

Generalized Results - Animals by Parameter - Fixed Time

For Study:	PR1000
Title:	28 Day Repeated Dose Study in the Rat
Requested By:	Danielle Gardner
Job Number:	31919
Base Day is Day:	1
Start Period:	Day 29 Relative to Start Date
End Period:	Day 29 Relative to Start Date
Subject Reference:	Subject Name
Subjects Included:	1001, 1002, 1003, 1004, 1005, 1006, 1007, 1008, 1009, 1010, 2001, 2002, 2003, 2004, 2005, 2006, 2007, 2008, 2009, 2010, 3001, 3002, 3003, 3004, 3005, 3006, 3007, 3008, 3009, 3010, 4001, 4002, 4003, 4004, 4005, 4006, 4007, 4008, 4009, 4010
Groups:	All
Measurements:	Terminal Bodyweight, Adrenal Glands (Both) Weight, Brain Weight, Heart Weight, Kidneys Weight, Liver Weight, Lungs Weight, Ovaries Weight, Testes Weight, Spleen Weight
Selected for Duplicate Results:	First value
Analysis by Sex:	Split
Suppress Blank Columns:	No
Show Comments:	Yes
Include Quality Flag Markers:	Yes
Include Out of Range Markers:	No
Style:	Narrow Landscape - Animals down the side
Exclusion Profile:	None

Appendix 08a - Organ Weights - males

PR1000 - 28 Day Repeated Dose Study in the Rat

Sex: Male Day(s): 29 Relative to Start Date

0 mg/kg/day	Organ Weights								
	Terminal Body Wt. (g)	Adrenals (g)	Brain (g)	Heart (g)	Kidneys (g)	Liver (g)	Lungs (g)	Testes (g)	Spleen (g)
1001	373.7	0.083	2.12	2.31 ^a	2.98	20.50	2.11	2.70	0.411
1002	381.5	0.087	2.16	2.40 ^a	3.61 ^a	20.41	2.27	2.68	0.430
1003	370.9	0.058	1.93	2.15 ^b	2.84	21.01	1.89	2.73	0.420
1004	378.1	0.083	2.08	2.31	2.96	20.72	1.67	2.81	0.340
1005	384.6	0.090	2.23	2.40	3.64	23.38 ^a	1.96	2.26 ^a	0.450
1006	369.6	0.040	1.79	1.99	2.70	17.77	0.82	1.96	0.230
1007	370.0	0.057	1.92	2.00	2.71	18.70	1.01	1.96	0.240
1008	371.0	0.075	2.05	2.24	2.86	20.69	1.15	2.61	0.320
1009	379.7	0.086	2.14	2.36	3.26	22.23 ^a	2.22	3.06	0.390
1010	370.9	0.072	1.94	2.18	2.86	19.95	1.09	2.27	0.300
Mean	375.00	0.0731	2.036	2.234	3.042	20.536	1.619	2.504	0.3531
SD	5.49	0.0164	0.136	0.152	0.345	1.585	0.551	0.371	0.0792
N	10	10	10	10	10	10	10	10	10
Median	-	0.079	-	-	-	-	-	-	-

^a [RC:Value verified]^b [RC:Value Verified]

Control Group is Group

Appendix 08a - Organ Weights - males

PR1000 - 28 Day Repeated Dose Study in the Rat

Sex: Male Day(s): 29 Relative to Start Date

100 mg/kg/day	Organ Weights								
	Terminal Body Wt. (g)	Adrenals (g)	Brain (g)	Heart (g)	Kidneys (g)	Liver (g)	Lungs (g)	Testes (g)	Spleen (g)
2001	363.0	0.092	1.88	2.04	2.74	20.29	1.08	2.58	0.320
2002	370.2	0.079	1.97	2.22	2.97	20.30	1.60	3.00	0.310
2003	365.3	0.082	1.89	2.13	2.77	20.29	1.28	2.65	0.310
2004	380.6	0.060	2.25	2.44	3.87 ^a	20.31	2.02	3.34	0.290
2005	363.0	0.061	1.84	1.99	2.10 ^a	20.27	1.03	2.50	0.320
2006	373.7	0.073	2.09	2.34	3.10	20.30	1.83	3.29	0.301
2007	371.7	0.083	2.03	2.33	3.09	20.30	1.74	3.11	0.303
2008	370.5	0.072	1.97	2.26	3.01	20.30	1.64	3.08	0.306
2009	-	NT	NT	NT	NT	NT	NT	NT	NT
2010	367.7	0.076	1.92	2.14	2.78	20.29	1.45	2.70	0.311
Mean	369.52	0.0753	1.982	2.210	2.937	20.294	1.519	2.917	0.3079
SD	5.62	0.0103	0.127	0.148	0.464	0.011	0.338	0.315	0.0094
N	9	9	9	9	9	9	9	9	9
Median	-	0.076	-	-	-	-	-	-	-

^a [RC:Value Verified]

