD	0.21	1.60	0.0	4.20	0.51	0.00	0.09	0.00
N	5	5	5	5	5	5	5	5

e - Terminal Sacrifice

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Study Report for Hematology

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

Animal ID	Basophils THSN/CU MM	Abnormal L THSN/CU MM	Other THSN/CU MM
GROUP: 1-F			
7570	e	e	e
7572	e	e	e
7574	e	e	e
7576	e	e	e
7578	e	e	e
7580	e	e	e
7582	e	e	e
7584	e	e	e
7586	e	e	e
7588	e	e	e
7590	0.0	0.0	0.0
7592	0.0	0.0	0.0
7594	0.0	0.0	0.0
7596	0.0	0.0	0.0
7598	0.0	0.0	0.0
MEAN	0.0	0.0	0.0
SD	0.00	0.00	0.00
N	5	5	5

e - Terminal Sacrifice

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Study Report for Hematology

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

Animal ID	Basophils THSN/CU MM	Abnormal L THSN/CU MM	Other THSN/CU MM
GROUP: 4-F			
7640	e	e	e
7642	e	e	e
7644	e	e	e
7646	e	e	e
7648	e	e	e
7650	e	e	e
7652	e	e	e
7654	e	e	e
7656	e	e	e
7658	e	e	e
7660	0.0	0.0	0.0
7662	0.0	0.0	0.0
7664	0.0	0.0	0.0
7666	0.0	0.0	0.0
7668	0.0	0.0	0.0
MEAN	0.0	0.0	0.0
SD	0.00	0.00	0.00
N	5	5	5

e - Terminal Sacrifice

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Study Report for Hematology

WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 1-M

SEX: MALE

Animal ID		TERMINAL	
		CNT	ABS
7569	Nucleated Red Cells	0	
	Lymphocytes	94	7.1
	Segmented Neutrophils	5	0.4
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	1	0.1
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		7.5
7571	Nucleated Red Cells	0	
	Lymphocytes	93	5.0
	Segmented Neutrophils	6	0.3
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	1	0.1
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		5.4
7573	Nucleated Red Cells	0	
	Lymphocytes	96	10.3
	Segmented Neutrophils	2	0.2
	Bands	0	0.0
	Monocytes	2	0.2
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		10.7

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Study Report for Hematology

WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

GROUP: 1-M

SEX: MALE

Animal ID		TERMINAL	
		CNT	ABS
7575	Nucleated Red Cells	0	
	Lymphocytes	90	18.5
	Segmented Neutrophils	8	1.6
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	2	0.4
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		20.6
7577	Nucleated Red Cells	0	
	Lymphocytes	93	7.1
	Segmented Neutrophils	7	0.5
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		7.6
7579	Nucleated Red Cells	0	
	Lymphocytes	92	11.8
	Segmented Neutrophils	7	0.9
	Bands	0	0.0
	Monocytes	1	0.1
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		12.8

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Study Report for Hematology

WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 1-M

SEX: MALE

Animal ID		TERMINAL	
		CNT	ABS
7581	Nucleated Red Cells	0	
	Lymphocytes	91	11.4
	Segmented Neutrophils	9	1.1
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		12.5
7583	Nucleated Red Cells	0	
	Lymphocytes	91	7.2
	Segmented Neutrophils	5	0.4
	Bands	1	0.1
	Monocytes	0	0.0
	Eosinophils	3	0.2
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		7.9
7585	Nucleated Red Cells	0	
	Lymphocytes	90	7.3
	Segmented Neutrophils	9	0.7
	Bands	0	0.0
	Monocytes	1	0.1
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		8.1

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Study Report for Hematology

WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 1-M

SEX: MALE

Animal ID		TERMINAL	
		CNT	ABS
7587	Nucleated Red Cells	1	
	Lymphocytes	93	6.4
	Segmented Neutrophils	6	0.4
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	1	0.1
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		6.9
7589	Nucleated Red Cells	0	
	Lymphocytes	0	--
	Segmented Neutrophils	0	--
	Bands	0	--
	Monocytes	0	--
	Eosinophils	0	--
	Basophils	0	--
	Abnormal Lymphocytes	0	--
	Other	0	--
	WBC		--
7591	Nucleated Red Cells	0	
	Lymphocytes	0	--
	Segmented Neutrophils	0	--
	Bands	0	--
	Monocytes	0	--
	Eosinophils	0	--
	Basophils	0	--
	Abnormal Lymphocytes	0	--
	Other	0	--
	WBC		--

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Study Report for Hematology

WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 1-M

SEX: MALE

Animal ID		TERMINAL	
		CNT	ABS
7593	Nucleated Red Cells	0	
	Lymphocytes	0	--
	Segmented Neutrophils	0	--
	Bands	0	--
	Monocytes	0	--
	Eosinophils	0	--
	Basophils	0	--
	Abnormal Lymphocytes	0	--
	Other	0	--
	WBC		--
7595	Nucleated Red Cells	0	
	Lymphocytes	0	--
	Segmented Neutrophils	0	--
	Bands	0	--
	Monocytes	0	--
	Eosinophils	0	--
	Basophils	0	--
	Abnormal Lymphocytes	0	--
	Other	0	--
	WBC		--
7597	Nucleated Red Cells	0	
	Lymphocytes	0	--
	Segmented Neutrophils	0	--
	Bands	0	--
	Monocytes	0	--
	Eosinophils	0	--
	Basophils	0	--
	Abnormal Lymphocytes	0	--
	Other	0	--
	WBC		--

(--) - Data Unavailable

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Study Report for Hematology

WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 2-M

SEX: MALE

Animal ID		TERMINAL	
		CNT	ABS
7599	Nucleated Red Cells	0	
	Lymphocytes	88	9.5
	Segmented Neutrophils	11	1.2
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	1	0.1
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		10.8
7601	Nucleated Red Cells	0	
	Lymphocytes	83	9.6
	Segmented Neutrophils	16	1.9
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	1	0.1
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		11.6
7603	Nucleated Red Cells	0	
	Lymphocytes	85	11.8
	Segmented Neutrophils	15	2.1
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		13.9

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Study Report for Hematology

WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 2-M

SEX: MALE

Animal ID		TERMINAL	
		CNT	ABS
7605	Nucleated Red Cells	0	
	Lymphocytes	89	15.6
	Segmented Neutrophils	10	1.8
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	1	0.2
	Other	0	0.0
	WBC		17.5
7607	Nucleated Red Cells	0	
	Lymphocytes	90	12.9
	Segmented Neutrophils	10	1.4
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		14.3
7609	Nucleated Red Cells	0	
	Lymphocytes	83	9.8
	Segmented Neutrophils	16	1.9
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	1	0.1
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		11.8

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Study Report for Hematology

WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 2-M

SEX: MALE

Animal ID		TERMINAL	
		CNT	ABS
7611	Nucleated Red Cells	0	
	Lymphocytes	80	6.6
	Segmented Neutrophils	19	1.6
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	1	0.1
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		8.3
7613	Nucleated Red Cells	0	
	Lymphocytes	88	9.8
	Segmented Neutrophils	12	1.3
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		11.1
7615	Nucleated Red Cells	0	
	Lymphocytes	92	7.1
	Segmented Neutrophils	7	0.5
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	1	0.1
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		7.7

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Study Report for Hematology

WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 2-M

SEX: MALE

Animal ID		TERMINAL	
		CNT	ABS
7617	Nucleated Red Cells	0	
	Lymphocytes	84	12.3
	Segmented Neutrophils	14	2.0
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	2	0.3
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		14.6

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Study Report for Hematology

WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 3-M

SEX: MALE

Animal ID		TERMINAL	
		CNT	ABS
7619	Nucleated Red Cells	0	
	Lymphocytes	90	8.1
	Segmented Neutrophils	10	0.9
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		9.0
7621	Nucleated Red Cells	0	
	Lymphocytes	95	9.5
	Segmented Neutrophils	5	0.5
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		10.0
7623	Nucleated Red Cells	0	
	Lymphocytes	93	8.0
	Segmented Neutrophils	7	0.6
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		8.6

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Study Report for Hematology

WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 3-M

SEX: MALE

Animal ID		TERMINAL	
		CNT	ABS
7625	Nucleated Red Cells	0	
	Lymphocytes	90	9.8
	Segmented Neutrophils	10	1.1
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		10.9
7627	Nucleated Red Cells	0	
	Lymphocytes	85	12.1
	Segmented Neutrophils	13	1.8
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	2	0.3
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		14.2
7629	Nucleated Red Cells	0	
	Lymphocytes	71	6.5
	Segmented Neutrophils	29	2.6
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		9.1

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Study Report for Hematology

WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 3-M

SEX: MALE

Animal ID		TERMINAL	
		CNT	ABS
7631	Nucleated Red Cells	0	
	Lymphocytes	88	12.7
	Segmented Neutrophils	11	1.6
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	1	0.1
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		14.4
7633	Nucleated Red Cells	0	
	Lymphocytes	96	13.9
	Segmented Neutrophils	2	0.3
	Bands	0	0.0
	Monocytes	1	0.1
	Eosinophils	1	0.1
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		14.5
7635	Nucleated Red Cells	0	
	Lymphocytes	93	6.5
	Segmented Neutrophils	7	0.5
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		7.0

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Study Report for Hematology

WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 3-M

SEX: MALE

Animal ID		TERMINAL	
		CNT	ABS
7637	Nucleated Red Cells	0	
	Lymphocytes	93	6.1
	Segmented Neutrophils	6	0.4
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	1	0.1
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		6.6

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Study Report for Hematology

WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 4-M

SEX: MALE

Animal ID		TERMINAL	
		CNT	ABS
7639	Nucleated Red Cells	0	
	Lymphocytes	85	8.5
	Segmented Neutrophils	15	1.5
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		10.0
7641	Nucleated Red Cells	0	
	Lymphocytes	91	11.2
	Segmented Neutrophils	7	0.9
	Bands	0	0.0
	Monocytes	2	0.2
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		12.3
7643	Nucleated Red Cells	0	
	Lymphocytes	95	7.8
	Segmented Neutrophils	5	0.4
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		8.2

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WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT		GROUP: 4-M		SEX: MALE	
STUDY NO: 132-007					
Animal ID		TERMINAL			
		CNT	ABS		
7645	Nucleated Red Cells	0			
	Lymphocytes	85	9.8		
	Segmented Neutrophils	12	1.4		
	Bands	0	0.0		
	Monocytes	3	0.3		
	Eosinophils	0	0.0		
	Basophils	0	0.0		
	Abnormal Lymphocytes	0	0.0		
	Other	0	0.0		
	WBC		11.5		
7647	Nucleated Red Cells	0			
	Lymphocytes	85	5.8		
	Segmented Neutrophils	11	0.7		
	Bands	0	0.0		
	Monocytes	2	0.1		
	Eosinophils	2	0.1		
	Basophils	0	0.0		
	Abnormal Lymphocytes	0	0.0		
	Other	0	0.0		
	WBC		6.8		
7649	Nucleated Red Cells	0			
	Lymphocytes	89	6.9		
	Segmented Neutrophils	10	0.8		
	Bands	0	0.0		
	Monocytes	1	0.1		
	Eosinophils	0	0.0		
	Basophils	0	0.0		
	Abnormal Lymphocytes	0	0.0		
	Other	0	0.0		
	WBC		7.8		

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WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 4-M

SEX: MALE

Animal ID		TERMINAL	
		CNT	ABS
7651	Nucleated Red Cells	0	
	Lymphocytes	90	8.7
	Segmented Neutrophils	7	0.7
	Bands	0	0.0
	Monocytes	1	0.1
	Eosinophils	2	0.2
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		9.7
7653	Nucleated Red Cells	0	
	Lymphocytes	84	6.6
	Segmented Neutrophils	14	1.1
	Bands	0	0.0
	Monocytes	2	0.2
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		7.9
7655	Nucleated Red Cells	0	
	Lymphocytes	95	11.4
	Segmented Neutrophils	4	0.5
	Bands	0	0.0
	Monocytes	1	0.1
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		12.0

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WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 4-M

SEX: MALE

Animal ID		TERMINAL	
		CNT	ABS
7657	Nucleated Red Cells	0	
	Lymphocytes	88	8.0
	Segmented Neutrophils	9	0.8
	Bands	0	0.0
	Monocytes	2	0.2
	Eosinophils	1	0.1
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		9.1
7659	Nucleated Red Cells	0	
	Lymphocytes	0	--
	Segmented Neutrophils	0	--
	Bands	0	--
	Monocytes	0	--
	Eosinophils	0	--
	Basophils	0	--
	Abnormal Lymphocytes	0	--
	Other	0	--
	WBC		--
7661	Nucleated Red Cells	0	
	Lymphocytes	0	--
	Segmented Neutrophils	0	--
	Bands	0	--
	Monocytes	0	--
	Eosinophils	0	--
	Basophils	0	--
	Abnormal Lymphocytes	0	--
	Other	0	--
	WBC		--

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STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 4-M

SEX: MALE

Animal ID		TERMINAL	
		CNT	ABS
7663	Nucleated Red Cells	0	
	Lymphocytes	0	--
	Segmented Neutrophils	0	--
	Bands	0	--
	Monocytes	0	--
	Eosinophils	0	--
	Basophils	0	--
	Abnormal Lymphocytes	0	--
	Other	0	--
	WBC		--
7665	Nucleated Red Cells	0	
	Lymphocytes	0	--
	Segmented Neutrophils	0	--
	Bands	0	--
	Monocytes	0	--
	Eosinophils	0	--
	Basophils	0	--
	Abnormal Lymphocytes	0	--
	Other	0	--
	WBC		--
7667	Nucleated Red Cells	0	
	Lymphocytes	0	--
	Segmented Neutrophils	0	--
	Bands	0	--
	Monocytes	0	--
	Eosinophils	0	--
	Basophils	0	--
	Abnormal Lymphocytes	0	--
	Other	0	--
	WBC		--

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WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 1-F

SEX: FEMALE

Animal ID		TERMINAL	
		CNT	ABS
7570	Nucleated Red Cells	0	
	Lymphocytes	87	7.7
	Segmented Neutrophils	7	0.6
	Bands	0	0.0
	Monocytes	4	0.4
	Eosinophils	2	0.2
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		8.8
7572	Nucleated Red Cells	0	
	Lymphocytes	91	9.0
	Segmented Neutrophils	7	0.7
	Bands	0	0.0
	Monocytes	2	0.2
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		9.9
7574	Nucleated Red Cells	0	
	Lymphocytes	89	3.0
	Segmented Neutrophils	11	0.4
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		3.4

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Study Report for Hematology

WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 1-F

SEX: FEMALE

Animal ID		TERMINAL	
		CNT	ABS
7576	Nucleated Red Cells	0	
	Lymphocytes	82	5.8
	Segmented Neutrophils	15	1.1
	Bands	0	0.0
	Monocytes	3	0.2
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		7.1
7578	Nucleated Red Cells	0	
	Lymphocytes	89	4.5
	Segmented Neutrophils	8	0.4
	Bands	0	0.0
	Monocytes	2	0.1
	Eosinophils	1	0.1
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		5.1
7580	Nucleated Red Cells	0	
	Lymphocytes	92	14.0
	Segmented Neutrophils	2	0.3
	Bands	0	0.0
	Monocytes	3	0.5
	Eosinophils	3	0.5
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		15.2

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Study Report for Hematology

WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 1-F

SEX: FEMALE

Animal ID		TERMINAL	
		CNT	ABS
7582	Nucleated Red Cells	0	
	Lymphocytes	93	9.5
	Segmented Neutrophils	5	0.5
	Bands	0	0.0
	Monocytes	1	0.1
	Eosinophils	1	0.1
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		10.2
7584	Nucleated Red Cells	0	
	Lymphocytes	96	14.3
	Segmented Neutrophils	2	0.3
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	2	0.3
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		14.9
7586	Nucleated Red Cells	0	
	Lymphocytes	87	12.2
	Segmented Neutrophils	11	1.5
	Bands	0	0.0
	Monocytes	2	0.3
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		14.0

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WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 1-F

SEX: FEMALE

Animal ID		TERMINAL	
		CNT	ABS
7588	Nucleated Red Cells	0	
	Lymphocytes	96	3.7
	Segmented Neutrophils	4	0.2
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		3.9
7590	Nucleated Red Cells	0	
	Lymphocytes	0	--
	Segmented Neutrophils	0	--
	Bands	0	--
	Monocytes	0	--
	Eosinophils	0	--
	Basophils	0	--
	Abnormal Lymphocytes	0	--
	Other	0	--
	WBC		--
7592	Nucleated Red Cells	0	
	Lymphocytes	0	--
	Segmented Neutrophils	0	--
	Bands	0	--
	Monocytes	0	--
	Eosinophils	0	--
	Basophils	0	--
	Abnormal Lymphocytes	0	--
	Other	0	--
	WBC		--

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WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 1-F

SEX: FEMALE

Animal ID		TERMINAL	
		CNT	ABS
7594	Nucleated Red Cells	0	
	Lymphocytes	0	--
	Segmented Neutrophils	0	--
	Bands	0	--
	Monocytes	0	--
	Eosinophils	0	--
	Basophils	0	--
	Abnormal Lymphocytes	0	--
	Other	0	--
	WBC		--
7596	Nucleated Red Cells	0	
	Lymphocytes	0	--
	Segmented Neutrophils	0	--
	Bands	0	--
	Monocytes	0	--
	Eosinophils	0	--
	Basophils	0	--
	Abnormal Lymphocytes	0	--
	Other	0	--
	WBC		--
7598	Nucleated Red Cells	0	
	Lymphocytes	0	--
	Segmented Neutrophils	0	--
	Bands	0	--
	Monocytes	0	--
	Eosinophils	0	--
	Basophils	0	--
	Abnormal Lymphocytes	0	--
	Other	0	--
	WBC		--

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Study Report for Hematology

WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 2-F

SEX: FEMALE

Animal ID		TERMINAL	
		CNT	ABS
7600	Nucleated Red Cells	0	
	Lymphocytes	91	9.9
	Segmented Neutrophils	7	0.8
	Bands	0	0.0
	Monocytes	1	0.1
	Eosinophils	1	0.1
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		10.9
7602	Nucleated Red Cells	0	
	Lymphocytes	87	7.6
	Segmented Neutrophils	10	0.9
	Bands	0	0.0
	Monocytes	3	0.3
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		8.7
7604	Nucleated Red Cells	0	
	Lymphocytes	91	7.6
	Segmented Neutrophils	6	0.5
	Bands	0	0.0
	Monocytes	2	0.2
	Eosinophils	1	0.1
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		8.4

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WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 2-F

SEX: FEMALE

Animal ID		TERMINAL	
		CNT	ABS
7606	Nucleated Red Cells	0	
	Lymphocytes	92	6.6
	Segmented Neutrophils	7	0.5
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	1	0.1
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		7.2
7608	Nucleated Red Cells	0	
	Lymphocytes	96	7.9
	Segmented Neutrophils	4	0.3
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		8.2
7610	Nucleated Red Cells	0	
	Lymphocytes	91	15.7
	Segmented Neutrophils	7	1.2
	Bands	0	0.0
	Monocytes	2	0.3
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		17.3

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Study Report for Hematology

WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 2-F

SEX: FEMALE

Animal ID		TERMINAL	
		CNT	ABS
7612	Nucleated Red Cells	0	
	Lymphocytes	89	10.1
	Segmented Neutrophils	9	1.0
	Bands	0	0.0
	Monocytes	1	0.1
	Eosinophils	1	0.1
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		11.3
7614	Nucleated Red Cells	0	
	Lymphocytes	0	--
	Segmented Neutrophils	0	--
	Bands	0	--
	Monocytes	0	--
	Eosinophils	0	--
	Basophils	0	--
	Abnormal Lymphocytes	0	--
	Other	0	--
	WBC		--
7616	Nucleated Red Cells	0	
	Lymphocytes	94	13.3
	Segmented Neutrophils	3	0.4
	Bands	0	0.0
	Monocytes	1	0.1
	Eosinophils	2	0.3
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		14.1

