

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, Ophthal, 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
1010	Kinked Tail Normal	22 to 29 -7 to 29

Values=Clin Obs Range

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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 Bruising, Slight, Right Flank, Red, Small (< 1 cm sq) Bruising, Slight, Right Flank, Purple, Small (< 1 cm sq) Bruising, Slight, Right Flank, Purple, Medium area (2-3cm sq)	-7 to 22 25 to 26 27 28 to 29
2004	Normal	-7 to 29
2005	Normal	-7 to 8
2006	Piloerection, Slight	15 to 29
2007	Normal Normal Bruising, Slight, Right Flank, Red, Small (< 1 cm sq) Bruising, Slight, Right Flank, Purple, Medium area (2-3cm sq) Bruising, Slight, Right Flank, Black, Medium area (2-3cm sq)	-7 to 29 -7 to 22 26 27 to 28 29
2008	Normal Pale, Slight	-7 to 22 29
2009	Normal	-7 to 15
2010	Found Dead Normal	17 -7 to 29

Values=Clin Obs Range

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

Values=Clin Obs Range

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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) Bruising, Moderate, Abdomen, Purple, Medium area (2-3cm sq) Bruising, Moderate, Abdomen, Black, Medium area (2-3cm sq) Pale, Moderate	22 to 23 24 to 26 27 to 29 29
3010	Normal Bruising, Moderate, Abdomen, Purple, Small (< 1 cm sq) Bruising, Moderate, Abdomen, Purple, Medium area (2-3cm sq) Bruising, Moderate, Abdomen, Black, Medium area (2-3cm sq)	-7 to 15 22 to 24 25 to 26 27 to 29

Values=Clin Obs Range

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

Values=Clin Obs Range

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

Values=Clin Obs Range

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

Values=Clin Obs Range

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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

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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 Kinked Tail	-7 to 15 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

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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 Cyanosed, Slight Circling, Moderate Cyanosed, Moderate	-7 to 8 15 to 22 29 29
3104	Normal	-7 to 29
3105	Normal Pale, Moderate Ataxia, Slight	-7 to 15 22 to 29 29
3106	Normal	-7 to 29
3107	Normal	-7 to 29
3108	Normal	-7 to 29
3109	Normal	-7 to 29
3110	Normal Piloerection, Slight	-7 to 22 29

Values=Clin Obs Range

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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

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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

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