Control Group is Group

Appendix 08a - Organ Weights - males

PR1000 - 28 Day Repeated Dose Study in the Rat

Sex: Male Day(s): 29 Relative to Start Date

500 mg/kg/day	Organ Weights								
	Terminal Body Wt. (g)	Adrenals (g)	Brain (g)	Heart (g)	Kidneys (g)	Liver (g)	Lungs (g)	Testes (g)	Spleen (g)
3001	371.8	0.095	2.20	2.44	3.17	19.90	1.65	4.03	0.310
3002	360.8	0.082	2.10	2.36	3.08	19.89	1.48	3.68	0.310
3003	358.9	0.081	2.02	2.23	2.84	19.88	1.23	3.14	0.320
3004	357.9	0.073	1.97	2.04	2.65	19.87	0.87	2.36	0.330
3005	363.8	0.090	2.14	2.40	3.12	19.89	1.57	3.86	0.310
3006	354.5	0.071	1.92	1.83 ^a	2.65	19.87	0.85	1.48 ^a	0.335
3007	358.5	0.078	2.00	2.05	2.83	19.88	1.17	2.40	0.326
3008	359.8	0.081	2.02	2.26	2.86	19.88	1.34	3.28	0.316
3009	370.3	0.091	2.18	2.41	3.17	19.90	1.65	3.91	0.309
3010	363.7	0.088	2.12	2.36	3.12	19.89	1.49	3.70	0.311
Mean	362.00	0.0830	2.067	2.238	2.949	19.885	1.330	3.184	0.3177
SD	5.50	0.0079	0.094	0.202	0.207	0.011	0.296	0.845	0.0096
N	10	10	10	10	10	10	10	10	10
Median	-	0.082	-	-	-	-	-	-	-

^a [RC:Value Verified]

Control Group is Group

Appendix 08a - Organ Weights - males

PR1000 - 28 Day Repeated Dose Study in the Rat

Sex: Male Day(s): 29 Relative to Start Date

1000 mg/kg/day	Organ Weights								
	Terminal Body Wt. (g)	Adrenals (g)	Brain (g)	Heart (g)	Kidneys (g)	Liver (g)	Lungs (g)	Testes (g)	Spleen (g)
4001	338.2	0.078	1.99	2.30	2.78	18.86	1.25	2.70	0.330
4002	333.0	0.075	1.90	2.17	2.73	18.85	1.14	2.66	0.340
4003	-	NT	NT	NT	NT	NT	NT	NT	NT
4004	338.9	0.102	2.01	2.36	3.13	18.86	1.34	2.88	0.330
4005	335.7	0.075	1.90	2.28	2.74	18.85	1.18	2.69	0.330
4006	329.0	0.054	1.79	2.02	2.44	18.84	0.92	2.41	0.353
4007	329.8	0.055	1.89	2.16	2.45	18.85	0.94	2.41	0.352
4008	342.0	0.107	2.06	2.39	3.20	18.87	1.40	3.44	0.330
4009	-	NT	NT	NT	NT	NT	NT	NT	NT
4010	345.0	0.113	2.13	2.42	3.29	18.87	1.46	4.14	0.326
Mean	336.45	0.0824	1.959	2.263	2.845	18.856	1.204	2.916	0.3364
SD	5.67	0.0227	0.109	0.136	0.328	0.011	0.200	0.592	0.0107
N	8	8	8	8	8	8	8	8	8
Median	-	0.077	-	-	-	-	-	-	-

Control Group is Group

Appendix 08a - Organ Weights - males

PR1000 - 28 Day Repeated Dose Study in the Rat

<u>Comments and Markers</u>							
<u>Page</u>	<u>Day</u>	<u>Group</u>	<u>Sex</u>	<u>Subject</u>	<u>Measurement</u>	<u>Type</u>	<u>Marker</u>
1	29	1	Male	1001	Heart Weight	Result	
			<i>Comment:</i> Value verified				
1	29	1	Male	1002	Heart Weight	Result	
			<i>Comment:</i> Value Verified				
1	29	1	Male	1002	Kidneys Weight	Result	
			<i>Comment:</i> Value Verified				
1	29	1	Male	1003	Heart Weight	Result	
			<i>Comment:</i> Value Verified				
1	29	1	Male	1005	Liver Weight	Result	
			<i>Comment:</i> Value Verified				
1	29	1	Male	1005	Testes Weight	Result	
			<i>Comment:</i> Value Verified				
1	29	1	Male	1009	Liver Weight	Result	
			<i>Comment:</i> Value verified				
2	29	2	Male	2004	Kidneys Weight	Result	
			<i>Comment:</i> Value Verified				
2	29	2	Male	2005	Kidneys Weight	Result	
			<i>Comment:</i> Value Verified				
2	29	2	Male	2009	Adrenal Glands Wt	Replacement	NT
2	29	2	Male	2009	Brain Weight	Replacement	NT
2	29	2	Male	2009	Heart Weight	Replacement	NT
2	29	2	Male	2009	Kidneys Weight	Replacement	NT
2	29	2	Male	2009	Liver Weight	Replacement	NT
2	29	2	Male	2009	Lungs Weight	Replacement	NT
2	29	2	Male	2009	Testes Weight	Replacement	NT
2	29	2	Male	2009	Spleen Weight	Replacement	NT
3	29	3	Male	3006	Heart Weight	Result	
			<i>Comment:</i> Value verified				