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Study Report for Hematology

WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 2-F

SEX: FEMALE

Animal ID		TERMINAL	
		CNT	ABS
7618	Nucleated Red Cells	0	
	Lymphocytes	86	12.6
	Segmented Neutrophils	10	1.5
	Bands	1	0.1
	Monocytes	1	0.1
	Eosinophils	2	0.3
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		14.6

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Study Report for Hematology

WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 3-F

SEX: FEMALE

Animal ID		TERMINAL	
		CNT	ABS
7620	Nucleated Red Cells	0	
	Lymphocytes	91	6.9
	Segmented Neutrophils	8	0.6
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	1	0.1
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		7.6
7622	Nucleated Red Cells	0	
	Lymphocytes	88	3.4
	Segmented Neutrophils	11	0.4
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	1	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		3.9
7624	Nucleated Red Cells	0	
	Lymphocytes	84	5.4
	Segmented Neutrophils	16	1.0
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		6.4

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WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

GROUP: 3-F

SEX: FEMALE

Animal ID		TERMINAL	
		CNT	ABS
7626	Nucleated Red Cells	0	
	Lymphocytes	91	9.6
	Segmented Neutrophils	8	0.8
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	1	0.1
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		10.6
7628	Nucleated Red Cells	0	
	Lymphocytes	83	4.1
	Segmented Neutrophils	15	0.7
	Bands	0	0.0
	Monocytes	1	0.0
	Eosinophils	1	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		4.9
7630	Nucleated Red Cells	0	
	Lymphocytes	76	8.1
	Segmented Neutrophils	22	2.3
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	1	0.1
	Basophils	0	0.0
	Abnormal Lymphocytes	1	0.1
	Other	0	0.0
	WBC		10.6

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WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 3-F

SEX: FEMALE

Animal ID		TERMINAL	
		CNT	ABS
7632	Nucleated Red Cells	0	
	Lymphocytes	91	8.8
	Segmented Neutrophils	9	0.9
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		9.7
7634	Nucleated Red Cells	0	
	Lymphocytes	93	5.0
	Segmented Neutrophils	5	0.3
	Bands	0	0.0
	Monocytes	2	0.1
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		5.4
7636	Nucleated Red Cells	0	
	Lymphocytes	94	3.1
	Segmented Neutrophils	6	0.2
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		3.3

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Study Report for Hematology

WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 3-F

SEX: FEMALE

Animal ID		TERMINAL	
		CNT	ABS
7638	Nucleated Red Cells	0	
	Lymphocytes	89	10.1
	Segmented Neutrophils	11	1.3
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		11.4

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Study Report for Hematology

WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 4-F

SEX: FEMALE

Animal ID		TERMINAL	
		CNT	ABS
7640	Nucleated Red Cells	0	
	Lymphocytes	95	4.4
	Segmented Neutrophils	4	0.2
	Bands	0	0.0
	Monocytes	1	0.0
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		4.6
7642	Nucleated Red Cells	0	
	Lymphocytes	95	11.2
	Segmented Neutrophils	4	0.5
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	1	0.1
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		11.8
7644	Nucleated Red Cells	0	
	Lymphocytes	82	2.5
	Segmented Neutrophils	16	0.5
	Bands	0	0.0
	Monocytes	1	0.0
	Eosinophils	1	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		3.1

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WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 4-F

SEX: FEMALE

Animal ID		TERMINAL	
		CNT	ABS
7646	Nucleated Red Cells	0	
	Lymphocytes	81	7.4
	Segmented Neutrophils	15	1.4
	Bands	0	0.0
	Monocytes	1	0.1
	Eosinophils	3	0.3
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		9.1
7648	Nucleated Red Cells	0	
	Lymphocytes	89	8.4
	Segmented Neutrophils	10	0.9
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	1	0.1
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		9.4
7650	Nucleated Red Cells	1	
	Lymphocytes	82	7.5
	Segmented Neutrophils	15	1.4
	Bands	0	0.0
	Monocytes	2	0.2
	Eosinophils	1	0.1
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		9.2

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WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 4-F

SEX: FEMALE

Animal ID		TERMINAL	
		CNT	ABS
7652	Nucleated Red Cells	0	
	Lymphocytes	81	5.6
	Segmented Neutrophils	18	1.2
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	1	0.1
	Other	0	0.0
	WBC		6.9
7654	Nucleated Red Cells	0	
	Lymphocytes	83	8.4
	Segmented Neutrophils	14	1.4
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	3	0.3
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		10.1
7656	Nucleated Red Cells	0	
	Lymphocytes	94	10.9
	Segmented Neutrophils	3	0.3
	Bands	0	0.0
	Monocytes	3	0.3
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		11.6

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WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT		GROUP: 4-F		SEX: FEMALE	
STUDY NO: 132-007					
Animal ID		TERMINAL			
		CNT	ABS		
7658	Nucleated Red Cells	0			
	Lymphocytes	90	10.5		
	Segmented Neutrophils	7	0.8		
	Bands	0	0.0		
	Monocytes	2	0.2		
	Eosinophils	1	0.1		
	Basophils	0	0.0		
	Abnormal Lymphocytes	0	0.0		
	Other	0	0.0		
	WBC		11.7		
7660	Nucleated Red Cells	0			
	Lymphocytes	0	--		
	Segmented Neutrophils	0	--		
	Bands	0	--		
	Monocytes	0	--		
	Eosinophils	0	--		
	Basophils	0	--		
	Abnormal Lymphocytes	0	--		
	Other	0	--		
	WBC		--		
7662	Nucleated Red Cells	0			
	Lymphocytes	0	--		
	Segmented Neutrophils	0	--		
	Bands	0	--		
	Monocytes	0	--		
	Eosinophils	0	--		
	Basophils	0	--		
	Abnormal Lymphocytes	0	--		
	Other	0	--		
	WBC		--		

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WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 4-F

SEX: FEMALE

Animal ID		TERMINAL	
		CNT	ABS
7664	Nucleated Red Cells	0	
	Lymphocytes	0	--
	Segmented Neutrophils	0	--
	Bands	0	--
	Monocytes	0	--
	Eosinophils	0	--
	Basophils	0	--
	Abnormal Lymphocytes	0	--
	Other	0	--
	WBC		--
7666	Nucleated Red Cells	0	
	Lymphocytes	0	--
	Segmented Neutrophils	0	--
	Bands	0	--
	Monocytes	0	--
	Eosinophils	0	--
	Basophils	0	--
	Abnormal Lymphocytes	0	--
	Other	0	--
	WBC		--
7668	Nucleated Red Cells	0	
	Lymphocytes	0	--
	Segmented Neutrophils	0	--
	Bands	0	--
	Monocytes	0	--
	Eosinophils	0	--
	Basophils	0	--
	Abnormal Lymphocytes	0	--
	Other	0	--
	WBC		--

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WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 1-M

SEX: MALE

Animal ID		RECOVERY	
		CNT	ABS
7569	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e
7571	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e
7573	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e

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STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 1-M

SEX: MALE

Animal ID		RECOVERY	
		CNT	ABS
7575	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e
7577	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e
7579	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e

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WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

GROUP: 1-M

SEX: MALE

Animal ID		RECOVERY	
		CNT	ABS
7581	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e
7583	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e
7585	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e

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WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 1-M

SEX: MALE

Animal ID		RECOVERY	
		CNT	ABS
7587	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e
7589	Nucleated Red Cells	0	
	Lymphocytes	92	12.0
	Segmented Neutrophils	7	0.9
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	1	0.1
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		13.0
7591	Nucleated Red Cells	0	
	Lymphocytes	95	18.2
	Segmented Neutrophils	5	1.0
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		19.2

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STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 1-M

SEX: MALE

Animal ID		RECOVERY	
		CNT	ABS
7593	Nucleated Red Cells	0	
	Lymphocytes	85	12.1
	Segmented Neutrophils	14	2.0
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	1	0.1
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		14.2
7595	Nucleated Red Cells	0	
	Lymphocytes	83	6.9
	Segmented Neutrophils	16	1.3
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	1	0.1
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		8.3
7597	Nucleated Red Cells	0	
	Lymphocytes	88	10.7
	Segmented Neutrophils	11	1.3
	Bands	0	0.0
	Monocytes	1	0.1
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		12.2

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STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 4-M

SEX: MALE

Animal ID		RECOVERY	
		CNT	ABS
7639	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e
7641	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e
7643	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e

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WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 4-M

SEX: MALE

Animal ID		RECOVERY	
		CNT	ABS
7645	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e
7647	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e
7649	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e

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Study Report for Hematology

WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 4-M

SEX: MALE

Animal ID		RECOVERY	
		CNT	ABS
7651	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e
7653	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e
7655	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e

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WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 4-M

SEX: MALE

Animal ID		RECOVERY	
		CNT	ABS
7657	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e
7659	Nucleated Red Cells	0	
	Lymphocytes	89	10.2
	Segmented Neutrophils	11	1.3
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		11.5
7661	Nucleated Red Cells	0	
	Lymphocytes	92	8.7
	Segmented Neutrophils	7	0.7
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	1	0.1
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		9.5

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Study Report for Hematology

WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 4-M

SEX: MALE

Animal ID		RECOVERY	
		CNT	ABS
7663	Nucleated Red Cells	0	
	Lymphocytes	89	6.2
	Segmented Neutrophils	10	0.7
	Bands	0	0.0
	Monocytes	1	0.1
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		7.0
7665	Nucleated Red Cells	0	
	Lymphocytes	85	10.7
	Segmented Neutrophils	13	1.6
	Bands	0	0.0
	Monocytes	2	0.3
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		12.6
7667	Nucleated Red Cells	0	
	Lymphocytes	88	14.8
	Segmented Neutrophils	11	1.8
	Bands	0	0.0
	Monocytes	1	0.2
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		16.8

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Study Report for Hematology

WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 1-F

SEX: FEMALE

Animal ID		RECOVERY	
		CNT	ABS
7570	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e
7572	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e
7574	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e

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Study Report for Hematology

WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 1-F

SEX: FEMALE

Animal ID		RECOVERY	
		CNT	ABS
7576	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e
7578	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e
7580	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e

(--) - Data Unavailable

e - Terminal Sacrifice

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APPENDIX 9

Study Report for Hematology

WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 1-F

SEX: FEMALE

Animal ID		RECOVERY	
		CNT	ABS
7582	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e
7584	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e
7586	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e

(--) - Data Unavailable

e - Terminal Sacrifice

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Study Report for Hematology

WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 1-F

SEX: FEMALE

Animal ID		RECOVERY	
		CNT	ABS
7588	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e
7590	Nucleated Red Cells	0	
	Lymphocytes	94	9.5
	Segmented Neutrophils	6	0.6
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		10.1
7592	Nucleated Red Cells	0	
	Lymphocytes	87	8.7
	Segmented Neutrophils	12	1.2
	Bands	0	0.0
	Monocytes	1	0.1
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		10.0

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Study Report for Hematology

WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 1-F

SEX: FEMALE

Animal ID		RECOVERY	
		CNT	ABS
7594	Nucleated Red Cells	0	
	Lymphocytes	91	6.5
	Segmented Neutrophils	9	0.6
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		7.1
7596	Nucleated Red Cells	0	
	Lymphocytes	92	11.8
	Segmented Neutrophils	8	1.0
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		12.8
7598	Nucleated Red Cells	0	
	Lymphocytes	91	7.9
	Segmented Neutrophils	9	0.8
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		8.7

(--) - Data Unavailable

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WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 4-F

SEX: FEMALE

Animal ID		RECOVERY	
		CNT	ABS
7640	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e
7642	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e
7644	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e

(--) - Data Unavailable

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Study Report for Hematology

WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

GROUP: 4-F

SEX: FEMALE

Animal ID		RECOVERY	
		CNT	ABS
7646	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e
7648	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e
7650	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e

(--) - Data Unavailable

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Study Report for Hematology

WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 4-F

SEX: FEMALE

Animal ID		RECOVERY	
		CNT	ABS
7652	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e
7654	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e
7656	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e

(--) - Data Unavailable

e - Terminal Sacrifice

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Study Report for Hematology

WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 4-F

SEX: FEMALE

Animal ID		RECOVERY	
		CNT	ABS
7658	Nucleated Red Cells	e	
	Lymphocytes	e	e
	Segmented Neutrophils	e	e
	Bands	e	e
	Monocytes	e	e
	Eosinophils	e	e
	Basophils	e	e
	Abnormal Lymphocytes	e	e
	Other	e	e
	WBC		e
7660	Nucleated Red Cells	0	
	Lymphocytes	94	5.6
	Segmented Neutrophils	5	0.3
	Bands	0	0.0
	Monocytes	1	0.1
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		6.0
7662	Nucleated Red Cells	0	
	Lymphocytes	86	4.6
	Segmented Neutrophils	14	0.8
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		5.4

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Study Report for Hematology

WHITE DIFFERENTIAL DATA

STUDY ID: 28-DAY ORAL DOSE/RAT

STUDY NO: 132-007

GROUP: 4-F

SEX: FEMALE

Animal ID		RECOVERY	
		CNT	ABS
7664	Nucleated Red Cells	0	
	Lymphocytes	92	14.8
	Segmented Neutrophils	7	1.1
	Bands	0	0.0
	Monocytes	1	0.2
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		16.1
7666	Nucleated Red Cells	0	
	Lymphocytes	76	5.2
	Segmented Neutrophils	24	1.7
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		6.9
7668	Nucleated Red Cells	0	
	Lymphocytes	88	7.5
	Segmented Neutrophils	12	1.0
	Bands	0	0.0
	Monocytes	0	0.0
	Eosinophils	0	0.0
	Basophils	0	0.0
	Abnormal Lymphocytes	0	0.0
	Other	0	0.0
	WBC		8.5

APPENDIX 10
INDIVIDUAL CLINICAL CHEMISTRY DATA

KEY TO CLINICAL CHEMISTRY TABLES

<u>ABBREVIATION</u>	<u>TERMINOLOGY</u>	<u>UNITS</u>
ALP	Alkaline Phosphatase	U/L
AST	Aspartate Aminotransferase	U/L
ALT	Alanine Aminotransferase	U/L
CHOL	Cholesterol	mg/dL
GLU	Glucose	mg/dL
BUN	Blood Urea Nitrogen	mg/dL
CREAT	Creatinine	mg/dL
TRIG	Triglycerides	mg/dL
PHOS	Phosphorus (inorganic)	mg/dL
TP	Total Protein	g/dL
ALB	Albumin	g/dL
GLOB	Globulin	g/dL
A/G	Albumin/Globulin Ratio	
CA	Calcium	mg/dL
CL	Chloride	mEq/L or mmol/L
NA	Sodium	mEq/L or mmol/L
K	Potassium	mEq/L or mmol/L
GGT	Gamma-glutamyltransferase	U/L
T-BIL	Total Bilirubin	mg/dL

APPENDIX 10

Study Report for Clinical Chemistry

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: TERMINAL

STUDY ID: 28-DAY ORAL DOSE/RAT								SEX: MALE
STUDY NO: 132-007								
Animal ID	TP g/dL	ALB g/dL	GLU mg/dL	CHOL mg/dL	T-BIL mg/dL	BUN mg/dL	CREAT mg/dL	ALT U/L
GROUP: 1-M								
7569	6.1	4.2	133	43	0.1	21	0.3	40
7571	6.4	4.2	156	76	0.2	20	0.4	39
7573	6.7	4.7	192	45	0.1	19	0.3	30
7575	6.1	4.1	248	58	0.1	19	0.3	41
7577	7.2	4.8	138	50	0.2	19	0.4	30
7579	5.6	4.0	138	76	0.1	15	0.4	43
7581	6.9	4.9	214	63	0.3	17	0.4	37
7583	6.6	4.6	136	60	0.2	17	0.3	28
7585	6.2	4.2	116	67	0.1	19	0.3	33
7587	6.1	4.1	137	107	0.2	13	0.3	27
7589	--	--	--	--	--	--	--	--
7591	--	--	--	--	--	--	--	--
7593	--	--	--	--	--	--	--	--
7595	--	--	--	--	--	--	--	--
7597	--	--	--	--	--	--	--	--
MEAN	6.4	4.4	161	64	0.2	18	0.3	35
SD	0.47	0.33	42.7	18.8	0.07	2.4	0.05	5.9
N	10	10	10	10	10	10	10	10
GROUP: 2-M								
7599	6.1	4.0	249	53	0.1	20	0.3	40
7601	6.2	4.1	159	65	0.1	20	0.3	40
7603	6.3	4.2	159	60	0.1	17	0.3	29
7605	6.5	4.4	249	48	0.1	20	0.4	47
7607	5.9	3.7	192	52	0.1	16	0.4	40
7609	6.6	4.6	128	76	0.2	20	0.4	51
7611	6.3	4.4	155	82	0.3	19	0.4	33
7613	6.0	4.1	137	78	0.2	17	0.3	26
7615	6.1	4.3	138	34	0.2	18	0.4	28
7617	6.0	4.1	122	63	0.2	16	0.3	32
MEAN	6.2	4.2	169	61	0.2	18	0.3	37
SD	0.23	0.25	46.7	15.0	0.07	1.7	0.05	8.4
N	10	10	10	10	10	10	10	10

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Study Report for Clinical Chemistry

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: TERMINALSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: MALE

Animal ID	TP g/dL	ALB g/dL	GLU mg/dL	CHOL mg/dL	T-BIL mg/dL	BUN mg/dL	CREAT mg/dL	ALT U/L
GROUP: 3-M								
7619	6.1	4.0	163	44	0.2	19	0.3	40
7621	6.7	4.4	140	59	0.1	16	0.3	39
7623	6.9	4.5	168	57	0.1	24	0.3	40
7625	6.5	4.2	181	106	0.1	21	0.3	33
7627	6.4	4.1	171	64	0.1	19	0.2	99
7629	6.2	4.1	124	65	0.2	16	0.4	26
7631	6.2	4.4	117	74	0.3	18	0.4	34
7633	6.8	4.8	131	74	0.3	23	0.3	150
7635	6.0	4.3	135	32	0.2	17	0.3	32
7637	5.9	4.3	137	53	0.2	19	0.3	33
MEAN	6.4	4.3	147	63	0.2	19	0.3	53
SD	0.35	0.23	22.1	19.9	0.08	2.7	0.06	40.0
N	10	10	10	10	10	10	10	10
GROUP: 4-M								
7639	7.0	5.0	170	30	0.2	18	0.3	40
7641	6.2	4.1	149	51	0.1	18	0.3	42
7643	6.3	4.1	153	45	0.2	21	0.3	88
7645	6.2	4.3	128	46	0.1	23	0.3	41
7647	6.1	4.3	123	38	0.2	21	0.3	38
7649	6.4	4.6	154	62	0.3	20	0.4	28
7651	6.4	4.6	104	64	0.4	16	0.3	48
7653	6.1	4.2	141	62	0.1	18	0.3	56
7655	6.1	4.5	124	57	0.2	21	0.4	36
7657	5.9	4.3	126	48	0.2	20	0.3	44
7659	--	--	--	--	--	--	--	--
7661	--	--	--	--	--	--	--	--
7663	--	--	--	--	--	--	--	--
7665	--	--	--	--	--	--	--	--
7667	--	--	--	--	--	--	--	--
MEAN	6.3	4.4	137	50	0.2	20	0.3	46
SD	0.30	0.28	19.6	11.2	0.09	2.1	0.04	16.5
N	10	10	10	10	10	10	10	10

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Study Report for Clinical Chemistry

