

Clinical Observations - Clinical Observations by Animal

For Study: PR1000
Title: 28 Day Repeated Dose Study in the Rat
Requested By: Danielle Gardner
Job Number: 31934
Base Day is Day: 1
Analysis Period: Day -7 Relative to Start Date to Day 29 Relative to Start Date
Split by Timeslot: No
Timeslots: Any Timeslots, a.m., p.m., 08.00, 12.00, 16.00, Pre Dose, 1 Hour Post Dose, 2 Hour Post Dose, 3 Hour Post Dose, 4 Hour Post Dose, 6 Hour Post Dose, 12 Hour Post Dose, 24 Hour Post Dose
Groups: All
Animal Reference: Animal Name
Animals Included: All
Observation Types: Routine, Ophthalmoscopy, Pup Observations, Veterinary
Symptoms: Ataxia, Biting Objects, Biting Self, Bruising, Circling, Coat Soiled, Cold To Touch, Compulsive Licking, Convulsion, Cuts On Body, Cyanosed, Damaged Ear, Damaged Forelimb, Damaged Hindlimb, Damaged Tail, + others.
Sites: Abdomen, Anus, Back, Both, Base, Chest, Ear, Eye, Head, Left, Left Ear, Left Eye, Left Flank, Left Fore Paw, + others.
Observation Order: Symptom, Severity, Site, Colour, Consistency, Direction, Opthal, Size, Area
Measurement: Clin Obs Range
Rationalization Set: None
Split Analysis by: Sex; Site; Modifier Category (All)
Exclusion Profile: None
Include: NAD Indicators; NTR Observations; Comments
Style: Landscape

Appendix 01a - Mortality and Clinical Signs

PR1000 - 28 Day Repeated Dose Study in the Rat

0 mg/kg/day Sex: Male	Observation Type: All Types	From Day -7 (Start Date) to 29 (Start Date)
1001	Normal	-7 to 29
1002	Normal	-7 to 29
1003	Normal	-7 to 29
1004	Normal	-7 to 29
1005	Normal	-7 to 29
1006	Normal	-7 to 29
1007	Normal	-7 to 29
1008	Normal	-7 to 29
1009	Normal	-7 to 15
	Kinked Tail	22 to 29
1010	Normal	-7 to 29

Values=Clin Obs Range

Appendix 01a - Mortality and Clinical Signs

PR1000 - 28 Day Repeated Dose Study in the Rat

100 mg/kg/day Sex: Male	Observation Type: All Types	From Day -7 (Start Date) to 29 (Start Date)
2001	Normal	-7 to 29
2002	Normal	-7 to 29
2003	Normal	-7 to 22
	Bruising, Slight, Right Flank, Red, Small (< 1 cm sq)	25 to 26
	Bruising, Slight, Right Flank, Purple, Small (< 1 cm sq)	27
	Bruising, Slight, Right Flank, Purple, Medium area (2-3cm sq)	28 to 29
2004	Normal	-7 to 29
2005	Normal	-7 to 8
	Piloerection, Slight	15 to 29
2006	Normal	-7 to 29
2007	Normal	-7 to 22
	Bruising, Slight, Right Flank, Red, Small (< 1 cm sq)	26
	Bruising, Slight, Right Flank, Purple, Medium area (2-3cm sq)	27 to 28
	Bruising, Slight, Right Flank, Black, Medium area (2-3cm sq)	29
2008	Normal	-7 to 22
	Pale, Slight	29
2009	Normal	-7 to 15
	Found Dead	17
2010	Normal	-7 to 29

Values=Clin Obs Range

Appendix 01a - Mortality and Clinical Signs

PR1000 - 28 Day Repeated Dose Study in the Rat

500 mg/kg/day Sex: Male	Observation Type: All Types	From Day -7 (Start Date) to 29 (Start Date)
3001	Normal	-7 to 22
	Bruising, Slight, Right Flank, Red, Small (< 1 cm sq)	25 to 26
	Bruising, Slight, Right Flank, Purple, Small (< 1 cm sq)	27
	Bruising, Slight, Right Flank, Purple, Medium area (2-3cm sq)	28 to 29
3002	Normal	-7 to 15
	Pale, Moderate	22 to 29
	Bruising, Slight, Right Flank, Red, Small (< 1 cm sq)	23 to 25
	Bruising, Slight, Right Flank, Purple, Small (< 1 cm sq)	26 to 27
	Bruising, Slight, Right Flank, Purple, Medium area (2-3cm sq)	28
	Bruising, Slight, Right Flank, Black, Medium area (2-3cm sq)	29
	Cyanosed, Slight	29
3003	Normal	-7 to 22
	Bruising, Slight, Right Flank, Red, Small (< 1 cm sq)	23
	Bruising, Slight, Right Flank, Purple, Small (< 1 cm sq)	24 to 26
	Bruising, Slight, Right Flank, Purple, Medium area (2-3cm sq)	27
	Bruising, Slight, Right Flank, Black, Medium area (2-3cm sq)	28 to 29
3004	Normal	-7 to 29
3005	Normal	-7 to 29
3006	Normal	-7 to 1
	Piloerection, Moderate	8 to 15
	Bruising, Slight, Right Flank, Red, Small (< 1 cm sq)	22 to 23
	Bruising, Slight, Right Flank, Purple, Small (< 1 cm sq)	24 to 25
	Bruising, Slight, Right Flank, Purple, Medium area (2-3cm sq)	26
	Bruising, Slight, Right Flank, Black, Medium area (2-3cm sq)	27 to 29
3007	Normal	-7 to 29
3008	Normal	-7 to 29
3009	Normal	-7 to 8
	Pale, Slight	15 to 22

