

Generalized Results - Animals by Mixed Parameter / Time

For Study: PR1000
Title: 28 Day Repeated Dose Study in the Rat
Requested By: Danielle Gardner
Job Number: 31921
Base Day is Day: 1
Start Period: Day -9999 Relative to Start Date
End Period: Day 9999 Relative to Start Date
Subject Reference: Subject Name
Subjects Included: 1001, 1002, 1003, 1004, 1005, 1006, 1007, 1008, 1009, 1010, 4001, 4002, 4003, 4004, 4005, 4006, 4007, 4008, 4009, 4010, 1101, 1102, 1103, 1104, 1105, 1106, 1107, 1108, 1109, 1110, 4101, 4102, 4103, 4104, 4105, 4106, 4107, 4108, 4109, 4110
Groups: 1, 4
Measurements: Sodium, Potassium, Creatinine, Albumin, Alkaline Phosphatase, Glucose, Calcium, Aspartate Aminotransferase, Alanine Aminotransferase
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 05b - Chemistry by parameter

PR1000 - 28 Day Repeated Dose Study in the Rat

Sex: Male Day(s) Relative to Start Date

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Appendix 05b - Chemistry by parameter**PR1000 - 28 Day Repeated Dose Study in the Rat**

Sex: Male Day(s) Relative to Start Date

1000 mg/kg/day	Chemistry											
	Sodium (mmol/L)	Sodium (mmol/L)	Sodium (mmol/L)	Sodium (mmol/L)	Potassium (mmol/L)	Potassium (mmol/L)	Potassium (mmol/L)	Potassium (mmol/L)	Creatin- ine (µmol/L)	Creatin- ine (µmol/L)	Creatin- ine (µmol/L)	Creatin- ine (µmol/L)
	-7	1	15	29	-7	1	15	29	-7	1	15	29
4001	146	147	141	140	5.7	5.8	4.7	7.0	60	59	73	50
4002	146	147	141	140	5.7	5.7	5.5	4.3	63	59	102	78
4003	149	145	141	.	5.7	5.9	5.6	.	62	50	68	.
4004	145	148	143	139	5.9	5.9	5.0	6.9	60	65	52	85
4005	148	147	139	140	5.9	5.7	6.1	7.1	62	62	97	36
4006	144	142	141	137	5.7	5.8	5.7	5.3	60	36	46	69
4007	143	146	139	140	5.7	5.7	5.7	7.7	60	54	46	97
4008	147	148	140	139	5.6	5.6	5.6	7.1	62	65	40	43
4009	142	142	142	.	5.6	5.6	5.6	.	61	37	53	.
4010	146	144	141	139	5.8	5.7	5.8	7.5	60	48	25	33
Mean	145.6	145.6	140.8	139.3	5.73	5.74	5.53	6.61	61.0	53.5	60.2	61.4
SD	2.2	2.3	1.2	1.0	0.11	0.11	0.40	1.18	1.2	10.6	24.7	24.1
N	10	10	10	8	10	10	10	8	10	10	10	8

Appendix 05b - Chemistry by parameter**PR1000 - 28 Day Repeated Dose Study in the Rat**

Sex: Male Day(s) Relative to Start Date

1000 mg/kg/day	Chemistry											
	Albumin (g/dL)	Albumin (g/dL)	Albumin (g/dL)	Albumin (g/dL)	ALP (IU/L)	ALP (IU/L)	ALP (IU/L)	ALP (IU/L)	Glucose (mmol/L)	Glucose (mmol/L)	Glucose (mmol/L)	Glucose (mmol/L)
	-7	1	15	29	-7	1	15	29	-7	1	15	29
4001	40.9	40.6	42.4	45.9	134	135	192	165	6.2	6.2	8.2	6.8
4002	40.9	41.0	38.8	47.4	136	134	136	177	6.4	6.6	5.7	7.0
4003	40.3	41.4	30.9	.	132	135	146	.	6.6	6.6	7.0	.
4004	41.3	40.0	40.7	40.1	135	132	61	76	6.6	6.6	7.3	7.0
4005	41.1	40.5	45.2	37.1	134	136	207	140	6.4	6.3	5.5	6.9
4006	39.4	39.5	37.2	29.2	133	136	87	96	6.6	6.4	7.2	8.9
4007	40.5	40.7	49.4	38.0	135	134	145	190	6.6	6.5	7.5	6.2
4008	41.2	40.2	32.5	43.7	135	132	144	99	6.2	6.6	7.6	5.8
4009	39.4	41.5	43.0	.	133	133	179	.	6.6	6.5	6.5	.
4010	40.1	39.5	49.0	36.9	133	133	169	139	6.4	6.3	5.4	6.5
Mean	40.51	40.49	40.91	39.79	134.0	134.0	146.6	135.3	6.46	6.46	6.79	6.89
SD	0.70	0.70	6.25	5.87	1.2	1.5	45.0	41.5	0.16	0.15	0.97	0.92
N	10	10	10	8	10	10	10	8	10	10	10	8