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: TERMINAL

STUDY ID: 28-DAY ORAL DOSE/RAT STUDY NO: 132-007								SEX: MALE
Animal ID	AST U/L	ALP U/L	GGT U/L	CA mg/dL	PHOS mg/dL	TRIG mg/dL	NA mmol/L	K mmol/L
GROUP: 1-M								
7569	107	162	0	11.2	10.8	34	149	7.0
7571	122	175	5	11.7	11.7	54	146	9.1
7573	96	215	0	12.3	11.5	35	146	9.1
7575	119	183	0	11.8	10.6	34	147	6.3
7577	114	238	0	11.4	11.4	34	148	7.6
7579	134	165	1	10.9	10.3	37	146	6.3
7581	135	128	0	12.2	11.5	29	144	9.5
7583	92	121	0	11.0	9.7	23	148	5.8
7585	91	119	0	11.2	10.3	16	141	9.9
7587	85	118	0	10.8	10.6	24	144	6.8
7589	--	--	--	--	--	--	--	--
7591	--	--	--	--	--	--	--	--
7593	--	--	--	--	--	--	--	--
7595	--	--	--	--	--	--	--	--
7597	--	--	--	--	--	--	--	--
MEAN	110	162	1	11.4	10.8	32	146	7.7
SD	18.1	41.9	1.6	0.53	0.66	10.2	2.4	1.52
N	10	10	10	10	10	10	10	10
GROUP: 2-M								
7599	128	132	0	11.7	10.5	74	145	6.3
7601	110	122	7	11.6	11.8	45	144	9.0
7603	97	135	0	11.6	11.0	17	146	8.4
7605	119	162	0	11.9	11.2	23	144	7.8
7607	158	129	0	11.2	10.6	36	144	7.2
7609	97	180	0	11.0	9.8	29	146	6.6
7611	111	160	0	10.9	10.2	33	145	7.6
7613	89	117	0	10.6	8.9	47	148	5.5
7615	108	236	0	10.7	9.8	11	147	5.6
7617	95	148	0	10.7	8.9	27	146	5.6
MEAN	111	152	1	11.2	10.3	34	146	7.0
SD	20.3	35.5	2.2	0.48	0.95	18.0	1.4	1.24
N	10	10	10	10	10	10	10	10

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Study Report for Clinical Chemistry

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: TERMINAL

STUDY ID: 28-DAY ORAL DOSE/RAT STUDY NO: 132-007								SEX: MALE
Animal ID	AST U/L	ALP U/L	GGT U/L	CA mg/dL	PHOS mg/dL	TRIG mg/dL	NA mmol/L	K mmol/L
GROUP: 3-M								
7619	126	114	1	11.3	9.2	26	144	7.0
7621	115	175	0	11.6	9.1	18	148	6.1
7623	123	192	0	12.0	10.2	23	146	7.0
7625	85	127	2	12.0	10.6	28	145	7.4
7627	219	143	0	11.3	10.5	26	145	7.9
7629	92	128	0	10.3	8.6	32	146	5.4
7631	100	130	0	10.8	8.3	36	148	5.7
7633	310	162	0	11.1	9.9	37	149	6.5
7635	105	166	0	10.7	8.7	12	148	5.5
7637	102	164	0	10.5	8.6	14	148	5.7
MEAN	138	150	0	11.2	9.4	25	147	6.4
SD	71.3	25.3	0.7	0.59	0.86	8.6	1.7	0.87
N	10	10	10	10	10	10	10	10
GROUP: 4-M								
7639	128	229	0	12.3	9.6	12	149	6.4
7641	145	147	0	11.3	9.8	28	146	7.4
7643	252	206	0	11.3	10.8	11	144	8.2
7645	121	141	0	10.4	7.9	32	144	4.8
7647	114	184	0	10.6	8.0	13	147	6.0
7649	94	110	0	10.7	9.7	25	146	6.7
7651	143	144	0	11.2	9.2	42	146	6.4
7653	108	193	0	10.8	9.0	30	149	5.2
7655	101	160	0	10.2	8.7	15	147	5.4
7657	128	211	0	10.4	8.2	21	150	5.0
7659	--	--	--	--	--	--	--	--
7661	--	--	--	--	--	--	--	--
7663	--	--	--	--	--	--	--	--
7665	--	--	--	--	--	--	--	--
7667	--	--	--	--	--	--	--	--
MEAN	133	172	0	10.9	9.1	23	147	6.2
SD	44.9	37.8	0.0	0.62	0.92	10.3	2.0	1.10
N	10	10	10	10	10	10	10	10

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Study Report for Clinical Chemistry

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: TERMINALSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: MALE

Animal ID	CL mmol/L	GLOB g/dL	A/G none
GROUP: 1-M			
7569	94	1.9	2.2
7571	93	2.2	1.9
7573	93	2.0	2.3
7575	98	2.0	2.0
7577	95	2.4	2.0
7579	101	1.6	2.5
7581	97	2.0	2.5
7583	97	2.0	2.3
7585	98	2.0	2.1
7587	98	2.0	2.0
7589	--	--	--
7591	--	--	--
7593	--	--	--
7595	--	--	--
7597	--	--	--
MEAN	96	2.0	2.2
SD	2.6	0.20	0.21
N	10	10	10
GROUP: 2-M			
7599	94	2.1	1.9
7601	93	2.1	2.0
7603	96	2.1	2.0
7605	97	2.1	2.1
7607	99	2.2	1.7
7609	101	2.0	2.3
7611	99	1.9	2.3
7613	100	1.9	2.2
7615	100	1.8	2.4
7617	100	1.9	2.2
MEAN	98	2.0	2.1
SD	2.8	0.13	0.21
N	10	10	10

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Study Report for Clinical Chemistry

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: TERMINALSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: MALE

Animal ID	CL mmol/L	GLOB g/dL	A/G none
GROUP: 3-M			
7619	99	2.1	1.9
7621	94	2.3	1.9
7623	96	2.4	1.9
7625	96	2.3	1.8
7627	97	2.3	1.8
7629	100	2.1	2.0
7631	102	1.8	2.4
7633	99	2.0	2.4
7635	101	1.7	2.5
7637	101	1.6	2.7
MEAN	98	2.1	2.1
SD	2.6	0.28	0.33
N	10	10	10
GROUP: 4-M			
7639	96	2.0	2.5
7641	100	2.1	2.0
7643	101	2.2	1.9
7645	103	1.9	2.3
7647	100	1.8	2.4
7649	100	1.8	2.6
7651	99	1.8	2.6
7653	101	1.9	2.2
7655	98	1.6	2.8
7657	100	1.6	2.7
7659	--	--	--
7661	--	--	--
7663	--	--	--
7665	--	--	--
7667	--	--	--
MEAN	100	1.9	2.4
SD	1.9	0.19	0.30
N	10	10	10

(--) - Data Unavailable

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Study Report for Clinical Chemistry

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: RECOVERY

STUDY ID: 28-DAY ORAL DOSE/RAT							SEX: MALE	
STUDY NO: 132-007								
Animal ID	TP g/dL	ALB g/dL	GLU mg/dL	CHOL mg/dL	T-BIL mg/dL	BUN mg/dL	CREAT mg/dL	ALT U/L
GROUP: 1-M								
7569	e	e	e	e	e	e	e	e
7571	e	e	e	e	e	e	e	e
7573	e	e	e	e	e	e	e	e
7575	e	e	e	e	e	e	e	e
7577	e	e	e	e	e	e	e	e
7579	e	e	e	e	e	e	e	e
7581	e	e	e	e	e	e	e	e
7583	e	e	e	e	e	e	e	e
7585	e	e	e	e	e	e	e	e
7587	e	e	e	e	e	e	e	e
7589	6.4	4.1	177	47	0.1	19	0.3	42
7591	6.6	4.6	184	66	0.2	18	0.3	47
7593	7.1	4.5	108	68	0.2	20	0.4	47
7595	6.9	4.6	191	61	0.2	18	0.4	44
7597	6.6	4.1	146	82	0.1	16	0.3	36
MEAN	6.7	4.4	161	65	0.2	18	0.3	43
SD	0.28	0.26	34.3	12.6	0.05	1.5	0.05	4.5
N	5	5	5	5	5	5	5	5

e - Terminal Sacrifice

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Study Report for Clinical Chemistry

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: MALE

Animal ID	TP g/dL	ALB g/dL	GLU mg/dL	CHOL mg/dL	T-BIL mg/dL	BUN mg/dL	CREAT mg/dL	ALT U/L
GROUP: 4-M								
7639	e	e	e	e	e	e	e	e
7641	e	e	e	e	e	e	e	e
7643	e	e	e	e	e	e	e	e
7645	e	e	e	e	e	e	e	e
7647	e	e	e	e	e	e	e	e
7649	e	e	e	e	e	e	e	e
7651	e	e	e	e	e	e	e	e
7653	e	e	e	e	e	e	e	e
7655	e	e	e	e	e	e	e	e
7657	e	e	e	e	e	e	e	e
7659	6.5	4.5	90	65	0.1	17	0.4	51
7661	6.8	4.6	156	76	0.1	17	0.4	46
7663	7.3	5.0	217	112	0.2	18	0.3	55
7665	6.3	4.0	149	59	0.1	15	0.2	41
7667	6.7	4.5	176	63	0.1	18	0.2	42
MEAN	6.7	4.5	158	75	0.1	17	0.3	47
SD	0.38	0.36	46.1	21.6	0.04	1.2	0.10	6.0
N	5	5	5	5	5	5	5	5

e - Terminal Sacrifice

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Study Report for Clinical Chemistry

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: RECOVERY

STUDY ID: 28-DAY ORAL DOSE/RAT							SEX: MALE	
STUDY NO: 132-007								
Animal ID	AST U/L	ALP U/L	GGT U/L	CA mg/dL	PHOS mg/dL	TRIG mg/dL	NA mmol/L	K mmol/L
GROUP: 1-M								
7569	e	e	e	e	e	e	e	e
7571	e	e	e	e	e	e	e	e
7573	e	e	e	e	e	e	e	e
7575	e	e	e	e	e	e	e	e
7577	e	e	e	e	e	e	e	e
7579	e	e	e	e	e	e	e	e
7581	e	e	e	e	e	e	e	e
7583	e	e	e	e	e	e	e	e
7585	e	e	e	e	e	e	e	e
7587	e	e	e	e	e	e	e	e
7589	91	134	5	12.0	10.1	25	146	7.2
7591	159	169	2	12.7	14.3	59	145	8.8
7593	115	161	0	12.3	12.5	36	146	10.4
7595	179	182	2	13.0	14.9	33	143	10.2
7597	81	150	0	11.9	10.6	71	147	6.8
MEAN	125	159	2	12.4	12.5	45	145	8.7
SD	42.6	18.3	2.0	0.47	2.14	19.3	1.5	1.66
N	5	5	5	5	5	5	5	5

e - Terminal Sacrifice

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Study Report for Clinical Chemistry

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: MALE

Animal ID	AST U/L	ALP U/L	GGT U/L	CA mg/dL	PHOS mg/dL	TRIG mg/dL	NA mmol/L	K mmol/L
GROUP: 4-M								
7639	e	e	e	e	e	e	e	e
7641	e	e	e	e	e	e	e	e
7643	e	e	e	e	e	e	e	e
7645	e	e	e	e	e	e	e	e
7647	e	e	e	e	e	e	e	e
7649	e	e	e	e	e	e	e	e
7651	e	e	e	e	e	e	e	e
7653	e	e	e	e	e	e	e	e
7655	e	e	e	e	e	e	e	e
7657	e	e	e	e	e	e	e	e
7659	101	157	1	12.3	12.2	20	145	10.4
7661	110	147	3	12.7	12.7	36	147	8.9
7663	186	178	6	13.5	12.9	121	145	8.8
7665	112	115	1	11.6	10.8	63	148	7.3
7667	96	150	1	12.4	10.2	37	150	6.0
MEAN	121	149	2	12.5	11.8	55	147	8.3
SD	36.9	22.7	2.2	0.69	1.20	39.8	2.1	1.68
N	5	5	5	5	5	5	5	5

e - Terminal Sacrifice

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Study Report for Clinical Chemistry

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: MALE

Animal ID	CL mmol/L	GLOB g/dL	A/G none
GROUP: 1-M			
7569	e	e	e
7571	e	e	e
7573	e	e	e
7575	e	e	e
7577	e	e	e
7579	e	e	e
7581	e	e	e
7583	e	e	e
7585	e	e	e
7587	e	e	e
7589	96	2.3	1.8
7591	97	2.0	2.3
7593	101	2.6	1.7
7595	98	2.3	2.0
7597	99	2.5	1.6
MEAN	98	2.3	1.9
SD	1.9	0.23	0.28
N	5	5	5

e - Terminal Sacrifice

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Study Report for Clinical Chemistry

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: MALE

Animal ID	CL mmol/L	GLOB g/dL	A/G none
GROUP: 4-M			
7639	e	e	e
7641	e	e	e
7643	e	e	e
7645	e	e	e
7647	e	e	e
7649	e	e	e
7651	e	e	e
7653	e	e	e
7655	e	e	e
7657	e	e	e
7659	103	2.0	2.2
7661	100	2.2	2.1
7663	94	2.3	2.2
7665	99	2.3	1.7
7667	98	2.2	2.0
MEAN	99	2.2	2.0
SD	3.3	0.12	0.21
N	5	5	5

e - Terminal Sacrifice

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INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: TERMINALSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

Animal ID	TP g/dL	ALB g/dL	GLU mg/dL	CHOL mg/dL	T-BIL mg/dL	BUN mg/dL	CREAT mg/dL	ALT U/L
GROUP: 1-F								
7570	6.8	4.6	108	53	0.2	21	0.5	37
7572	7.2	4.9	149	75	0.2	17	0.5	36
7574	6.7	4.8	166	79	0.2	24	0.5	40
7576	6.8	5.0	131	78	0.2	20	0.5	34
7578	7.2	5.0	161	97	0.1	19	0.4	44
7580	7.1	5.0	146	82	0.2	16	0.4	81
7582	6.1	4.2	176	67	0.2	22	0.4	43
7584	6.5	4.5	143	58	0.2	20	0.4	45
7586	7.1	4.8	179	68	0.2	21	0.4	45
7588	7.0	5.0	195	72	0.2	14	0.4	25
7590	--	--	--	--	--	--	--	--
7592	--	--	--	--	--	--	--	--
7594	--	--	--	--	--	--	--	--
7596	--	--	--	--	--	--	--	--
7598	--	--	--	--	--	--	--	--
MEAN	6.8	4.8	155	73	0.2	19	0.4	43
SD	0.35	0.27	25.4	12.5	0.03	3.0	0.05	14.7
N	10	10	10	10	10	10	10	10
GROUP: 2-F								
7600	7.2	5.2	107	66	0.2	20	0.4	44
7602	7.0	5.1	98	55	0.3	22	0.4	42
7604	6.8	4.7	128	81	0.1	23	0.5	24
7606	6.8	4.8	126	86	0.2	25	0.4	35
7608	6.6	4.7	159	67	0.2	19	0.4	39
7610	6.8	4.7	171	96	0.2	19	0.5	34
7612	7.0	5.3	200	71	0.2	20	0.4	33
7614	6.9	4.8	197	58	0.2	24	0.4	31
7616	7.3	5.4	220	58	0.2	14	0.4	33
7618	7.0	4.9	129	76	0.2	18	0.4	33
MEAN	6.9	5.0	154	71	0.2	20	0.4	35
SD	0.21	0.27	42.2	13.4	0.05	3.2	0.04	5.7
N	10	10	10	10	10	10	10	10

(--) - Data Unavailable

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Study Report for Clinical Chemistry

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: TERMINALSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

Animal ID	TP g/dL	ALB g/dL	GLU mg/dL	CHOL mg/dL	T-BIL mg/dL	BUN mg/dL	CREAT mg/dL	ALT U/L
GROUP: 3-F								
7620	6.9	4.7	143	66	0.2	19	0.4	36
7622	6.8	4.8	136	67	0.3	22	0.4	30
7624	6.2	3.9	117	64	0.3	20	0.4	31
7626	7.4	5.2	152	61	0.2	23	0.5	34
7628	7.0	4.8	135	88	0.2	21	0.5	41
7630	7.0	4.5	106	79	0.2	23	0.4	37
7632	6.7	4.8	115	60	0.2	21	0.5	35
7634	6.5	4.7	200	40	0.2	24	0.4	46
7636	6.8	4.9	182	44	0.1	21	0.4	35
7638	6.4	4.5	146	48	0.2	18	0.3	50
MEAN	6.8	4.7	143	62	0.2	21	0.4	38
SD	0.34	0.34	29.4	15.0	0.06	1.9	0.06	6.4
N	10	10	10	10	10	10	10	10
GROUP: 4-F								
7640	6.2	4.3	151	68	0.1	23	0.4	42
7642	6.8	4.8	127	63	0.1	21	0.4	37
7644	6.2	4.0	107	96	0.2	24	0.4	36
7646	6.2	4.4	147	77	0.1	18	0.3	37
7648	7.1	5.1	155	63	0.2	15	0.5	35
7650	6.4	4.6	134	66	0.2	23	0.4	34
7652	6.5	4.3	109	85	0.1	22	0.4	36
7654	6.4	4.4	95	52	0.2	21	0.4	38
7656	7.1	5.4	137	89	0.2	22	0.4	36
7658	6.8	4.9	126	68	0.2	18	0.4	30
7660	--	--	--	--	--	--	--	--
7662	--	--	--	--	--	--	--	--
7664	--	--	--	--	--	--	--	--
7666	--	--	--	--	--	--	--	--
7668	--	--	--	--	--	--	--	--
MEAN	6.6	4.6	129	73	0.2	21	0.4	36
SD	0.36	0.43	20.1	13.7	0.05	2.8	0.05	3.0
N	10	10	10	10	10	10	10	10

(--) - Data Unavailable

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Study Report for Clinical Chemistry

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: TERMINALSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

Animal ID	AST U/L	ALP U/L	GGT U/L	CA mg/dL	PHOS mg/dL	TRIG mg/dL	NA mmol/L	K mmol/L
GROUP: 1-F								
7570	116	121	3	12.3	12.1	34	148	6.8
7572	141	77	0	11.7	9.8	51	145	6.3
7574	99	118	2	11.8	9.4	27	146	8.2
7576	123	124	0	11.4	10.0	26	143	9.2
7578	113	88	0	12.0	9.8	36	143	8.8
7580	204	67	0	12.0	10.3	33	142	9.9
7582	103	54	1	11.3	9.8	38	145	7.2
7584	118	66	1	11.4	9.5	35	143	6.8
7586	116	124	1	12.1	9.8	45	145	6.8
7588	104	66	1	12.0	8.2	42	145	7.8
7590	--	--	--	--	--	--	--	--
7592	--	--	--	--	--	--	--	--
7594	--	--	--	--	--	--	--	--
7596	--	--	--	--	--	--	--	--
7598	--	--	--	--	--	--	--	--
MEAN	124	90	1	11.8	9.9	37	144	7.8
SD	30.6	28.3	1.0	0.34	0.96	7.7	1.8	1.21
N	10	10	10	10	10	10	10	10
GROUP: 2-F								
7600	156	96	0	11.7	10.0	20	143	9.0
7602	134	82	0	11.7	11.7	26	144	11.7
7604	74	64	0	11.4	9.7	29	144	7.6
7606	103	108	0	11.9	10.9	39	142	10.6
7608	105	58	0	11.4	9.6	41	144	8.3
7610	95	54	0	11.8	9.9	31	143	8.4
7612	102	110	0	12.2	9.4	44	143	8.7
7614	116	85	1	12.4	10.1	24	144	8.7
7616	125	77	5	12.2	10.5	29	139	10.6
7618	99	58	0	11.8	9.7	26	144	7.3
MEAN	111	79	1	11.9	10.1	31	143	9.1
SD	22.9	20.7	1.6	0.33	0.70	7.9	1.6	1.42
N	10	10	10	10	10	10	10	10