Appendix 08a - Organ Weights - males

PR1000 - 28 Day Repeated Dose Study in the Rat

Comments and Markers

<u>Page</u>	<u>Day</u>	<u>Group</u>	<u>Sex</u>	<u>Subject</u>	<u>Measurement</u>	<u>Type</u>	<u>Marker</u>
3	29	3	Male	3006	Testes Weight	Result	
			<i>Comment:</i> Value verified				
4	29	4	Male	4003	Adrenal Glands Wt	Replacement	NT
4	29	4	Male	4003	Brain Weight	Replacement	NT
4	29	4	Male	4003	Heart Weight	Replacement	NT
4	29	4	Male	4003	Kidneys Weight	Replacement	NT
4	29	4	Male	4003	Liver Weight	Replacement	NT
4	29	4	Male	4003	Lungs Weight	Replacement	NT
4	29	4	Male	4003	Testes Weight	Replacement	NT
4	29	4	Male	4003	Spleen Weight	Replacement	NT
4	29	4	Male	4009	Adrenal Glands Wt	Replacement	NT
4	29	4	Male	4009	Brain Weight	Replacement	NT
4	29	4	Male	4009	Heart Weight	Replacement	NT
4	29	4	Male	4009	Kidneys Weight	Replacement	NT
4	29	4	Male	4009	Liver Weight	Replacement	NT
4	29	4	Male	4009	Lungs Weight	Replacement	NT
4	29	4	Male	4009	Testes Weight	Replacement	NT
4	29	4	Male	4009	Spleen Weight	Replacement	NT

Appendix 08a - Organ Weights - males**PR1000 - 28 Day Repeated Dose Study in the Rat**

Key Page**General Footnotes**

Control Group is Group

Replacement Values

<u>Value</u>	<u>Description</u>
NT	Not Taken

Measurement Descriptions

<u>Headings Used</u>	<u>Description</u>
Terminal Body Wt.	Terminal Bodyweight
Organ Weights - Adrenals	Adrenal Glands (Both) Weight
Organ Weights - Brain	Brain Weight
Organ Weights - Heart	Heart Weight
Organ Weights - Kidneys	Kidneys Weight
Organ Weights - Liver	Liver Weight
Organ Weights - Lungs	Lungs Weight
Organ Weights - Testes	Testes Weight
Organ Weights - Spleen	Spleen Weight

Unit Descriptions

<u>Headings Used</u>	<u>Description</u>
g	g

Appendix 08a - Organ Weights - males

PR1000 - 28 Day Repeated Dose Study in the Rat

Key Page**Time-Points/Ranges**

<u>Measurement</u>	<u>From</u>	<u>To</u>	<u>Report As</u>
Terminal Body Wt.	-9,999	9,999	29
Organ Weights - Adrenals	-9,999	9,999	29
Organ Weights - Brain	-9,999	9,999	29
Organ Weights - Heart	-9,999	9,999	29
Organ Weights - Kidneys	-9,999	9,999	29
Organ Weights - Liver	-9,999	9,999	29
Organ Weights - Lungs	-9,999	9,999	29
Organ Weights - Testes	-9,999	9,999	29
Organ Weights - Spleen	-9,999	9,999	29

Measurement/Statistics

<u>Measurement</u>	<u>Descriptive</u>
Terminal Body Wt.	Mean Standard Deviation Count (N)
Organ Weights - Adrenals	Mean Standard Deviation Count (N) Median
Organ Weights - Brain	Mean Standard Deviation Count (N)
Organ Weights - Heart	Mean Standard Deviation Count (N)

Appendix 08a - Organ Weights - males

PR1000 - 28 Day Repeated Dose Study in the Rat

Key Page**Measurement/Statistics (Continued)**

<u>Measurement</u>	<u>Descriptive</u>
Organ Weights - Kidneys	Mean Standard Deviation Count (N)
Organ Weights - Liver	Mean Standard Deviation Count (N)
Organ Weights - Lungs	Mean Standard Deviation Count (N)
Organ Weights - Testes	Mean Standard Deviation Count (N)
Organ Weights - Spleen	Mean Standard Deviation Count (N)

Group Information

<u>Short Name</u>	<u>Long Name</u>	<u>Type</u>	<u>Report Headings 1-4</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

Comment Abbreviations

RC = Result Comment

Appendix 08a - Organ Weights - males

PR1000 - 28 Day Repeated Dose Study in the Rat

End of Print