Values=Clin Obs Range

Appendix 01a - Mortality and Clinical Signs

PR1000 - 28 Day Repeated Dose Study in the Rat

500 mg/kg/day Sex: Male	Observation Type: All Types	From Day -7 (Start Date) to 29 (Start Date)
3009	Bruising, Moderate, Abdomen, Purple, Small (< 1 cm sq)	22 to 23
	Bruising, Moderate, Abdomen, Purple, Medium area (2-3cm sq)	24 to 26
	Bruising, Moderate, Abdomen, Black, Medium area (2-3cm sq)	27 to 29
	Pale, Moderate	29
3010	Normal	-7 to 15
	Bruising, Moderate, Abdomen, Purple, Small (< 1 cm sq)	22 to 24
	Bruising, Moderate, Abdomen, Purple, Medium area (2-3cm sq)	25 to 26
	Bruising, Moderate, Abdomen, Black, Medium area (2-3cm sq)	27 to 29

Values=Clin Obs Range

Appendix 01a - Mortality and Clinical Signs

PR1000 - 28 Day Repeated Dose Study in the Rat

1000 mg/kg/day Sex: Male	Observation Type: All Types	From Day -7 (Start Date) to 29 (Start Date)
4001	Normal	-7,8 to 29
	Salivation, Slight, Clear	1
4002	Normal	-7 to 15
	Bruising, Slight, Abdomen, Red, Small (< 1 cm sq)	20 to 22
	Pale, Moderate	22,29
	Bruising, Slight, Abdomen, Purple, Small (< 1 cm sq)	23 to 24
	Bruising, Slight, Abdomen, Purple, Medium area (2-3cm sq)	25 to 27
	Bruising, Slight, Abdomen, Black, Medium area (2-3cm sq)	28 to 29
	Cyanosed, Slight	29
4003	Normal	-7 to 8
	Pale, Slight	15
	Bruising, Slight, Abdomen, Red, Small (< 1 cm sq)	20 to 22
	Cyanosed, Slight	22
	Pale, Moderate	22,24
	Bruising, Slight, Abdomen, Purple, Small (< 1 cm sq)	23 to 24
	Humane Sacrifice	24
	Convulsion	24
	Cyanosed, Moderate	24
4004	Normal	-7 to 15
	Bruising, Slight, Back, Red, Small (< 1 cm sq)	21 to 22
	Bruising, Slight, Back, Purple, Medium area (2-3cm sq)	23 to 24
	Bruising, Slight, Back, Blue, Medium area (2-3cm sq)	25 to 28
	Bruising, Slight, Back, Black, Medium area (2-3cm sq)	29
4005	Normal	-7 to 15
	Bruising, Slight, Left Flank, Red, Small (< 1 cm sq)	22
	Bruising, Slight, Left Flank, Purple, Small (< 1 cm sq)	23 to 24
	Bruising, Slight, Left Flank, Purple, Medium area (2-3cm sq)	25 to 27
	Bruising, Slight, Left Flank, Black, Medium area (2-3cm sq)	28 to 29

Values=Clin Obs Range

Appendix 01a - Mortality and Clinical Signs

PR1000 - 28 Day Repeated Dose Study in the Rat

1000 mg/kg/day Sex: Male	Observation Type: All Types	From Day -7 (Start Date) to 29 (Start Date)
4006	Normal	-7 to 15
	Bruising, Slight, Left Flank, Red, Small (< 1 cm sq)	21 to 22
	Bruising, Slight, Left Flank, Purple, Small (< 1 cm sq)	22 to 23
	Bruising, Slight, Left Flank, Purple, Medium area (2-3cm sq)	24 to 29
4007	Normal	-7 to 15
	Bruising, Moderate, Right Fore Paw, Blue, Medium area (2-3cm sq)	21
	Bruising, Moderate, Right Fore Paw, Blue, Small (< 1 cm sq)	22
	Bruising, Moderate, Right Fore Paw, Purple, Small (< 1 cm sq)	22 to 26
	Pale, Slight	22
	Bruising, Moderate, Right Fore Paw, Black, Small (< 1 cm sq)	27 to 29
	Pale, Moderate	29
4008	Normal	-7 to 8
	Cyanosed, Slight	15,22,29
	Bruising, Slight, Left Flank, Red, Small (< 1 cm sq)	21 to 22
	Bruising, Slight, Left Flank, Purple, Small (< 1 cm sq)	22 to 23
	Pale, Moderate	22
	Bruising, Slight, Left Flank, Purple, Medium area (2-3cm sq)	24 to 27
	Bruising, Slight, Left Flank, Black, Medium area (2-3cm sq)	28 to 29
4009	Normal	-7 to 1
	Pale, Slight	8 to 21
	Bruising, Slight, Neck, Blue, Small (< 1 cm sq)	21
	Bruising, Slight, Neck, Red, Small (< 1 cm sq)	22 to 23
	Cyanosed, Slight	22 to 23
	Bruising, Slight, Neck, Purple, Small (< 1 cm sq)	24 to 25
	Cyanosed, Moderate	24 to 25
	Humane Sacrifice	25
	Ataxia, Extreme	25
	Pale, Extreme	25