(--) - Data Unavailable

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Study Report for Clinical Chemistry

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: TERMINALSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

Animal ID	AST U/L	ALP U/L	GGT U/L	CA mg/dL	PHOS mg/dL	TRIG mg/dL	NA mmol/L	K mmol/L
GROUP: 3-F								
7620	111	108	0	11.7	11.2	28	145	8.5
7622	116	105	0	11.6	11.3	51	142	8.8
7624	113	93	0	10.9	9.6	40	147	6.6
7626	125	109	0	11.9	9.9	27	146	9.1
7628	134	97	0	11.9	10.7	42	145	8.7
7630	98	102	1	11.3	10.0	36	143	6.6
7632	132	107	1	11.5	11.0	28	144	9.6
7634	91	104	0	11.7	8.9	33	143	8.5
7636	116	97	0	11.4	11.1	22	145	8.8
7638	97	86	0	11.8	11.2	33	145	8.3
MEAN	113	101	0	11.6	10.5	34	144	8.4
SD	14.7	7.4	0.4	0.31	0.83	8.6	1.5	0.99
N	10	10	10	10	10	10	10	10
GROUP: 4-F								
7640	120	83	0	10.8	9.1	45	148	5.7
7642	101	101	0	11.9	10.5	26	145	7.7
7644	110	87	0	10.8	8.0	30	146	6.2
7646	97	85	0	11.6	9.9	54	144	7.3
7648	126	105	1	12.0	8.1	31	147	6.5
7650	97	82	1	11.4	9.4	23	143	6.8
7652	110	66	0	10.9	9.0	34	146	6.7
7654	110	92	0	11.2	10.9	22	144	8.3
7656	96	127	0	12.1	10.8	29	145	8.1
7658	121	74	1	11.7	9.8	30	146	7.1
7660	--	--	--	--	--	--	--	--
7662	--	--	--	--	--	--	--	--
7664	--	--	--	--	--	--	--	--
7666	--	--	--	--	--	--	--	--
7668	--	--	--	--	--	--	--	--
MEAN	109	90	0	11.4	9.6	32	145	7.0
SD	10.9	17.3	0.5	0.50	1.03	9.9	1.5	0.83
N	10	10	10	10	10	10	10	10

(--) - Data Unavailable

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Study Report for Clinical Chemistry

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: TERMINALSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

Animal ID	CL mmol/L	GLOB g/dL	A/G none
GROUP: 1-F			
7570	106	2.2	2.1
7572	105	2.3	2.1
7574	103	1.9	2.5
7576	104	1.8	2.8
7578	102	2.2	2.3
7580	100	2.1	2.4
7582	103	1.9	2.2
7584	103	2.0	2.2
7586	101	2.3	2.1
7588	104	2.0	2.5
7590	--	--	--
7592	--	--	--
7594	--	--	--
7596	--	--	--
7598	--	--	--
MEAN	103	2.1	2.3
SD	1.8	0.18	0.23
N	10	10	10
GROUP: 2-F			
7600	102	2.0	2.6
7602	107	1.9	2.7
7604	101	2.1	2.2
7606	103	2.0	2.4
7608	105	1.9	2.5
7610	98	2.1	2.2
7612	100	1.7	3.1
7614	101	2.1	2.3
7616	102	1.9	2.8
7618	102	2.1	2.3
MEAN	102	2.0	2.5
SD	2.5	0.13	0.29
N	10	10	10

(--) - Data Unavailable

LABCAT CC4.41c

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Study Report for Clinical Chemistry

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: TERMINALSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

Animal ID	CL mmol/L	GLOB g/dL	A/G none
GROUP: 3-F			
7620	102	2.2	2.1
7622	103	2.0	2.4
7624	105	2.3	1.7
7626	104	2.2	2.4
7628	104	2.2	2.2
7630	103	2.5	1.8
7632	105	1.9	2.5
7634	105	1.8	2.6
7636	104	1.9	2.6
7638	100	1.9	2.4
MEAN	104	2.1	2.3
SD	1.6	0.22	0.32
N	10	10	10
GROUP: 4-F			
7640	104	1.9	2.3
7642	105	2.0	2.4
7644	105	2.2	1.8
7646	104	1.8	2.4
7648	103	2.0	2.5
7650	107	1.8	2.6
7652	104	2.2	2.0
7654	105	2.0	2.2
7656	103	1.7	3.2
7658	102	1.9	2.6
7660	--	--	--
7662	--	--	--
7664	--	--	--
7666	--	--	--
7668	--	--	--
MEAN	104	2.0	2.4
SD	1.4	0.16	0.38
N	10	10	10

(--) - Data Unavailable

LABCAT CC4.41c

03-NOV-2000

APPENDIX 10

Study Report for Clinical Chemistry

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

Animal ID	TP g/dL	ALB g/dL	GLU mg/dL	CHOL mg/dL	T-BIL mg/dL	BUN mg/dL	CREAT mg/dL	ALT U/L
GROUP: 1-F								
7570	e	e	e	e	e	e	e	e
7572	e	e	e	e	e	e	e	e
7574	e	e	e	e	e	e	e	e
7576	e	e	e	e	e	e	e	e
7578	e	e	e	e	e	e	e	e
7580	e	e	e	e	e	e	e	e
7582	e	e	e	e	e	e	e	e
7584	e	e	e	e	e	e	e	e
7586	e	e	e	e	e	e	e	e
7588	e	e	e	e	e	e	e	e
7590	7.9	5.2	147	106	0.2	31	0.6	34
7592	7.2	5.2	107	62	0.2	22	0.4	59
7594	7.1	5.3	112	59	0.2	18	0.4	44
7596	7.6	5.8	287	92	0.2	16	0.4	57
7598	6.8	4.9	176	103	0.2	18	0.3	71
MEAN	7.3	5.3	166	84	0.2	21	0.4	53
SD	0.43	0.33	73.3	22.5	0.00	6.0	0.11	14.3
N	5	5	5	5	5	5	5	5

e - Terminal Sacrifice

LABCAT CC4.41c

03-NOV-2000

APPENDIX 10

Study Report for Clinical Chemistry

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

Animal ID	TP g/dL	ALB g/dL	GLU mg/dL	CHOL mg/dL	T-BIL mg/dL	BUN mg/dL	CREAT mg/dL	ALT U/L
GROUP: 4-F								
7640	e	e	e	e	e	e	e	e
7642	e	e	e	e	e	e	e	e
7644	e	e	e	e	e	e	e	e
7646	e	e	e	e	e	e	e	e
7648	e	e	e	e	e	e	e	e
7650	e	e	e	e	e	e	e	e
7652	e	e	e	e	e	e	e	e
7654	e	e	e	e	e	e	e	e
7656	e	e	e	e	e	e	e	e
7658	e	e	e	e	e	e	e	e
7660	7.6	5.6	99	76	0.3	29	0.6	45
7662	7.4	5.4	119	63	0.2	16	0.3	39
7664	6.7	4.7	114	57	0.2	20	0.4	32
7666	7.0	4.8	233	82	0.1	17	0.4	35
7668	6.9	4.9	111	80	0.1	23	0.3	34
MEAN	7.1	5.1	135	72	0.2	21	0.4	37
SD	0.37	0.40	55.2	11.0	0.08	5.2	0.12	5.1
N	5	5	5	5	5	5	5	5

e - Terminal Sacrifice

LABCAT CC4.41c

03-NOV-2000

APPENDIX 10

Study Report for Clinical Chemistry

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

Animal ID	AST U/L	ALP U/L	GGT U/L	CA mg/dL	PHOS mg/dL	TRIG mg/dL	NA mmol/L	K mmol/L
GROUP: 1-F								
7570	e	e	e	e	e	e	e	e
7572	e	e	e	e	e	e	e	e
7574	e	e	e	e	e	e	e	e
7576	e	e	e	e	e	e	e	e
7578	e	e	e	e	e	e	e	e
7580	e	e	e	e	e	e	e	e
7582	e	e	e	e	e	e	e	e
7584	e	e	e	e	e	e	e	e
7586	e	e	e	e	e	e	e	e
7588	e	e	e	e	e	e	e	e
7590	153	83	1	12.9	10.7	48	146	8.1
7592	248	91	2	12.6	12.6	29	142	11.7
7594	170	86	1	12.4	12.5	32	146	9.2
7596	126	88	0	13.1	13.6	52	144	9.0
7598	275	65	0	13.4	12.3	63	144	7.9
MEAN	194	83	1	12.9	12.3	45	144	9.2
SD	63.9	10.3	0.8	0.40	1.05	14.2	1.7	1.52
N	5	5	5	5	5	5	5	5

e - Terminal Sacrifice

LABCAT CC4.41c

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APPENDIX 10

Study Report for Clinical Chemistry

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

Animal ID	AST U/L	ALP U/L	GGT U/L	CA mg/dL	PHOS mg/dL	TRIG mg/dL	NA mmol/L	K mmol/L
GROUP: 4-F								
7640	e	e	e	e	e	e	e	e
7642	e	e	e	e	e	e	e	e
7644	e	e	e	e	e	e	e	e
7646	e	e	e	e	e	e	e	e
7648	e	e	e	e	e	e	e	e
7650	e	e	e	e	e	e	e	e
7652	e	e	e	e	e	e	e	e
7654	e	e	e	e	e	e	e	e
7656	e	e	e	e	e	e	e	e
7658	e	e	e	e	e	e	e	e
7660	295	107	0	13.0	13.3	24	142	10.3
7662	236	74	3	12.4	10.1	28	148	7.5
7664	184	88	1	11.9	9.1	36	146	6.1
7666	106	76	1	12.5	11.6	50	145	7.5
7668	124	63	1	11.6	9.4	23	146	7.5
MEAN	189	82	1	12.3	10.7	32	145	7.8
SD	78.4	16.7	1.1	0.54	1.74	11.2	2.2	1.53
N	5	5	5	5	5	5	5	5

e - Terminal Sacrifice

LABCAT CC4.41c

03-NOV-2000

APPENDIX 10

Study Report for Clinical Chemistry

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

Animal ID	CL mmol/L	GLOB g/dL	A/G none
GROUP: 1-F			
7570	e	e	e
7572	e	e	e
7574	e	e	e
7576	e	e	e
7578	e	e	e
7580	e	e	e
7582	e	e	e
7584	e	e	e
7586	e	e	e
7588	e	e	e
7590	100	2.7	1.9
7592	106	2.0	2.6
7594	105	1.8	2.9
7596	100	1.8	3.2
7598	101	1.9	2.6
MEAN	102	2.0	2.6
SD	2.9	0.38	0.48
N	5	5	5

e - Terminal Sacrifice

LABCAT CC4.41c

03-NOV-2000

APPENDIX 10

Study Report for Clinical Chemistry

INDIVIDUAL ANIMAL REPORT BY GROUP
PERIOD: RECOVERYSTUDY ID: 28-DAY ORAL DOSE/RAT
STUDY NO: 132-007

SEX: FEMALE

Animal ID	CL mmol/L	GL08 g/dL	A/G none
GROUP: 4-F			
7640	e	e	e
7642	e	e	e
7644	e	e	e
7646	e	e	e
7648	e	e	e
7650	e	e	e
7652	e	e	e
7654	e	e	e
7656	e	e	e
7658	e	e	e
7660	103	2.0	2.8
7662	103	2.0	2.7
7664	102	2.0	2.3
7666	105	2.2	2.2
7668	107	2.0	2.5
MEAN	104	2.0	2.5
SD	2.0	0.09	0.25
N	5	5	5

e - Terminal Sacrifice

LABCAT CC4.41c

03-NOV-2000

APPENDIX 11
HISTORICAL CONTROL CLINICAL CHEMISTRY DATA

PRIMEDICA
CLINICAL CHEMISTRY HISTORICAL DATA

Sprague-Dawley Rats

N = 100

PARAMETER	ABBREVIATION	UNITS	HISTORICAL RANGE
Glucose	GLU	mg/dL	111 - 161
Blood Urea Nitrogen	BUN	mg/dL	12 - 18
Creatinine	CREAT	mg/dL	0.2 - 0.4
Sodium	NA or Na	mEq/L or mmol/L	139 - 145
Potassium	K	mEq/L or mmol/L	5.3 - 7.3
Alkaline Phosphatase	ALP	U/L	82 - 134
Aspartate Aminotransferase	AST	U/L	73 - 157
Alanine Aminotransferase	ALT	U/L	21 - 57
Chloride	CL or Cl	mEq/L or mmol/L	94 - 104
Calcium	CA or Ca	mg/dL	10.1 - 11.1
Total Bilirubin	T-BIL	mg/dL	0.1 - 0.3
Albumin	ALB	g/dL	3.9 - 4.7
Phosphorus	PHOS	mg/dL	7.7 - 10.5
Gamma-glutamyltransferase	GGT	U/L	0 - 2
Triglycerides	TRIG	mg/dL	39 - 137
Total Protein	TP	g/dL	6.4 - 7.8
Cholesterol	CHOL	mg/dL	64 - 110

N = 20

PARAMETER	ABBREVIATION	UNITS	HISTORICAL RANGE
Creatine Kinase	CK	U/L	141 - 463
Lactate Dehydrogenase	LDH	U/L	62 - 396

N = Number of Values

Historical data include all animals regardless of blood collection site. Hemolyzed specimens and obvious outliers are not excluded.

**APPENDIX 12
INDIVIDUAL ORGAN WEIGHTS**

APPENDIX 12

INDIVIDUAL ORGAN WEIGHTS

STUDY: T-7485		GROUP: 1-M						
SEX: MALE		FATES: SCHEDULED SACRIFICE			DAYS: 29-29		ALL BALANCES	
ANIMAL ID:	7569	7571	7573	7575	7577	7579	7581	7583
BODY WEIGHT (G)	292.000	368.000	353.000	354.000	313.000	343.000	353.000	335.000
ADRENAL GLANDS (G)	0.064	0.065	0.068	0.063	0.070	0.073	0.069	0.073
% BODY WEIGHT	0.022	0.018	0.019	0.018	0.022	0.021	0.020	0.022
% BRAIN WEIGHT	2.967	3.237	3.335	2.938	3.457	3.838	3.694	3.709
BRAIN (G)	2.157	2.008	2.039	2.144	2.025	1.902	1.868	1.968
% BODY WEIGHT	0.739	0.546	0.578	0.606	0.647	0.555	0.529	0.587
HEART (G)	1.062	1.193	1.317	1.160	1.198	1.265	1.134	1.191
% BODY WEIGHT	0.364	0.324	0.373	0.328	0.383	0.369	0.321	0.356
% BRAIN WEIGHT	49.235	59.412	64.590	54.104	59.160	66.509	60.707	60.518
KIDNEYS (G)	2.715	2.832	3.037	2.651	2.482	2.666	3.062	2.444
% BODY WEIGHT	0.930	0.770	0.860	0.749	0.793	0.777	0.867	0.730
% BRAIN WEIGHT	125.869	141.036	148.946	123.647	122.568	140.168	163.919	124.187
LIVER (G)	8.667	11.220	10.850	9.856	8.705	9.414	10.677	9.384
% BODY WEIGHT	2.968	3.049	3.074	2.784	2.781	2.745	3.025	2.801
% BRAIN WEIGHT	401.808	558.765	532.124	459.702	429.877	494.953	571.574	476.829
SPLEEN (G)	0.565	0.699	0.571	0.764	0.507	0.761	0.631	0.648
% BODY WEIGHT	0.193	0.190	0.162	0.216	0.162	0.222	0.179	0.193
% BRAIN WEIGHT	26.194	34.811	28.004	35.634	25.037	40.011	33.779	32.927
TESTES (G)	3.106	3.501	3.481	3.167	3.066	3.387	3.242	2.771
% BODY WEIGHT	1.064	0.951	0.986	0.895	0.980	0.987	0.918	0.827
% BRAIN WEIGHT	143.996	174.353	170.721	147.715	151.407	178.076	173.555	140.803
THYMUS (G)	0.421	0.480	0.634	0.555	0.437	0.399	0.598	0.479
% BODY WEIGHT	0.144	0.130	0.180	0.157	0.140	0.116	0.169	0.143
% BRAIN WEIGHT	19.518	23.904	31.094	25.886	21.580	20.978	32.013	24.339

PRIMEDICA REDFIELD STUDY NUMBER 132-007

APPENDIX 12

INDIVIDUAL ORGAN WEIGHTS

STUDY: T-7485

SEX: MALE

GROUP: 1-M

FATES: SCHEDULED SACRIFICE

DAYS: 29-29

ALL BALANCES

ANIMAL ID:	7585	7587
BODY WEIGHT (G)	340.000	392.000
ADRENAL GLANDS (G)	0.077	0.062
% BODY WEIGHT	0.023	0.016
% BRAIN WEIGHT	4.085	3.224
BRAIN (G)	1.885	1.923
% BODY WEIGHT	0.554	0.491
HEART (G)	1.303	1.372
% BODY WEIGHT	0.383	0.350
% BRAIN WEIGHT	69.125	71.347
KIDNEYS (G)	2.348	3.276
% BODY WEIGHT	0.691	0.836
% BRAIN WEIGHT	124.562	170.359
LIVER (G)	9.825	11.824
% BODY WEIGHT	2.890	3.016
% BRAIN WEIGHT	521.220	614.873
SPLEEN (G)	0.676	0.695
% BODY WEIGHT	0.199	0.177
% BRAIN WEIGHT	35.862	36.141
TESTES (G)	3.031	3.579
% BODY WEIGHT	0.891	0.913
% BRAIN WEIGHT	160.796	186.115
THYMUS (G)	0.578	0.491
% BODY WEIGHT	0.170	0.125
% BRAIN WEIGHT	30.663	25.533

PRIMEDICA REDFIELD STUDY NUMBER 132-007

APPENDIX 12

INDIVIDUAL ORGAN WEIGHTS

STUDY: T-7485

SEX: MALE

GROUP: 2-M

FATES: SCHEDULED SACRIFICE

DAYS: 29-29

ALL BALANCES

ANIMAL ID:	7599	7601	7603	7605	7607	7609	7611	7613
BODY WEIGHT (G)	331.000	339.000	338.000	334.000	352.000	380.000	359.000	381.000
ADRENAL GLANDS (G)	0.066	0.086	0.085	0.065	0.069	0.071	0.065	0.097
% BODY WEIGHT	0.020	0.025	0.025	0.019	0.020	0.019	0.018	0.025
% BRAIN WEIGHT	3.078	4.157	4.397	3.142	3.384	3.362	3.310	4.395
BRAIN (G)	2.144	2.069	1.933	2.069	2.039	2.112	1.964	2.207
% BODY WEIGHT	0.648	0.610	0.572	0.619	0.579	0.556	0.547	0.579
HEART (G)	1.266	1.263	1.187	1.158	1.441	1.257	1.196	1.237
% BODY WEIGHT	0.382	0.373	0.351	0.347	0.409	0.331	0.333	0.325
% BRAIN WEIGHT	59.049	61.044	61.407	55.969	70.672	59.517	60.896	56.049
KIDNEYS (G)	2.606	2.797	2.714	2.663	2.788	3.140	2.653	3.114
% BODY WEIGHT	0.787	0.825	0.803	0.797	0.792	0.826	0.739	0.817
% BRAIN WEIGHT	121.549	135.186	140.404	128.710	136.734	148.674	135.082	141.097
LIVER (G)	10.553	10.462	9.988	10.373	10.674	11.235	11.223	13.086
% BODY WEIGHT	3.188	3.086	2.955	3.106	3.032	2.957	3.126	3.435
% BRAIN WEIGHT	492.211	505.655	516.710	501.353	523.492	531.960	571.436	592.932
SPLEEN (G)	0.588	0.701	0.748	0.537	0.911	0.674	0.710	0.829
% BODY WEIGHT	0.178	0.207	0.221	0.161	0.259	0.177	0.198	0.218
% BRAIN WEIGHT	27.425	33.881	38.696	25.955	44.679	31.913	36.151	37.562
TESTES (G)	3.203	2.601	2.845	3.416	2.239	2.999	2.894	3.089
% BODY WEIGHT	0.968	0.767	0.842	1.023	0.636	0.789	0.806	0.811
% BRAIN WEIGHT	149.394	125.713	147.181	165.104	109.809	141.998	147.352	139.964
THYMUS (G)	0.447	0.480	0.436	0.451	0.821	0.644	0.484	0.434
% BODY WEIGHT	0.135	0.142	0.129	0.135	0.233	0.169	0.135	0.114
% BRAIN WEIGHT	20.849	23.200	22.556	21.798	40.265	30.492	24.644	19.665

PRIMEDICA REDFIELD STUDY NUMBER 132-007

APPENDIX 12

INDIVIDUAL ORGAN WEIGHTS

STUDY: T-7485

SEX: MALE

GROUP: 2-M

FATES: SCHEDULED SACRIFICE

DAYS: 29-29

ALL BALANCES

ANIMAL ID: 7615 7617

BODY WEIGHT (G) 313.000 362.000

ADRENAL GLANDS (G) 0.063 0.083

% BODY WEIGHT 0.020 0.023

% BRAIN WEIGHT 3.147 4.069

BRAIN (G) 2.002 2.040

% BODY WEIGHT 0.640 0.564

HEART (G) 1.139 1.193

% BODY WEIGHT 0.364 0.330

% BRAIN WEIGHT 56.893 58.480

KIDNEYS (G) 2.451 2.809

% BODY WEIGHT 0.783 0.776

% BRAIN WEIGHT 122.428 137.696

LIVER (G) 7.839 10.552

% BODY WEIGHT 2.504 2.915

% BRAIN WEIGHT 391.558 517.255

SPLEEN (G) 0.622 0.879

% BODY WEIGHT 0.199 0.243

% BRAIN WEIGHT 31.069 43.088

TESTES (G) 3.161 3.009

% BODY WEIGHT 1.010 0.831

% BRAIN WEIGHT 157.892 147.500

THYMUS (G) 0.585 0.534

% BODY WEIGHT 0.187 0.148

% BRAIN WEIGHT 29.221 26.176

PRIMEDICA REDFIELD STUDY NUMBER 132-007

APPENDIX 12

INDIVIDUAL ORGAN WEIGHTS

STUDY: T-7485

SEX: MALE

GROUP: 3-M

FATES: SCHEDULED SACRIFICE

DAYS: 29-29

ALL BALANCES

ANIMAL ID:	7619	7621	7623	7625	7627	7629	7631	7633
BODY WEIGHT (G)	283.000	353.000	319.000	337.000	329.000	384.000	360.000	339.000
ADRENAL GLANDS (G)	0.066	0.057	0.052	0.067	0.059	0.076	0.073	0.074
% BODY WEIGHT	0.023	0.016	0.016	0.020	0.018	0.020	0.020	0.022
% BRAIN WEIGHT	3.275	2.798	2.315	3.575	2.751	3.693	3.661	3.487
BRAIN (G)	2.015	2.037	2.246	1.874	2.145	2.058	1.994	2.122
% BODY WEIGHT	0.712	0.577	0.704	0.556	0.652	0.536	0.554	0.626
HEART (G)	0.915	1.301	1.193	1.190	1.041	1.269	1.198	1.141
% BODY WEIGHT	0.323	0.369	0.374	0.353	0.316	0.330	0.333	0.337
% BRAIN WEIGHT	45.409	63.868	53.117	63.501	48.531	61.662	60.080	53.770
KIDNEYS (G)	2.012	3.589	2.954	2.738	2.909	2.912	2.970	3.126
% BODY WEIGHT	0.711	1.017	0.926	0.812	0.884	0.758	0.825	0.922
% BRAIN WEIGHT	99.851	176.191	131.523	146.105	135.618	141.497	148.947	147.314
LIVER (G)	7.949	11.983	9.711	12.169	11.010	12.353	12.271	10.941
% BODY WEIGHT	2.809	3.395	3.044	3.611	3.347	3.217	3.409	3.227
% BRAIN WEIGHT	394.491	588.267	432.369	649.360	513.287	600.243	615.396	515.599
SPLEEN (G)	0.582	0.758	0.643	0.698	0.655	0.878	0.725	0.674
% BODY WEIGHT	0.206	0.215	0.202	0.207	0.199	0.229	0.201	0.199
% BRAIN WEIGHT	28.883	37.212	28.629	37.247	30.536	42.663	36.359	31.762
TESTES (G)	2.721	3.104	3.179	3.297	2.955	4.054	3.716	3.380
% BODY WEIGHT	0.961	0.879	0.997	0.978	0.898	1.056	1.032	0.997
% BRAIN WEIGHT	135.037	152.381	141.541	175.934	137.762	196.987	186.359	159.284
THYMUS (G)	0.456	0.488	0.504	0.371	0.505	0.511	0.508	0.552
% BODY WEIGHT	0.161	0.138	0.158	0.110	0.153	0.133	0.141	0.163
% BRAIN WEIGHT	22.630	23.957	22.440	19.797	23.543	24.830	25.476	26.013

PRIMEDICA REDFIELD STUDY NUMBER 132-007

APPENDIX 12

INDIVIDUAL ORGAN WEIGHTS

STUDY: T-7485

SEX: MALE

GROUP: 3-M

FATES: SCHEDULED SACRIFICE

DAYS: 29-29

ALL BALANCES

ANIMAL ID:	7635	7637
BODY WEIGHT (G)	290.000	378.000
ADRENAL GLANDS (G)	0.053	0.089
% BODY WEIGHT	0.018	0.024
% BRAIN WEIGHT	2.797	4.000
BRAIN (G)	1.895	2.225
% BODY WEIGHT	0.653	0.589
HEART (G)	1.221	1.376
% BODY WEIGHT	0.421	0.364
% BRAIN WEIGHT	64.433	61.843
KIDNEYS (G)	2.437	3.348
% BODY WEIGHT	0.840	0.886
% BRAIN WEIGHT	128.602	150.472
LIVER (G)	9.078	10.914
% BODY WEIGHT	3.130	2.887
% BRAIN WEIGHT	479.050	490.517
SPLEEN (G)	0.658	0.813
% BODY WEIGHT	0.227	0.215
% BRAIN WEIGHT	34.723	36.539
TESTES (G)	2.957	3.344
% BODY WEIGHT	1.020	0.885
% BRAIN WEIGHT	156.042	150.292
THYMUS (G)	0.455	0.595
% BODY WEIGHT	0.157	0.157
% BRAIN WEIGHT	24.011	26.742

PRIMEDICA REDFIELD STUDY NUMBER 132-007

APPENDIX 12

INDIVIDUAL ORGAN WEIGHTS

STUDY: T-7485

SEX: MALE

GROUP: 4-M

FATES: SCHEDULED SACRIFICE

DAYS: 29-29

ALL BALANCES

ANIMAL ID:	7639	7641	7643	7645	7647	7649	7651	7653
BODY WEIGHT (G)	282.000	336.000	300.000	307.000	330.000	376.000	369.000	347.000
ADRENAL GLANDS (G)	0.056	0.056	0.066	0.056	0.050	0.093	0.070	0.073
% BODY WEIGHT	0.020	0.017	0.022	0.018	0.015	0.025	0.019	0.021
% BRAIN WEIGHT	2.857	2.888	3.720	2.969	2.591	4.443	3.271	3.566
BRAIN (G)	1.960	1.939	1.774	1.886	1.930	2.093	2.140	2.047
% BODY WEIGHT	0.695	0.577	0.591	0.614	0.585	0.557	0.580	0.590
HEART (G)	1.000	1.131	1.122	1.109	1.227	1.248	1.271	1.205
% BODY WEIGHT	0.355	0.337	0.374	0.361	0.372	0.332	0.344	0.347
% BRAIN WEIGHT	51.020	58.329	63.247	58.802	63.575	59.627	59.393	58.867
KIDNEYS (G)	2.804	2.554	2.594	2.227	2.754	3.124	3.064	3.130
% BODY WEIGHT	0.994	0.760	0.865	0.725	0.835	0.831	0.830	0.902
% BRAIN WEIGHT	143.061	131.717	146.223	118.081	142.694	149.259	143.178	152.907
LIVER (G)	12.465	10.927	10.695	11.216	11.423	15.198	14.735	13.194
% BODY WEIGHT	4.420	3.252	3.565	3.653	3.462	4.042	3.993	3.802
% BRAIN WEIGHT	635.969	563.538	602.875	594.698	591.865	726.135	688.551	644.553
SPLEEN (G)	0.620	0.662	0.459	0.580	0.678	0.810	0.599	0.627
% BODY WEIGHT	0.220	0.197	0.153	0.189	0.205	0.215	0.162	0.181
% BRAIN WEIGHT	31.633	34.141	25.874	30.753	35.130	38.700	27.991	30.630
TESTES (G)	3.141	3.135	2.920	3.226	3.215	3.341	3.217	3.186
% BODY WEIGHT	1.114	0.933	0.973	1.051	0.974	0.889	0.872	0.918
% BRAIN WEIGHT	160.255	161.681	164.600	171.050	166.580	159.627	150.327	155.642
THYMUS (G)	0.363	0.519	0.318	0.396	0.626	0.718	0.445	0.568
% BODY WEIGHT	0.129	0.154	0.106	0.129	0.190	0.191	0.121	0.164
% BRAIN WEIGHT	18.520	26.766	17.926	20.997	32.435	34.305	20.794	27.748

PRIMEDICA REDFIELD STUDY NUMBER 132-007

APPENDIX 12

INDIVIDUAL ORGAN WEIGHTS

STUDY: T-7485

SEX: MALE

GROUP: 4-M

FATES: SCHEDULED SACRIFICE

DAYS: 29-29

ALL BALANCES

ANIMAL ID:	7655	7657
BODY WEIGHT (G)	335.000	376.000
ADRENAL GLANDS (G)	0.076	0.079
% BODY WEIGHT	0.023	0.021
% BRAIN WEIGHT	3.666	3.794
BRAIN (G)	2.073	2.082
% BODY WEIGHT	0.619	0.554
HEART (G)	1.104	1.273
% BODY WEIGHT	0.330	0.339
% BRAIN WEIGHT	53.256	61.143
KIDNEYS (G)	3.011	3.419
% BODY WEIGHT	0.899	0.909
% BRAIN WEIGHT	145.248	164.217
LIVER (G)	12.465	14.400
% BODY WEIGHT	3.721	3.830
% BRAIN WEIGHT	601.303	691.643
SPLEEN (G)	0.678	0.838
% BODY WEIGHT	0.202	0.223
% BRAIN WEIGHT	32.706	40.250
TESTES (G)	3.562	3.552
% BODY WEIGHT	1.063	0.945
% BRAIN WEIGHT	171.828	170.605
THYMUS (G)	0.580	0.632
% BODY WEIGHT	0.173	0.168
% BRAIN WEIGHT	27.979	30.355

PRIMEDICA REDFIELD STUDY NUMBER 132-007

APPENDIX 12

INDIVIDUAL ORGAN WEIGHTS

STUDY: T-7485

SEX: FEMALE

GROUP: 1-F

FATES: SCHEDULED SACRIFICE

DAYS: 29-29

ALL BALANCES

ANIMAL ID:	7570	7572	7574	7576	7578	7580	7582	7584
BODY WEIGHT (G)	212.000	252.000	244.000	209.000	218.000	230.000	223.000	223.000
ADRENAL GLANDS (G)	0.071	0.082	0.101	0.089	0.078	0.095	0.067	0.080
% BODY WEIGHT	0.033	0.033	0.041	0.043	0.036	0.041	0.030	0.036
% BRAIN WEIGHT	3.606	4.084	4.858	5.159	3.879	4.781	3.510	4.171
BRAIN (G)	1.969	2.008	2.079	1.725	2.011	1.987	1.909	1.918
% BODY WEIGHT	0.929	0.797	0.852	0.825	0.922	0.864	0.856	0.860
HEART (G)	0.800	0.943	0.956	0.829	0.885	0.937	0.806	0.886
% BODY WEIGHT	0.377	0.374	0.392	0.397	0.406	0.407	0.361	0.397
% BRAIN WEIGHT	40.630	46.962	45.984	48.058	44.008	47.157	42.221	46.194
KIDNEYS (G)	1.583	1.750	1.925	1.779	1.882	2.133	1.720	1.750
% BODY WEIGHT	0.747	0.694	0.789	0.851	0.863	0.927	0.771	0.785
% BRAIN WEIGHT	80.396	87.151	92.593	103.130	93.585	107.348	90.100	91.241
LIVER (G)	6.103	7.560	7.534	6.447	6.755	9.176	6.316	5.970
% BODY WEIGHT	2.879	3.000	3.088	3.085	3.099	3.990	2.832	2.677
% BRAIN WEIGHT	309.954	376.494	362.386	373.739	335.903	461.802	330.854	311.262
OVARIES (G)	0.114	0.112	0.114	0.098	0.121	0.139	0.095	0.105
% BODY WEIGHT	0.054	0.044	0.047	0.047	0.056	0.060	0.043	0.047
% BRAIN WEIGHT	5.790	5.578	5.483	5.681	6.017	6.995	4.976	5.474
SPLEEN (G)	0.461	0.542	0.523	0.456	0.521	0.577	0.507	0.478
% BODY WEIGHT	0.217	0.215	0.214	0.218	0.239	0.251	0.227	0.214
% BRAIN WEIGHT	23.413	26.992	25.156	26.435	25.908	29.039	26.558	24.922
THYMUS (G)	0.528	0.461	0.604	0.415	0.395	0.405	0.330	0.403
% BODY WEIGHT	0.249	0.183	0.248	0.199	0.181	0.176	0.148	0.181
% BRAIN WEIGHT	26.816	22.958	29.052	24.058	19.642	20.382	17.287	21.011

PRIMEDICA REDFIELD STUDY NUMBER 132-007

APPENDIX 12

INDIVIDUAL ORGAN WEIGHTS

STUDY: T-7485

SEX: FEMALE

GROUP: 1-F

FATES: SCHEDULED SACRIFICE

DAYS: 29-29

ALL BALANCES

ANIMAL ID:	7586	7588
BODY WEIGHT (G)	203.000	239.000
ADRENAL GLANDS (G)	0.063	0.110
% BODY WEIGHT	0.031	0.046
% BRAIN WEIGHT	3.383	5.985
BRAIN (G)	1.862	1.838
% BODY WEIGHT	0.917	0.769
HEART (G)	0.897	0.926
% BODY WEIGHT	0.442	0.387
% BRAIN WEIGHT	48.174	50.381
KIDNEYS (G)	1.644	2.030
% BODY WEIGHT	0.810	0.849
% BRAIN WEIGHT	88.292	110.446
LIVER (G)	6.003	7.288
% BODY WEIGHT	2.957	3.049
% BRAIN WEIGHT	322.395	396.518
OVARIES (G)	0.088	0.095
% BODY WEIGHT	0.043	0.040
% BRAIN WEIGHT	4.726	5.169
SPLEEN (G)	0.411	0.481
% BODY WEIGHT	0.202	0.201
% BRAIN WEIGHT	22.073	26.170
THYMUS (G)	0.408	0.516
% BODY WEIGHT	0.201	0.216
% BRAIN WEIGHT	21.912	28.074

PRIMEDICA REDFIELD STUDY NUMBER 132-007

APPENDIX 12

INDIVIDUAL ORGAN WEIGHTS

STUDY: T-7485

SEX: FEMALE

GROUP: 2-F

FATES: SCHEDULED SACRIFICE

DAYS: 29-29

ALL BALANCES

ANIMAL ID:	7600	7602	7604	7606	7608	7610	7612	7614
BODY WEIGHT (G)	209.000	223.000	232.000	239.000	209.000	226.000	214.000	219.000
ADRENAL GLANDS (G)	0.075	0.074	0.082	0.078	0.091	0.063	0.081	0.090
% BODY WEIGHT	0.036	0.033	0.035	0.033	0.044	0.028	0.038	0.041
% BRAIN WEIGHT	3.945	3.551	4.318	3.858	4.705	3.340	4.010	4.675
BRAIN (G)	1.901	2.084	1.899	2.022	1.934	1.886	2.020	1.925
% BODY WEIGHT	0.910	0.935	0.819	0.846	0.925	0.835	0.944	0.879
HEART (G)	0.856	1.081	0.894	0.933	0.818	0.814	0.874	0.874
% BODY WEIGHT	0.410	0.485	0.385	0.390	0.391	0.360	0.408	0.399
% BRAIN WEIGHT	45.029	51.871	47.077	46.142	42.296	43.160	43.267	45.403
KIDNEYS (G)	1.939	2.083	2.047	1.981	1.741	1.826	1.840	1.825
% BODY WEIGHT	0.928	0.934	0.882	0.829	0.833	0.808	0.860	0.833
% BRAIN WEIGHT	101.999	99.952	107.794	97.972	90.021	96.819	91.089	94.805
LIVER (G)	7.556	7.436	7.676	7.195	6.280	7.043	6.592	6.430
% BODY WEIGHT	3.615	3.335	3.309	3.010	3.005	3.116	3.080	2.936
% BRAIN WEIGHT	397.475	356.814	404.213	355.836	324.716	373.436	326.337	334.026
OVARIES (G)	0.104	0.114	0.102	0.120	0.091	0.104	0.098	0.081
% BODY WEIGHT	0.050	0.051	0.044	0.050	0.044	0.046	0.046	0.037
% BRAIN WEIGHT	5.471	5.470	5.371	5.935	4.705	5.514	4.851	4.208
SPLEEN (G)	0.499	0.475	0.604	0.521	0.501	0.681	0.451	0.387
% BODY WEIGHT	0.239	0.213	0.260	0.218	0.240	0.301	0.211	0.177
% BRAIN WEIGHT	26.249	22.793	31.806	25.767	25.905	36.108	22.327	20.104
THYMUS (G)	0.475	0.392	0.631	0.409	0.522	0.399	0.416	0.388
% BODY WEIGHT	0.227	0.176	0.272	0.171	0.250	0.177	0.194	0.177
% BRAIN WEIGHT	24.987	18.810	33.228	20.228	26.991	21.156	20.594	20.156

PRIMEDICA REDFIELD STUDY NUMBER 132-007

APPENDIX 12

INDIVIDUAL ORGAN WEIGHTS			
STUDY: T-7485		GROUP: 2-F	
SEX: FEMALE		FATES: SCHEDULED SACRIFICE	ALL BALANCES
		DAYS: 29-29	
ANIMAL ID:	7616	7618	
BODY WEIGHT (G)	206.000	229.000	
ADRENAL GLANDS (G)	0.078	0.094	
% BODY WEIGHT	0.038	0.041	
% BRAIN WEIGHT	4.021	4.981	
BRAIN (G)	1.940	1.887	
% BODY WEIGHT	0.942	0.824	
HEART (G)	0.904	0.848	
% BODY WEIGHT	0.439	0.370	
% BRAIN WEIGHT	46.598	44.939	
KIDNEYS (G)	1.922	2.049	
% BODY WEIGHT	0.933	0.895	
% BRAIN WEIGHT	99.072	108.585	
LIVER (G)	7.150	7.642	
% BODY WEIGHT	3.471	3.337	
% BRAIN WEIGHT	368.557	404.982	
OVARIES (G)	0.125	0.094	
% BODY WEIGHT	0.061	0.041	
% BRAIN WEIGHT	6.443	4.981	
SPLEEN (G)	0.646	0.586	
% BODY WEIGHT	0.314	0.256	
% BRAIN WEIGHT	33.299	31.055	
THYMUS (G)	0.510	0.469	
% BODY WEIGHT	0.248	0.205	
% BRAIN WEIGHT	26.289	24.854	