Values=Clin Obs Range

Appendix 01a - Mortality and Clinical Signs

PR1000 - 28 Day Repeated Dose Study in the Rat

1000 mg/kg/day Sex: Male	Observation Type: All Types	From Day -7 (Start Date) to 29 (Start Date)
4009 4010	Pupil Dilated, Left Normal Bruising, Moderate, Abdomen, Red, Small (< 1 cm sq) Bruising, Moderate, Abdomen, Purple, Medium area (2-3cm sq) Bruising, Moderate, Abdomen, Black, Medium area (2-3cm sq)	25 -7 to 22 24 to 25 26 to 27 28 to 29

Values=Clin Obs Range

Appendix 01a - Mortality and Clinical Signs

PR1000 - 28 Day Repeated Dose Study in the Rat

0 mg/kg/day Sex: Female	Observation Type: All Types	From Day -7 (Start Date) to 29 (Start Date)
1101	Normal	-7 to 29
1102	Normal	-7 to 29
1103	Normal	-7 to 29
1104	Normal	-7 to 29
1105	Normal	-7 to 29
1106	Normal	-7 to 29
1107	Normal	-7 to 29
1108	Normal	-7 to 29
1109	Normal	-7 to 29
1110	Normal	-7 to 29

Values=Clin Obs Range

Appendix 01a - Mortality and Clinical Signs

PR1000 - 28 Day Repeated Dose Study in the Rat

100 mg/kg/day Sex: Female	Observation Type: All Types	From Day -7 (Start Date) to 29 (Start Date)
2101	Normal	-7 to 29
2102	Normal	-7 to 29
2103	Normal	-7 to 29
2104	Normal	-7 to 15
	Kinked Tail	22 to 29
2105	Normal	-7 to 29
2106	Normal	-7 to 29
2107	Normal	-7 to 29
2108	Normal	-7 to 29
2109	Normal	-7 to 29
2110	Normal	-7 to 29

Values=Clin Obs Range

Appendix 01a - Mortality and Clinical Signs

PR1000 - 28 Day Repeated Dose Study in the Rat

500 mg/kg/day Sex: Female	Observation Type: All Types	From Day -7 (Start Date) to 29 (Start Date)
3101	Normal	-7 to 29
3102	Normal	-7 to 29
3103	Normal	-7 to 8
	Cyanosed, Slight	15 to 22
	Circling, Moderate	29
	Cyanosed, Moderate	29
3104	Normal	-7 to 29
3105	Normal	-7 to 15
	Pale, Moderate	22 to 29
	Ataxia, Slight	29
3106	Normal	-7 to 29
3107	Normal	-7 to 29
3108	Normal	-7 to 29
3109	Normal	-7 to 29
3110	Normal	-7 to 22
	Piloerection, Slight	29

Values=Clin Obs Range

Appendix 01a - Mortality and Clinical Signs

PR1000 - 28 Day Repeated Dose Study in the Rat

1000 mg/kg/day Sex: Female	Observation Type: All Types	From Day -7 (Start Date) to 29 (Start Date)
4101	Normal Pale, Slight Pale, Moderate Circling, Slight	-7 to 1 8 to 15 22 to 29 29
4102	Normal	-7 to 29
4103	Normal	-7 to 29
4104	Normal Pale, Slight Pale, Moderate	-7 to 8 15 to 22 29
4105	Normal	-7 to 29
4106	Normal Cyanosed, Moderate Ataxia, Moderate Cyanosed, Extreme	-7 to 8 15 to 22 29 29
4107	Normal Cyanosed, Moderate Convulsion Cyanosed, Extreme	-7 to 15 22 29 29
4108	Normal	-7 to 29
4109	Normal	-7 to 29
4110	Normal	-7 to 29

Values=Clin Obs Range

Appendix 01a - Mortality and Clinical Signs

PR1000 - 28 Day Repeated Dose Study in the Rat

Key Page**Group Information**

<u>Short Name</u>	<u>Long Name</u>	<u>Type</u>	<u>Report Headings</u>	
1	1 - Vehicle Control	Control	0	mg/kg/day
2	2 - Low Dose	Dose	100	mg/kg/day
3	3 - Mid-dose	Dose	500	mg/kg/day
4	4 - High Dose	Dose	1000	mg/kg/day

Appendix 01a - Mortality and Clinical Signs

PR1000 - 28 Day Repeated Dose Study in the Rat

End of Print