PRIMEDICA REDFIELD STUDY NUMBER 132-007

APPENDIX 12

INDIVIDUAL ORGAN WEIGHTS

STUDY: T-7485

SEX: FEMALE

GROUP: 3-F

FATES: SCHEDULED SACRIFICE

DAYS: 29-29

ALL BALANCES

ANIMAL ID:	7620	7622	7624	7626	7628	7630	7632	7634
BODY WEIGHT (G)	215.000	235.000	226.000	216.000	222.000	257.000	236.000	218.000
ADRENAL GLANDS (G)	0.078	0.076	0.079	0.085	0.079	0.062	0.078	0.095
% BODY WEIGHT	0.036	0.032	0.035	0.039	0.036	0.024	0.033	0.044
% BRAIN WEIGHT	4.176	4.038	4.173	4.422	3.758	3.234	3.894	5.029
BRAIN (G)	1.868	1.882	1.893	1.922	2.102	1.917	2.003	1.889
% BODY WEIGHT	0.869	0.801	0.838	0.890	0.947	0.746	0.849	0.867
HEART (G)	0.890	0.839	0.860	0.911	0.879	1.071	0.799	0.777
% BODY WEIGHT	0.414	0.357	0.381	0.422	0.396	0.417	0.339	0.356
% BRAIN WEIGHT	47.645	44.580	45.431	47.399	41.817	55.869	39.890	41.133
KIDNEYS (G)	1.885	2.090	1.822	1.629	1.800	1.937	1.835	1.769
% BODY WEIGHT	0.877	0.889	0.806	0.754	0.811	0.754	0.778	0.811
% BRAIN WEIGHT	100.910	111.052	96.249	84.755	85.633	101.043	91.613	93.647
LIVER (G)	7.304	7.457	7.219	6.609	7.420	7.250	6.366	6.603
% BODY WEIGHT	3.397	3.173	3.194	3.060	3.342	2.821	2.697	3.029
% BRAIN WEIGHT	391.006	396.227	381.352	343.861	352.997	378.195	317.823	349.550
OVARIES (G)	0.095	0.140	0.101	0.111	0.113	0.115	0.103	0.116
% BODY WEIGHT	0.044	0.060	0.045	0.051	0.051	0.045	0.044	0.053
% BRAIN WEIGHT	5.086	7.439	5.335	5.775	5.376	5.999	5.142	6.141
SPLEEN (G)	0.446	0.514	0.468	0.470	0.392	0.546	0.560	0.364
% BODY WEIGHT	0.207	0.219	0.207	0.218	0.177	0.212	0.237	0.167
% BRAIN WEIGHT	23.876	27.311	24.723	24.454	18.649	28.482	27.958	19.269
THYMUS (G)	0.446	0.492	0.320	0.432	0.403	0.450	0.444	0.448
% BODY WEIGHT	0.207	0.209	0.142	0.200	0.182	0.175	0.188	0.206
% BRAIN WEIGHT	23.876	26.142	16.904	22.477	19.172	23.474	22.167	23.716

PRIMEDICA REDFIELD STUDY NUMBER 132-007

APPENDIX 12

INDIVIDUAL ORGAN WEIGHTS

STUDY: T-7485

SEX: FEMALE

GROUP: 3-F

FATES: SCHEDULED SACRIFICE

DAYS: 29-29

ALL BALANCES

ANIMAL ID:	7636	7638
BODY WEIGHT (G)	206.000	242.000
ADRENAL GLANDS (G)	0.099	0.083
% BODY WEIGHT	0.048	0.034
% BRAIN WEIGHT	5.132	4.373
BRAIN (G)	1.929	1.898
% BODY WEIGHT	0.936	0.784
HEART (G)	0.768	0.816
% BODY WEIGHT	0.373	0.337
% BRAIN WEIGHT	39.813	42.993
KIDNEYS (G)	1.919	1.956
% BODY WEIGHT	0.932	0.808
% BRAIN WEIGHT	99.482	103.056
LIVER (G)	6.657	8.121
% BODY WEIGHT	3.232	3.356
% BRAIN WEIGHT	345.101	427.872
OVARIES (G)	0.099	0.102
% BODY WEIGHT	0.048	0.042
% BRAIN WEIGHT	5.132	5.374
SPLEEN (G)	0.469	0.510
% BODY WEIGHT	0.228	0.211
% BRAIN WEIGHT	24.313	26.870
THYMUS (G)	0.461	0.425
% BODY WEIGHT	0.224	0.176
% BRAIN WEIGHT	23.898	22.392

PRIMEDICA REDFIELD STUDY NUMBER 132-007

APPENDIX 12

INDIVIDUAL ORGAN WEIGHTS

STUDY: T-7485

SEX: FEMALE

GROUP: 4-F

FATES: SCHEDULED SACRIFICE

DAYS: 29-29

ALL BALANCES

ANIMAL ID:	7640	7642	7644	7646	7648	7650	7652	7654
BODY WEIGHT (G)	200.000	247.000	241.000	238.000	228.000	225.000	239.000	241.000
ADRENAL GLANDS (G)	0.079	0.082	0.060	0.091	0.072	0.079	0.079	0.075
% BODY WEIGHT	0.040	0.033	0.025	0.038	0.032	0.035	0.033	0.031
% BRAIN WEIGHT	4.029	3.984	3.197	4.774	3.915	4.112	3.946	3.952
BRAIN (G)	1.961	2.058	1.877	1.906	1.839	1.921	2.002	1.898
% BODY WEIGHT	0.981	0.833	0.779	0.801	0.807	0.854	0.838	0.788
HEART (G)	0.875	0.921	0.819	0.888	1.003	0.773	0.796	0.824
% BODY WEIGHT	0.438	0.373	0.340	0.373	0.440	0.344	0.333	0.342
% BRAIN WEIGHT	44.620	44.752	43.633	46.590	54.541	40.239	39.760	43.414
KIDNEYS (G)	2.086	2.130	2.223	1.961	2.025	2.013	1.834	2.047
% BODY WEIGHT	1.043	0.862	0.922	0.824	0.888	0.895	0.767	0.849
% BRAIN WEIGHT	106.374	103.499	118.434	102.886	110.114	104.789	91.608	107.850
LIVER (G)	6.578	7.812	8.853	7.713	7.884	6.970	6.368	6.986
% BODY WEIGHT	3.289	3.163	3.673	3.241	3.458	3.098	2.664	2.899
% BRAIN WEIGHT	335.441	379.592	471.657	404.670	428.711	362.832	318.082	368.072
OVARIES (G)	0.098	0.106	0.110	0.159	0.105	0.135	0.103	0.099
% BODY WEIGHT	0.049	0.043	0.046	0.067	0.046	0.060	0.043	0.041
% BRAIN WEIGHT	4.997	5.151	5.860	8.342	5.710	7.028	5.145	5.216
SPLEEN (G)	0.547	0.590	0.592	0.498	0.447	0.491	0.560	0.545
% BODY WEIGHT	0.274	0.239	0.246	0.209	0.196	0.218	0.234	0.226
% BRAIN WEIGHT	27.894	28.669	31.540	26.128	24.307	25.560	27.972	28.714
THYMUS (G)	0.316	0.536	0.339	0.516	0.482	0.315	0.474	0.541
% BODY WEIGHT	0.158	0.217	0.141	0.217	0.211	0.140	0.198	0.224
% BRAIN WEIGHT	16.114	26.045	18.061	27.072	26.210	16.398	23.676	28.504

PRIMEDICA REDFIELD STUDY NUMBER 132-007

APPENDIX 12

INDIVIDUAL ORGAN WEIGHTS

STUDY: T-7485

SEX: FEMALE

GROUP: 4-F

FATES: SCHEDULED SACRIFICE

DAYS: 29-29

ALL BALANCES

ANIMAL ID:	7656	7658
BODY WEIGHT (G)	217.000	225.000
ADRENAL GLANDS (G)	0.092	0.080
% BODY WEIGHT	0.042	0.036
% BRAIN WEIGHT	4.930	3.968
BRAIN (G)	1.866	2.016
% BODY WEIGHT	0.860	0.896
HEART (G)	0.816	0.766
% BODY WEIGHT	0.376	0.340
% BRAIN WEIGHT	43.730	37.996
KIDNEYS (G)	1.958	1.877
% BODY WEIGHT	0.902	0.834
% BRAIN WEIGHT	104.930	93.105
LIVER (G)	7.283	7.176
% BODY WEIGHT	3.356	3.189
% BRAIN WEIGHT	390.300	355.952
OVARIES (G)	0.070	0.108
% BODY WEIGHT	0.032	0.048
% BRAIN WEIGHT	3.751	5.357
SPLEEN (G)	0.448	0.480
% BODY WEIGHT	0.206	0.213
% BRAIN WEIGHT	24.009	23.810
THYMUS (G)	0.380	0.441
% BODY WEIGHT	0.175	0.196
% BRAIN WEIGHT	20.364	21.875

PRIMEDICA REDFIELD STUDY NUMBER 132-007

APPENDIX 12

INDIVIDUAL ORGAN WEIGHTS

STUDY: T-7485

SEX: MALE

GROUP: 1-M

FATES: SCHEDULED SACRIFICE

DAYS: 44-44

ALL BALANCES

ANIMAL ID:	7589	7591	7593	7595	7597
BODY WEIGHT (G)	409.000	436.000	433.000	403.000	443.000
ADRENAL GLANDS (G)	0.058	0.092	0.073	0.066	0.077
% BODY WEIGHT	0.014	0.021	0.017	0.016	0.017
% BRAIN WEIGHT	2.922	4.236	3.456	2.993	3.441
BRAIN (G)	1.985	2.172	2.112	2.205	2.238
% BODY WEIGHT	0.485	0.498	0.488	0.547	0.505
HEART (G)	1.281	1.567	1.573	1.374	1.373
% BODY WEIGHT	0.313	0.359	0.363	0.341	0.310
% BRAIN WEIGHT	64.534	72.145	74.479	62.313	61.349
KIDNEYS (G)	3.660	3.388	3.301	3.737	3.353
% BODY WEIGHT	0.895	0.777	0.762	0.927	0.757
% BRAIN WEIGHT	184.383	155.985	156.297	169.479	149.821
LIVER (G)	13.527	14.481	16.351	15.507	15.860
% BODY WEIGHT	3.307	3.321	3.776	3.848	3.580
% BRAIN WEIGHT	681.461	666.713	774.195	703.265	708.669
SPLEEN (G)	0.975	0.992	0.784	0.762	0.709
% BODY WEIGHT	0.238	0.228	0.181	0.189	0.160
% BRAIN WEIGHT	49.118	45.672	37.121	34.558	31.680
TESTES (G)	2.959	3.309	2.734	3.007	3.183
% BODY WEIGHT	0.723	0.759	0.631	0.746	0.719
% BRAIN WEIGHT	149.068	152.348	129.451	136.372	142.225
THYMUS (G)	0.472	0.592	0.559	0.588	0.491
% BODY WEIGHT	0.115	0.136	0.129	0.146	0.111
% BRAIN WEIGHT	23.778	27.256	26.468	26.667	21.939

PRIMEDICA REDFIELD STUDY NUMBER 132-007

APPENDIX 12

INDIVIDUAL ORGAN WEIGHTS

STUDY: T-7485

SEX: MALE

GROUP: 4-M

FATES: SCHEDULED SACRIFICE

DAYS: 44-44

ALL BALANCES

ANIMAL ID:	7659	7661	7663	7665	7667
BODY WEIGHT (G)	365.000	389.000	431.000	422.000	379.000
ADRENAL GLANDS (G)	0.054	0.067	0.091	0.070	0.061
% BODY WEIGHT	0.015	0.017	0.021	0.017	0.016
% BRAIN WEIGHT	2.439	3.057	4.365	3.028	2.777
BRAIN (G)	2.214	2.192	2.085	2.312	2.197
% BODY WEIGHT	0.607	0.563	0.484	0.548	0.580
HEART (G)	1.344	1.445	1.424	1.776	1.306
% BODY WEIGHT	0.368	0.371	0.330	0.421	0.345
% BRAIN WEIGHT	60.705	65.922	68.297	76.817	59.445
KIDNEYS (G)	3.415	3.315	3.555	4.209	3.477
% BODY WEIGHT	0.936	0.852	0.825	0.997	0.917
% BRAIN WEIGHT	154.246	151.232	170.504	182.050	158.261
LIVER (G)	14.018	13.117	16.825	16.803	12.722
% BODY WEIGHT	3.841	3.372	3.904	3.982	3.357
% BRAIN WEIGHT	633.153	598.403	806.955	726.773	579.062
SPLEEN (G)	0.911	0.598	0.667	0.665	0.716
% BODY WEIGHT	0.250	0.154	0.155	0.158	0.189
% BRAIN WEIGHT	41.147	27.281	31.990	28.763	32.590
TESTES (G)	3.167	3.346	3.295	3.748	3.592
% BODY WEIGHT	0.868	0.860	0.765	0.888	0.948
% BRAIN WEIGHT	143.044	152.646	158.034	162.111	163.496
THYMUS (G)	0.456	0.482	0.558	0.585	0.636
% BODY WEIGHT	0.125	0.124	0.129	0.139	0.168
% BRAIN WEIGHT	20.596	21.989	26.763	25.303	28.949

PRIMEDICA REDFIELD STUDY NUMBER 132-007

APPENDIX 12

INDIVIDUAL ORGAN WEIGHTS

STUDY: T-7485

SEX: FEMALE

GROUP: 1-F

FATES: SCHEDULED SACRIFICE

DAYS: 44-44

ALL BALANCES

ANIMAL ID:	7590	7592	7594	7596	7598
BODY WEIGHT (G)	262.000	244.000	241.000	242.000	227.000
ADRENAL GLANDS (G)	0.079	0.080	0.097	0.081	0.062
% BODY WEIGHT	0.030	0.033	0.040	0.033	0.027
% BRAIN WEIGHT	3.899	3.830	4.823	4.429	3.202
BRAIN (G)	2.026	2.089	2.011	1.829	1.936
% BODY WEIGHT	0.773	0.856	0.834	0.756	0.853
HEART (G)	1.044	0.986	0.987	0.931	0.847
% BODY WEIGHT	0.398	0.404	0.410	0.385	0.373
% BRAIN WEIGHT	51.530	47.200	49.080	50.902	43.750
KIDNEYS (G)	2.272	2.310	2.300	1.894	1.901
% BODY WEIGHT	0.867	0.947	0.954	0.783	0.837
% BRAIN WEIGHT	112.142	110.579	114.371	103.554	98.192
LIVER (G)	8.567	9.019	9.777	8.659	6.715
% BODY WEIGHT	3.270	3.696	4.057	3.578	2.958
% BRAIN WEIGHT	422.853	431.738	486.176	473.428	346.849
OVARIES (G)	0.122	0.111	0.122	0.082	0.085
% BODY WEIGHT	0.047	0.045	0.051	0.034	0.037
% BRAIN WEIGHT	6.022	5.314	6.067	4.483	4.390
SPLEEN (G)	0.529	0.566	0.645	0.549	0.446
% BODY WEIGHT	0.202	0.232	0.268	0.227	0.196
% BRAIN WEIGHT	26.111	27.094	32.074	30.016	23.037
THYMUS (G)	0.587	0.448	0.532	0.666	0.299
% BODY WEIGHT	0.224	0.184	0.221	0.275	0.132
% BRAIN WEIGHT	28.973	21.446	26.455	36.413	15.444

PRIMEDICA REDFIELD STUDY NUMBER 132-007

APPENDIX 12

INDIVIDUAL ORGAN WEIGHTS

STUDY: T-7485

SEX: FEMALE

GROUP: 4-F

FATES: SCHEDULED SACRIFICE

DAYS: 44-44

ALL BALANCES

ANIMAL ID:	7660	7662	7664	7666	7668
BODY WEIGHT (G)	237.000	247.000	241.000	246.000	239.000
ADRENAL GLANDS (G)	0.097	0.105	0.080	0.076	0.089
% BODY WEIGHT	0.041	0.043	0.033	0.031	0.037
% BRAIN WEIGHT	5.157	5.250	4.022	4.011	4.302
BRAIN (G)	1.881	2.000	1.989	1.895	2.069
% BODY WEIGHT	0.794	0.810	0.825	0.770	0.866
HEART (G)	0.947	0.869	0.857	0.984	1.015
% BODY WEIGHT	0.400	0.352	0.356	0.400	0.425
% BRAIN WEIGHT	50.346	43.450	43.087	51.926	49.058
KIDNEYS (G)	1.877	2.409	2.238	2.186	2.423
% BODY WEIGHT	0.792	0.975	0.929	0.889	1.014
% BRAIN WEIGHT	99.787	120.450	112.519	115.356	117.110
LIVER (G)	7.741	8.557	8.831	8.678	10.320
% BODY WEIGHT	3.266	3.464	3.664	3.528	4.318
% BRAIN WEIGHT	411.536	427.850	443.992	457.942	498.792
OVARIES (G)	0.089	0.110	0.109	0.090	0.112
% BODY WEIGHT	0.038	0.045	0.045	0.037	0.047
% BRAIN WEIGHT	4.732	5.500	5.480	4.749	5.413
SPLEEN (G)	0.503	0.557	0.588	0.546	0.536
% BODY WEIGHT	0.212	0.226	0.244	0.222	0.224
% BRAIN WEIGHT	26.741	27.850	29.563	28.813	25.906
THYMUS (G)	0.408	0.328	0.513	0.354	0.499
% BODY WEIGHT	0.172	0.133	0.213	0.144	0.209
% BRAIN WEIGHT	21.691	16.400	25.792	18.681	24.118

PRIMEDICA REDFIELD STUDY NUMBER 132-007

APPENDIX 13
FORMULATED TEST MATERIAL ANALYSIS REPORT

**DOSE FORMULATION ANALYSIS OF
PERFLUOROBUTANESULFONATE
IN 1% CMC BY HPLC/MS**

STUDY ID: A098.1

SPONSOR STUDY NO. 132-007

**Southern Research Institute
2000 Ninth Avenue South
P.O. Box 55537
Birmingham, AL 35255-5537**

SUMMARY

A total of 24 formulated dose samples including blanks ranging in concentration from 4 to 40 mg/mL were analyzed by analytical method BACG 3533 to determine the concentration of perfluorobutanesulfonate (PFBS) in the formulated mixture. All dose formulations were found to be acceptable by the sponsor.

KEY PERSONNEL

James D. Johnson, M.S., MBA
Manager
Bioanalytical Chemistry Group

Gregory S. Gorman, Ph.D.
Staff Chemist
Bioanalytical Chemistry Group

1. OBJECTIVE

The objective of this study was to determine the dose concentration of PFBS in the supplied dosing solutions received from the study director.

2. SAFETY

All necessary procedures to ensure safety of the analysts were based on information contained in the Material Safety and Data Sheets (MSDS), provided by the study director for the test article used in this study.

3. Compliance

This work was performed using a validated analytical method (BACG 3533), which along with the validation report is included in the appendix of this report. While this work was not audited in compliance with GLP regulations, it was performed in the spirit of the regulations using calibrated and validated instrumentation.

4. EXPERIMENTAL

4.1 Analytical Procedures

The sample preparation and analysis procedures as described in the analytical method BACG 3533 were employed for all analyses. Each sample was allowed to warm to room temperature and was then vortexed well before an aliquot was taken. Duplicated aliquots were taken from each sample and diluted as described in the method. Three standard curves was prepared over a concentration range of 500 to 10,000 ng/mL and analyzed along with the samples. No outliers in the calibration standards were noted and subsequently no standards were dropped from either of the calibration curves.

4.2 Results

The results of the analysis are presented in the Table I at the end of the report.

5.0 Conclusion

A total of 24 dose formulation samples ranging in concentration from 4 to 40 mg/mL were analyzed by BACG 3533. All samples were found to be acceptable by the sponsor.

Table I

PFBS Dose Formulation Summary in 1 % CMC

Day	0 mg/mL	4 mg/mL	12 mg/mL	40 mg/mL
1	ND	4.57	8.20	39.91
7	ND	4.12	10.80	39.79
14	ND**	4.13	11.48	40.38
21	ND	3.74	11.47	38.86
28	-----***	3.80	11.54	39.63
32	-----***	3.89	11.62	39.31

ND = not detected

* Results represent average of duplicate analysis

** One of the day 14 controls (0 mg/mL) was inadvertently contaminated during preparation. Result based on single analysis.

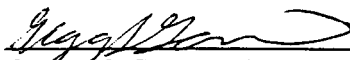
*** No sample received

Statement of Compliance

Study A098.1

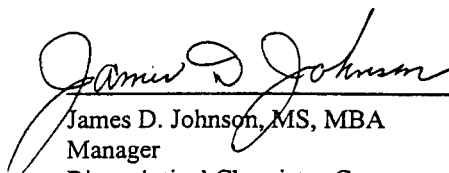
Sponsor Study 132-007

This work was performed using a validated analytical method (BACG 3533). While this work was not audited in compliance with GLP regulations, it was performed in the spirit of the regulations using calibrated and validated methods and instrumentation.



Gregory S. Gorman, Ph.D.
Staff Chemist
Bioanalytical Chemistry Group

7-5-01
Date



James D. Johnson, MS, MBA
Manager
Bioanalytical Chemistry Group

7/5/01
Date

METHOD VALIDATION REPORT

**VALIDATION OF ANALYTICAL METHOD FOR DOSE FORMULATION ANALYSIS
OF PERFLUOROBUTANE SULFONATE (PFBS) IN 1% CARBOXYMETHYL
CELLULOSE (CMC)**

STUDY ID: A098.1

**Southern Research Institute
2000 Ninth Avenue South
P.O. Box 55537
Birmingham, AL 35255-5537**

SUMMARY

Southern Research Institute has successfully validated for 3M an analytical method (BACG 3533) entitled "Dose Formulation Analysis of Perfluorobutane Sulfonate in 1% Carboxymethyl Cellulose by HPLC Mass Spectrometry". Calibration standards were prepared by spiking solvent solutions with known amounts of test article, PFBS, and internal standard,

The calibration standards were prepared over a concentration range of 500 to 10,000 ng/mL and the carboxymethyl cellulose (CMC) concentration was adjusted to equal that of each diluted sample in each set. Additionally, three standard curves were prepared and analyzed which contained no CMC as controls. A total of 6 calibration curves were generated during the study which produced correlation coefficients ranging from 0.9992 to 0.9999.

KEY PERSONNEL

James D. Johnson, M.S.
Manager
Bioanalytical Chemistry Group

Gregory S. Gorman, Ph.D.
Research Chemist III
Bioanalytical Chemistry Group

Lester Williams, B.S.
Associate Chemist II
Bioanalytical Chemistry Group

1. OBJECTIVE

The objective of this study was to provide a validated analytical method for the determination of PFBS concentration in dose formulation samples containing 1% CMC.

2. SAFETY

All necessary procedures to ensure safety of the analysts were based on information contained in the Material Safety and Data Sheets (MSDS), provided by 3M for the test article used in this study.

3. EXPERIMENTAL

3.1 Analytical Procedures

The sample preparation and analysis procedures as described in the analytical method BACG 3533 were employed for all analyses. For the preparation of the calibration standards, a known volume of a solvent (e.g., 1 mL) containing CMC was spiked with a known amount of test article and internal standard and vortexed briefly to ensure mixing. Each formulation sample was diluted to a final concentration of 3200 ng/mL and an aliquot of this was placed into autosampler vials for analysis.

3.2 Method Validation

Validation for BACG 3533 "Dose Formulation Analysis of Perfluorobutane Sulfonate in 1% Carboxymethyl Cellulose by HPLC Mass Spectrometry" consisted of analyzing three standard curves containing CMC at the concentration present in the diluted 4 mg/mL dose formulation samples (0.001%) and three curves prepared without CMC. The concentration range for both sets ranged from 500 to 10,000 ng/mL. A total of 7 calibration levels in each curve containing CMC and 6 in each of the three without CMC were evaluated. The summaries are given below:

Calibration Results 0% CMC

A total of three standard curves each containing 6 individual standards encompassing a range of 500 to 10,000 ng/mL were analyzed in duplicate. The correlation coefficient for the composite curve comprising a total of 36 data points was found to be 0.9992. No data points were dropped from the analysis. A statistical summary for the composite curve is shown below:

STANDARD COMPOSITE CURVE PFBS (0% CMC)

Concen. (ng/mL)	500	1000	3000	5000	8000	10,000
# of Standards	6	6	6	6	6	6
Mean % Accur.	97.71	102.9	99.73	99.52	100.1	100.2
Std. Deviation	19.47	55.85	110.6	187.8	288.2	356.4

Calibration Results (CMC = 0.001%)

Three standards curves containing a total of 21 single standards encompassing a range of 500 to 10,000 ng/mL were analyzed. The correlation coefficient for the calibration curve was found to be 0.9997. No data points were dropped from the analysis. A statistical summary for the composite curve is shown below:

STANDARD COMPOSITE CURVE PFBS (0.001% CMC)

Concen. (ng/mL)	500	1000	3000	3200	5000	8000	10,000
# of Standards	3	3	3	3	3	3	- 3
Mean % Accur.	98.11	101.5	101	101	98.44	99.31	100.7
Std. Deviation	18.19	17.72	48.33	49.67	81.61	76.38	203.4

3.3 Calculations

Calculations were performed using TurboQuan (Version 1.0). The amount of analyte in the diluted dose formulation samples (ng/mL) was back calculated using a calibration curve generated from a set of calibration standards containing the equivalent amount of CMC as in the diluted samples. The calibration curve was generated by a regression analysis to determine the best fit curve (e.g., linear, quadratic etc.) and amount of weighting. A quadratic fit with 1/X weighting was determined to be the best fit :

$$y = ax^2 + bx + c$$

where:

y = Peak area response of test article

x = Concentration of the test article in standards.

a, b, c = Constants derived from the regression analysis.

4.0 Conclusion

A quantitative method (BAGC 3533) has been developed and validated for the determination of PFBS in dose formulation solutions containing 1% CMC. Quantitation for this method is based on internal standard which produces standard curves with a correlation coefficients of 0.9992 or greater over a concentration range of 500 to 10,000 ng/mL.

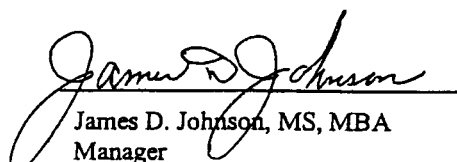
5.0 Approvals



Gregory S. Gorman, Ph.D.
Staff Chemist
Bioanalytical Chemistry Group

7-5-01

Date



James D. Johnson, MS, MBA
Manager
Bioanalytical Chemistry Group

7/5/01

Date

ANALYTICAL METHOD

Method No.: BACG-3533

Title: Dose Formulation Analysis of Perfluorobutane Sulfonate in 1 % Carboxymethyl Cellulose by HPLC/Mass Spectrometry (HPLC/MS)

1.0 PRINCIPLE

Dose formulation samples of perfluorobutane sulfonate (PFBS) in 1 % carboxymethyl cellulose (CMC) are diluted down to 3200 ng/mL and analyzed by HPLC/MS. Quantitation is based on an internal standard using back calculated values from a calibration curve encompassing a concentration range from 500 to 10,000 ng/mL and containing the same concentration of CMC as the dose formulations in the diluted form.

2.0 REAGENTS AND SOLUTIONS

The listed reagents or their equivalents may be used.

2.1 Neat Reagents

2.1.1 Water, deionized and organic free (from in-house purification system; e.g., Ingalls 210N)

2.1.2 Methanol, HPLC grade

2.1.3 Perfluorobutanesulfonate (analyte), as provided by the client

2.1.4 (internal standard), 97%

2.1.5 Ammonium acetate, HPLC grade

2.2 Prepared Solutions

Appropriate changes in the solutions may be made at the discretion of the analyst

2.2.1 5 mM Ammonium acetate in organic free water

ANALYTICAL METHOD

Method No.: BACG-3533

Title: Dose Formulation Analysis of Perfluorobutane Sulfonate in 1% Carboxymethyl Cellulose by HPLC/Mass Spectrometry (HPLC/MS)

- 2.2.1.1 For example, to prepare 4 liters, measure out ammonium acetate (e.g., 1.542 g) and add in organic-free water (e.g., 4 L). Mix well and filter through HPLC mobile phase filtration apparatus.

3.0 INSTRUMENTS, MATERIALS, AND APPARATUS

The following or their equivalents may be used.

- 3.1 HPLC pump(s), autosampler, and single quadrupole mass spectrometer
- 3.2 Autosampler vials with inserts
- 3.3 Vortex mixers (e.g., touch mixer and IKA-Vibrax[®] platform mixer)
- 3.4 HPLC mobile phase filtration apparatus
- 3.5 Filters for HPLC mobile phase filtration apparatus (e.g., Nylon-66, 0.20 μ m)
- 3.7 Analytical balance
- 3.8 Volumetric flasks (e.g., 10 and 25 mL)
- 3.9 Disposable Pasteur pipets
- 3.10 Micropipettor(s) with tips
- 3.11 Culture tubes with teflon-lined caps
- 3.12 Assorted glassware and syringes

ANALYTICAL METHOD

Method No.: BACG-3533

Title: Dose Formulation Analysis of Perfluorobutane Sulfonate in 1% Carboxymethyl Cellulose by HPLC/Mass Spectrometry (HPLC/MS)

4.0 PREPARATION OF STOCKS AND WORKING STOCKS

Appropriate changes in the concentrations of the solutions may be made at the discretion of the analyst. Actual dilutions will be documented on the preparation sheets.

4.1 Main Stock Solution of PFBS ~1000 µg/mL

- 4.1.1 Prepare an ~1000 µg/mL solution of PFBS in mobile phase (e.g., accurately weigh about 10 mg PFBS into a 10-mL volumetric flask). Add mobile phase to dissolve. Dilute to the mark. Alternatively, weigh the compound into an appropriate vessel (e.g., culture tube) and add 10 mL of mobile phase. Mix well. Transfer the solution to a clean vessel if desired.

4.2 Spiking Stock Solution of PFBS ~50 µg/mL

- 4.2.1 Prepare an ~50 µg/mL solution of PFBS in mobile phase (e.g., measure about 500 µL of ~1000 µg/mL PFBS into a 10-mL volumetric flask). Add mobile phase to dissolve. Dilute to the mark. Alternatively, weigh the compound into an appropriate vessel (e.g., culture tube) and add 10 mL of mobile phase. Mix well. Transfer the solution to a clean vessel if desired.

4.3 Stock Solution of Internal Standard ~200 µg/mL

- 4.3.1 Prepare an ~200 µg/mL solution of _____ in deionized organic-free water (e.g., accurately weigh about 10 mg into a 50-mL volumetric flask). Add deionized organic-free water to dissolve and dilute to the mark with deionized organic-free water. Alternatively, weigh the compound into an appropriate vessel (e.g., culture tube) and add 50 mL of deionized organic-free water. Mix well. Transfer the solution to a clean vessel if desired.

ANALYTICAL METHOD

Method No.: BACG-3533

Title: Dose Formulation Analysis of Perfluorobutane Sulfonate in 1% Carboxymethyl Cellulose by HPLC/Mass Spectrometry (HPLC/MS)

4.3 Working Stock Solutions of PFBS

- 4.3.1 To prepare working stock solutions, make the proper dilutions as shown in the following table. Prepare in 10-mL volumetric flasks or other appropriate glassware. If desired a modified dilution scheme can be used and documented in the study records.

Working Stock Level (WSL) Approximate Concentration (ng/mL)	Volume of Internal Standard (μ L)	Volume of PFBS spiking solution (μ L)	Volume of mobile phase (μ L)
500	200	10	790
1000	200	20	780
3000	200	60	740
3200	200	64	736
5000	200	100	700
8000	200	160	640
10000	200	200	600

Note: The mobile phase used for each standard curve should contain the same concentration of CMC as the samples. For example, the dilution factor of a 4 mg/mL sample is 1000 (prior to addition of IS). The mobile phase for a 4 mg/mL sample prepared in 1% CMC should contain 1/1000% CMC to account for the dilution.

5.0 PREPARATION OF SPIKED STANDARDS AND BLANKS

Appropriate changes in the concentrations of the solutions may be made at the discretion of the analyst.

ANALYTICAL METHOD

Method No.: BACG-3533

Title: Dose Formulation Analysis of Perfluorobutane Sulfonate in 1 % Carboxymethyl Cellulose by HPLC/Mass Spectrometry (HPLC/MS)

-
- 5.1 Multiple (e.g., about three) sets of standards blanks (blank + IS) are analyzed with each set of unknown samples. A double blank (blank-IS) may also be analyzed if desired. Standards may be prepared as shown in the table in 4.3.1.

6.0 PREPARATION OF SAMPLES

- 6.1 All samples are to be diluted to approximately the middle of the curve (e.g. 3200 ng/mL). Dilutions are to be made with mobile phase. For example, for a 4 mg/mL sample, take 1 mL and dilute with mobile phase in a 10 mL volumetric flask. Then take 100 μ L of the diluted sample and dilute that with mobile phase in a 10 mL volumetric flask. Take 800 μ L of the second dilution, place in an autosampler vial, add 200 μ L of IS, mix, and analyze.

7.0 ANALYSIS BY HIGH PERFORMANCE LIQUID CHROMATOGRAPHY MASS SPECTROMETRY/MASS SPECTROMETRY (HPLC/MS/MS)

- 7.1 Conditions are to be optimized if necessary.

7.1.1 HPLC Conditions

Analytical Column:	none
Guard Column:	Fluofix 120E 10 mm x 2 mm
Elution Flow rate:	1000 μ L/min.
Injection volume:	5 μ L
Mobile phase:	A: 5mM ammonium acetate buffer B: methanol
Elution Profile:	Isocratic 30% A : 70% B
Temperature:	Ambient

7.1.2 PE Sciex API 150EX Single Quadrupole Mass Spectrometer Conditions

Page 6 of 8

ANALYTICAL METHOD

Method No.: BACG-3533

Title: Dose Formulation Analysis of Perfluorobutane Sulfonate in 1% Carboxymethyl Cellulose by HPLC/Mass Spectrometry (HPLC/MS)

Software: PE Sciex TurboQuan

Turboion Spray Source

Note: Values listed under "MS/MS Acquisition Conditions" override parameters in this table.

Auxiliary Gas: Air (e.g., Grade 0.1) at 85 pounds per square inch

<u>Parameter</u>	<u>Value</u>
IS	-5000
NC	0
TEM	450
OR	-25
RNG	-170
Q0	10
IQ1	11
ST	16
ROI	11
DF	300
CEM	2400
NEB	15
CUR	8
CAD	0
QPE	0
POL	0
VCM	0
IPE	0

ANALYTICAL METHOD

Method No.: BACG-3533

Title: Dose Formulation Analysis of Perfluorobutane Sulfonate in 1% Carboxymethyl Cellulose by HPLC/Mass Spectrometry (HPLC/MS)

Masses requested:

PFBS:	
<u>Q1 Mass (amu)</u>	<u>Dwell Time (ms)</u>
299.2	200

(IS)	
<u>Q1 Mass (amu)</u>	<u>Dwell Time (ms)</u>
	200

8.0 CALCULATIONS

- 8.1 At the end of the analytical run, review each chromatogram to ensure the retention time, peak shape, and peak height and peak area determination of the test article and the IS are acceptable. The data may be smoothed as appropriate. For quantitation, use the ion profiles at the following mass-to-charge ratios:

<u>Analyte</u>	<u>Ion Profile</u>
PFBS	299.2

- 8.2 Plot the peak area response of PFBS divided by the peak area response of the IS from all standards versus the concentration of the test article in the standards. Alternatively, the peak heights may be used instead of peak areas. Obtain the best curve fit of the data (e.g., quadratic fit weighted with 1/concentration of the test article or a quadratic fit). Note: The best curve fit may be dependent on the range of the standard curve and it may be necessary to have more than one standard curve for various concentration ranges using the following:

$$y = ax^2 + bx + c$$

where y = Peak height response of PFBS divided by peak height response of the IS in standards.
x = Concentration of the PFBS in standards.

ANALYTICAL METHOD

Method No.: BACG-3533

Title: Dose Formulation Analysis of Perfluorobutane Sulfonate in 1% Carboxymethyl Cellulose by HPLC/Mass Spectrometry (HPLC/MS)

a, b, c = Constants derived from the regression analysis.

- 8.3 Using the standard curve, calculate the level of PFBS in each unknown sample. Correct the results of samples for any dilutions.

9.0 ACCEPTANCE AND REJECTION CRITERIA

- 9.1 Refer to SOP SRI 91-3 for acceptance/rejection criteria except acceptable accuracy for standards is 80-120% of theoretical.

10.0 REPORTING

- 10.1 Results of all analyses are tabulated, and the raw data, original chromatograms, and reports are to be filed in the appropriate study file.

Authors:

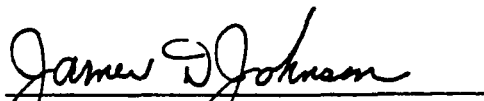


Gregory S. Gorman, Ph.D., Research Chemist III

7-17-2000

Date

Approved by:

James D. Johnson, MS, MBA, Manager
Bioanalytical Chemistry Group7-17-2000

Date

**APPENDIX 14
CERTIFICATE OF ANALYSIS**

Certificate Of Analysis

$\text{C}_4\text{F}_9\text{SO}_3\text{K}^+$ PFBS)
, Lot 2 (1999)

April 17, 2000

(Supersedes Certificate of Analysis dated April 11, 2000)

This sample was analyzed using LC/MS, , and elemental analyses techniques. The results of these tests show the sample to contain the following weight percent composition:

	0.13 %
$\text{C}_4\text{F}_9\text{SO}_3\text{K}^+$	97.90%
	1.96 %

Additionally, the isomer distribution of the sample was determined using techniques and found to contain the following weight percent composition:

$\text{CF}_3(\text{CF}_2)_3\text{-SO}_3\text{K}^+$	97.86 %
	0.04 %

Analytical Study Number: 60488

**APPENDIX 15
PROTOCOL AND AMENDMENT**

Primedica Redfield Protocol

Protocol Number: 132-007

A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-DAWLEY RATS

PROTOCOL NO.: 132-007

OBJECTIVE: To evaluate the toxicity potential associated with oral (gavage) administration of T-7485 in Sprague-Dawley rats for a 28-day repeated dose with an approximate 14-day recovery period.

LOCATION OF STUDY AND CONDITIONS OF TESTING:

It is the intention of 3M Corporate Toxicology, through the conduct of this study, to generate animal safety data that may be submitted to regulatory authorities. Primedica Redfield, 100 East Boone Street, Redfield, Arkansas, 72132, is accredited by AAALAC and licensed by the United States Department of Agriculture to conduct research in laboratory animals. All the conditions of testing will conform to the Animal Welfare Act (CFR 9) and its amendments. Primedica Redfield will follow all requirements specified in this approved protocol as well as Primedica Redfield's Standard Operating Procedures. Changes in the protocol may be made by consultation with and approval from 3M Corporate Toxicology followed by written verification of the change. 3M Corporate Toxicology reserves the right to inspect facilities and procedures used for this study by means of announced or unannounced site visits. Primedica Redfield will notify 3M Corporate Toxicology promptly by telephone prior to release of any data for review.

SPONSOR: 3M Corporate Toxicology
3M Center, Building 220-2E-02
P.O. Box 33220
St. Paul, MN 55133-3320

SPONSOR'S REPRESENTATIVE: Ph.D., DABT, CIH
Senior Laboratory Manager
Telephone:
FAX:

TESTING FACILITY: Primedica Redfield
Mail: P.O. Box 308
Deliveries: 100 East Boone St.
Redfield, AR 72132
Telephone: 501-397-2540
FAX: 501-397-2002

PERSONNEL: Study Director: John Seng, Ph.D.
Principle Investigator: Karen Tranter, B.A., LATG
Veterinarian: Allan Manus, D.V.M., M.Sc., ACLAM
Clinical Pathology: Phyllis Powell, B.S., M.T., ASCP
Head Technician: Martha Downing, B.S.

PROPOSED STUDY DATES: Experimental Start Date: August 31, 2000
Experimental Termination Date: October 13, 2000
Draft Report Date: December 12, 2000

Primedica Redfield Protocol*Protocol Number: 132-007*

1. REGULATORY COMPLIANCE AND QUALITY ASSURANCE

This study will be conducted in accordance with the following Good Laboratory Practice Regulations/Standards/Guidelines:

☒ C(81)30 (Final) (OECD)

The Quality Assurance Unit, in accordance with Primedica Redfield's Standard Operating Procedures (SOPs), will audit the protocol, study conduct, and the final report.

2. INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE REVIEW

The protocol will be reviewed and approved by Primedica Redfield's Institutional Animal Care and Use Committee (IACUC) for compliance with regulations prior to study initiation.

In the opinion of the Sponsor, indicated by the signature on this protocol, the study does not unnecessarily duplicate any previous work.

3. MATERIALS

TEST MATERIAL	T-7485 (Potassium perfluorobutane sulfonate, PFBS)
IDENTIFICATION	The lot number will be listed in the raw data and final report.
PHYSICAL DESCRIPTION	White powder
VEHICLE CONTROL	1% carboxymethylcellulose (aqueous, medium viscosity)
IDENTIFICATION	The lot number will be listed in the raw data and final report.
PHYSICAL DESCRIPTION	White powder

STORAGE CONDITIONS

The bulk test material will be stored in its original container at room temperature. The formulated test and vehicle control material will be stored at 2° to 8°C.

ANALYTICAL CHEMISTRY

The Sponsor assumes responsibility for characterization (identity, purity, and stability) of the bulk test material (including under test conditions). Information on the composition and method of synthesis of the bulk test material will be held by the Sponsor. The doses, unless otherwise stated, will be calculated assuming the test material to be 100% pure.

DOSE PREPARATION AND CONCENTRATION

Doses will be formulated every ten days by Primedica Redfield. The carboxymethylcellulose will be prepared at 1% in deionized water and may be prepared prior to Study Day 1.

Primedica Redfield Protocol*Protocol Number: 132-007*

INVENTORY

The test material container(s) will be inventoried when received at the testing laboratory, and a record of all test material use will be maintained. The technician dosing the animals will: 1) Record the weight or volume of the test material container immediately before and after dosing; 2) Compute and record the amount used and compare it to the theoretical amount immediately after dosing; 3) Keep the formulated test material use log in the animal study books at all times; 4) Assure the dose used is within $\pm 10\%$ of theoretical.

ANALYTICAL SAMPLES

A sample of each concentration of the formulated test material and vehicle will be retained pretest and after completion of treatment with each batch and frozen at approximately -20°C for analysis. Prior to dosing, all pretest samples will be sent to and analyzed by the below mentioned laboratory. All end of batch samples will be sent after study termination to:

Greg Gorman, Ph.D.
Research Chemist III
Southern Research Institution
2000 Ninth Avenue South
Birmingham, AL 35205
Telephone: (205) 581-2725
FAX: (205) 581-2726

This laboratory, will provide their own report regarding the analysis of the vehicle and test material, validation of the test system, analyses of the data, and QAU audits or audit reports. This report will be added as an appendix to the study report.

RESERVE SAMPLES

A reserve sample of each lot of test and vehicle control material will be retained for archiving in accordance with the selected Good Laboratory Practices.

TEST MATERIAL RETENTION

Unused test material may be returned to the Sponsor or designee at the termination of the study, or retained for use on future studies. The Sponsor will be notified in advance of shipping, and a transmittal letter will accompany the shipment. The material will be packed in a suitable container to maintain the conditions specified by the Sponsor during transit plus an adequate margin of safety for any transit delays.

SAFETY PRECAUTIONS

General safety precautions as required by Primedica Redfield's policies and procedures will be followed. The Sponsor's Representative will be notified of any personnel exposures requiring a physician's examination or care.

Primedica Redfield ProtocolProtocol Number: 132-007

4. ANIMALS

Species: Rat
Strain/Source: Crl:CD®(SD) albino rats, Charles River Laboratories, Inc.
Age at Initiation: Six to eight weeks
Number and Sex: 50 male and 50 female (female nulliparous and non pregnant)
Identification: Uniquely numbered ear tag and cage card

ANIMAL HUSBANDRY**HOUSING**

The animals will be individually housed in stainless steel cages. The cages conform to standards set forth in the Guide for the Care and Use of Laboratory Animals, National Academy Press, Washington, D.C., 1996.

FEED

Teklad Certified Rodent Diet #8728 will be provided *ad libitum*. This diet is routinely analyzed by the manufacturer for nutritional components and environmental contaminants. Results of the manufacturer's analyses are on file at Primedica Redfield.

WATER

Filtered tap water will be provided *ad libitum*. Samples of the water are analyzed for total dissolved solids, hardness, specified microbiological content, and for environmental contaminants. Results of these analyses are on file at Primedica Redfield.

CONTAMINANTS

There are no known contaminants in the feed or water that would be expected to interfere with this study.

ENVIRONMENT

Environmental controls are set to maintain a temperature of 18° to 26°C (64° to 79°F) with a relative humidity of 30% to 70%. These parameters are recorded at least once daily. A 12:12 hour light:dark cycle is maintained.

ACCLIMATION

Animals will be acclimated for a minimum of seven days prior to the study start. An adequate number of extra animals will be purchased so that no animal in obviously poor health is placed on test. At the request of the Study Director, excess animals may be used as replacement animals. Animals will be examined by the Staff Veterinarian prior to release of that shipment of animals for use on the study.

JUSTIFICATION FOR SPECIES SELECTION AND NUMBER OF ANIMALS

Rats are an animal model for studies of this type. The number of animals assigned to this study represents the minimum required to meet the objective(s) of the OECD Guideline #407.

Primedica Redfield Protocol

Protocol Number: 132-007

5. EXPERIMENTAL METHODOLOGY

STUDY DESIGN

Group Number	Group Designation	Dosage Level (mg/kg)	Dosage Concentration (mg/mL)	Dosage Volume (mL/kg)	Number of Animals*	
					Males	Females
1	Vehicle Control	0	0	25	10 (5)	10 (5)
2	Mid-dose	100	4	25	10	10
3	Mid-high dose	300	12	25	10	10
4	High-dose	900	36	25	10 (5)	10 (5)

*Number in parenthesis indicates the number of recovery animals

ASSIGNMENT TO GROUPS

Animals will be randomly assigned to groups by a weight-ordered distribution such that individual body weights will not exceed $\pm 20\%$ of mean weight for each sex.

FREQUENCY AND DURATION OF ADMINISTRATION

Doses will be administered via oral gavage for twenty-eight consecutive days. The dose volume will be 25 mL/kg. The first day of dosing on the study will be Study Day 1. Individual dose volumes will be calculated using the most recently collected body weights. Rats (5/sex/group) in the vehicle control and high dose groups will be allowed an approximate fourteen-day recovery period.

JUSTIFICATION FOR ROUTE OF ADMINISTRATION AND DOSE LEVEL

In the assessment and evaluation of the toxic characteristics of a substance, determination of acute oral toxicity is usually an initial step. Dose levels were chosen by the Sponsor and based on the findings reported in Primedica Redfield Study Number 132-006.

ANTEMORTEM OBSERVATIONS

CLINICAL OBSERVATIONS

Observations will be performed and recorded twice daily (a.m. and p.m.) for moribundity and mortality.

Cageside observations will be performed approximately one to two hours postdose, according to Primedica Redfield's SOPs, and recorded once daily and when a change is noted.

Once before the first dose (to allow for within-subject comparisons), and at least weekly thereafter or when a change is noted, detailed clinical observations will be made in all animals. These observations will be made outside the home cage and preferably at approximately the same time of day, each time. Effort should be made to ensure that variations in the test conditions are minimal. Signs noted should include, but not be limited to, changes in skin, fur, eyes, mucous membranes, occurrence of secretions and excretions, and autonomic activity. Changes in gait, posture, and response to handling as well as the presence of clonic or tonic movement, stereotypes, or bizarre behavior should also be recorded.

Primedica Redfield Protocol*Protocol Number: 132-007*

During Study Week 4, sensory reactivity to stimuli of different types (e.g. auditory, visual, and proprioceptive stimuli), assessment of grip strength, and motor activity assessment will be conducted.

BODY WEIGHTS

Body weights will be recorded pretest, on Study Day 1, approximately weekly, prior to terminal fasting, and prior to necropsy.

FEED CONSUMPTION

Feed consumption will be measured approximately weekly and will be reported as an average daily consumption.

HEMATOLOGY

Blood samples will be obtained prior to necropsy while under anesthesia (CO₂) via cardiac puncture. Feed will be withheld overnight prior to collection. Blood samples collected (using EDTA for hematology and sodium citrate for coagulation indices) will be evaluated for the following parameters:

- Total and relative differential leukocyte counts
- Erythrocyte counts
- Hemoglobin concentration
- Hematocrit value
- Mean corpuscular volume
- Mean corpuscular hemoglobin
- Mean corpuscular hemoglobin concentration
- Platelet counts
- Prothrombin time
- Activated partial thromboplastin time

CLINICAL CHEMISTRY

Blood samples will be obtained prior to necropsy while under anesthesia (CO₂) via cardiac puncture. Feed will be withheld overnight prior to collection. Blood samples collected for clinical chemistry will be processed and evaluated for the parameters specified below:

- | | |
|----------------------------|------------------------------|
| • Total Protein | • Globulin |
| • Albumin | • Albumin/Globulin ratio |
| • Glucose | • Cholesterol |
| • Triglycerides | • Total Bilirubin |
| • Urea Nitrogen | • Creatinine |
| • Alanine Aminotransferase | • Aspartate Aminotransferase |
| • Alkaline Phosphatase | • Gamma-glutamyltransferase |
| • Calcium | • Phosphorus |
| • Sodium | • Chloride |
| • Potassium | |

POSTMORTEM OBSERVATIONS**MORIBUND ANIMALS AND ANIMALS FOUND DEAD**

Animals unlikely to survive until the next scheduled observation will be weighed, euthanized, and necropsied. Animals found dead will be weighed and necropsied. In either case, blood samples will not be collected and a complete necropsy will be performed as detailed below.

Primedica Redfield Protocol

Protocol Number: 132-007

EUTHANASIA

All animals will be humanely euthanized via anesthesia with carbon dioxide to effect followed by exsanguination. Euthanasia will be performed in accordance with accepted American Veterinary Medical Association (AVMA) guidelines [*J. Amer. Vet. Med. Assoc.*, 202:229-249, 1993].

NECROPSY

With the exception of the recovery animals, on Study Day 29, the animals will be sacrificed rotating sequentially through groups for each sex. Recovery animals will be sacrificed rotating sequentially through the groups for each sex on approximately Study Day 44. All animals that die during the study, or are killed at study termination, will be subjected to a complete necropsy examination. A complete necropsy is defined as examination of the external surface of the body, all orifices, and the cranial, thoracic, and abdominal cavities (and their contents).

The following organs will be weighed prior to fixation: adrenal glands, brain, heart, kidneys, liver, ovaries, spleen, testes, and thymus. Paired organs will be weighed together.

Organ weights will not be taken from animals that die or are euthanized prior to scheduled necropsy.

Organs (or samples of organs) and tissues listed below will be examined *in situ*, dissected free, and fixed in 10% neutral buffered formalin or other suitable fixative for possible histopathological examination. Observations noted at necropsy will be recorded on the Individual Animal Necropsy Record.

- | | |
|------------------------|--------------------|
| • Adrenal glands | • Lymph nodes |
| • Aorta | mandibular |
| • Bone marrow | mesenteric |
| sternum | • Mammary gland |
| • Brain | • Ovaries |
| brain stem | • Oviducts |
| cerebellum | • Pancreas |
| cerebrum | • Pituitary gland |
| • Cervix | • Prostate gland |
| • Epididymides | • Salivary gland |
| • Esophagus | mandibular |
| • Eyes | • Sciatic nerve |
| with optic nerve | • Seminal vesicles |
| • Femur | • Skeletal muscle |
| with articular surface | • Spinal cord |
| • Gross lesions | cervical |
| • Harderian gland | lumbar |
| • Heart | thoracic |

Primedica Redfield Protocol**Protocol Number: 132-007**

- | | |
|--------------------|-----------------------|
| • Intestine, large | • Spleen |
| cecum | • Stomach |
| colon | forestomach |
| rectum | glandular |
| • Intestine, small | • Testes |
| duodenum | • Thymus |
| ileum | • Thyroid/parathyroid |
| jejunum | • Tongue |
| • Kidneys | • Trachea |
| • Lacrimal gland | • Uterus |
| • Liver | • Urinary bladder |
| • Lungs | • Vagina |
| with bronchi | • Zymbal's gland |

Animal identification will be saved.

HISTOPATHOLOGY

Histopathology will be performed on all tissues from the vehicle control, high dose group, recovery animals, all gross lesions, and all animals found dead or sacrificed *in extremis*. Target tissues in the intermediate groups may be examined at additional cost to the Sponsor. Additional histopathology may be done at an additional cost to the Sponsor.

Tissues will be trimmed, embedded, and sectioned. Slides will be stained with hematoxylin and eosin. Special stains may be used at the direction of the Study Pathologist, at the approval of the Sponsor, and at additional cost. Slides will be read and interpreted by a qualified veterinary pathologist. Data will be summarized in tabular form and will be accompanied by a narrative prepared by the Study Pathologist.

6. STATISTICAL ANALYSIS

Means and standard deviations will be calculated for all quantitative data. Treated groups of the same sex will be compared to Group 1 at common time points using an ANOVA with a *post hoc* Dunnett's t Test (Dunnett, C.W., J. Amer. Statis. Assoc., 50:1096-1121, 1955) or another appropriate test. A two-sided α of 0.05/0.01 will be used to determine if statistically significant differences exist between the vehicle control and treated groups. If no significant differences exist at the 0.05 level, then no comparison is necessary at the 0.01 level. Statistical program names and compile dates are available in the Primedica Argus Research Laboratories Computer Operations Department. The SAS version is 6.12, from the SAS Institute, Inc., SAS Campus Drive, Cary, North Carolina, 27513.

7. REPORT

A draft report will be sent to the Sponsor. Revisions to the initial draft report will be provided to the Sponsor by mail or fax transmission as printed copies of the corrected pages only. Additional revisions or complete copies of the revised draft reports will be provided at additional expense to the Sponsor.

Primedica Redfield Protocol*Protocol Number: 132-007*

Three copies of the approved final report, two bound and one unbound, will be submitted to the Sponsor approximately two weeks after approval of the draft report. The final report will include all elements required/recommended by the regulations and guidelines.

The report will include, but is not limited to, those items listed below:

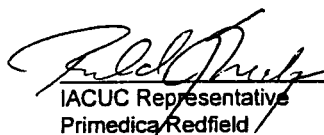
- Descriptive text of the study objective
- Summary
- Test material identification (Certificate of Analysis, stability data, and analytical analysis if any are performed)
- Formulation reports
- Methods
- Results and conclusions
- Body weights and body weight changes
- Feed consumption
- Functional clinical observations report
- Necropsy report
- Histopathology report
- Organ weights
- Serum chemistry and hematology
- A copy of the protocol, all protocol amendments, and all protocol deviations that may affect the integrity of the study

8. MAINTENANCE OF RAW DATA AND RECORDS

Original data or copies thereof, will be available at Primedica Redfield to facilitate auditing the study during its progress and before acceptance of the final report. When the final report is completed, all original paper data and the original final report will be retained in the archives of the laboratory for at least five years. Wet tissues, slides, and blocks (if generated) will be retained at Primedica Redfield for one year. After one year, the storage of the wet tissues, slides, and blocks will be negotiated with the Sponsor. After five years, the storage of the paper data will be negotiated with the Sponsor. The Sponsor will be notified prior to disposal of any original study data.

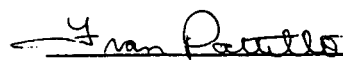
9. INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC) REVIEW

This is to certify that this protocol has been reviewed by IACUC.

 8/30/00
IACUC Representative Date
Primedica Redfield

10. QUALITY ASSURANCE REVIEW

This is to certify that this protocol has been reviewed by Quality Assurance.

 8-29-00
Fran Pattillo, M.S., RQAP-GLP Date
Quality Assurance Manager
Primedica Redfield

Primedica Redfield Protocol

Protocol Number: 132-007

11. APPROVALS

Ph.D, DABT, CIH
Senior Laboratory Manager
3M Corporate Toxicology

Date _____

8/31/00


John Seng, Ph.D.
Study Director
Primedica Redfield

Date _____

8/29/00

Primedica Redfield Protocol Amendment

Protocol Number: 132-007

STUDY NUMBER: 132-007
AMENDMENT: 1
STUDY TITLE: A 28-DAY ORAL (GAVAGE) TOXICITY STUDY OF T-7485 IN SPRAGUE-
DAWLEY RATS
DATE ISSUED: September 19, 2000

AMENDMENT # 1

ITEM 1: Page 2, Section 3, Dose Preparation and Concentration

CHANGED FROM: Doses will be formulated every ten days by Primedica Redfield.
CHANGED TO: Each batch of dosing solutions will be formulated a maximum of 14 days prior to the last day of use. The batch size will be sufficient for ten days of administration.
REASON: To allow time for analysis prior to the use of each batch on study.

ITEM 2: Page 3, Section 3, Analytical Samples

CHANGED FROM: A sample of each concentration of the formulated test material and vehicle will be retained pretest and after completion of treatment with each batch and frozen at approximately -20°C for analysis. Prior to dosing, all pretest samples will be sent to and analyzed by the below mentioned laboratory. All end of batch samples will be sent after study termination to:
CHANGED TO: A sample of each concentration of the formulated test material and vehicle will be retained predose and after completion of treatment with each batch and frozen at approximately -20°C for analysis. Prior to dosing, all pretest samples will be sent to and analyzed by the below mentioned laboratory. All end of batch samples will be collected on the last day of dosing for each batch prior to release of that aliquot for dosing. All samples will be sent to:
REASON: Clarification.

APPROVALS:

Ph.D., DABT, CIH
Senior Laboratory Manager
3M Corporate Toxicology

Date

9/24/00

John Seng, Ph.D.
Study Director
Primedica Redfield

Date

9/19/00

APPENDIX 16
PROTOCOL DEVIATIONS

PROTOCOL DEVIATIONS

There were no protocol deviations that adversely affected the integrity of the study.

**APPENDIX 17
KEY PERSONNEL**

KEY PERSONNEL

Study Number: 132-007

Study Director John Seng, Ph.D.
Principle Investigator Karen Tranter, B.A., LATG
Head Technician Lance Williams, B.S.
Veterinarian Allan Manus, D.V.M., M.Sc., ACLAM
Clinical Pathology Phyllis Powell, B.S., M.T., ASCP
Quality Assurance Shevonya Noble, B.A.
Report Coordination Amy Babb, B.S.
Report Preparation Tammy Peckham, Ad. Asst.
Dana Rose, Ad. Asst.