Appendix 05b - Chemistry by parameter**PR1000 - 28 Day Repeated Dose Study in the Rat**

Sex: Male Day(s) Relative to Start Date

1000 mg/kg/day	Chemistry											
	Calcium (mmol/L)	Calcium (mmol/L)	Calcium (mmol/L)	Calcium (mmol/L)	AST (IU/L)	AST (IU/L)	AST (IU/L)	AST (IU/L)	ALT (IU/L)	ALT (IU/L)	ALT (IU/L)	ALT (IU/L)
	-7	1	15	29	-7	1	15	29	-7	1	15	29
4001	3.05	3.07	1.06	4.45	66	68	63	69	63.3	92.3	384.5	976.9
4002	3.01	3.08	3.64	1.36	66	68	85	91	65.0	93.0	387.2	984.9
4003	3.02	3.03	3.07	.	66	67	57	.	66.5	95.9	389.6	.
4004	2.95	2.93	3.94	1.18	66	63	52	39	66.7	98.4	391.3	991.9
4005	2.96	3.03	2.37	4.41	66	66	71	69	68.2	100.6	401.4	992.7
4006	3.07	3.08	3.68	4.53	66	64	49	46	70.8	101.3	404.0	1006.1
4007	2.89	2.93	1.48	3.44	66	69	72	62	71.6	102.8	405.2	1008.0
4008	3.06	3.08	4.96	3.44	66	64	53	71	73.6	104.8	411.4	1011.5
4009	3.08	2.94	2.45	.	66	64	39	.	74.9	104.8	412.6	.
4010	3.05	2.98	4.53	1.64	66	66	85	27	79.4	106.8	412.9	1020.8
Mean	3.014	3.015	3.118	3.056	66.0	65.9	62.6	59.3	70.00	100.07	400.01	999.10
SD	0.062	0.065	1.273	1.446	0.0	2.1	15.4	20.6	5.00	5.05	11.00	14.83
N	10	10	10	8	10	10	10	8	10	10	10	8

Appendix 05b - Chemistry by parameter

PR1000 - 28 Day Repeated Dose Study in the Rat

Sex: Female Day(s) Relative to Start Date

Appendix 05b - Chemistry by parameter

PR1000 - 28 Day Repeated Dose Study in the Rat

Sex: Female Day(s) Relative to Start Date

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PR1000 - 28 Day Repeated Dose Study in the Rat

Sex: Female Day(s) Relative to Start Date

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PR1000 - 28 Day Repeated Dose Study in the Rat

Sex: Female Day(s) Relative to Start Date

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Sex: Female Day(s) Relative to Start Date

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PR1000 - 28 Day Repeated Dose Study in the Rat

Sex: Female Day(s) Relative to Start Date

Appendix 05b - Chemistry by parameter**PR1000 - 28 Day Repeated Dose Study in the Rat**

[Key Page](#)**Measurement Descriptions**

<u>Headings Used</u>	<u>Description</u>
Chemistry - Sodium	Sodium
Chemistry - Potassium	Potassium
Chemistry - Creatin- ine	Creatinine
Chemistry - Albumin	Albumin
Chemistry - ALP	Alkaline Phosphatase
Chemistry - Glucose	Glucose
Chemistry - Calcium	Calcium
Chemistry - AST	Aspartate Aminotransferase
Chemistry - ALT	Alanine Aminotransferase

Unit Descriptions

<u>Headings Used</u>	<u>Description</u>
µmol/L	µmol/L
g/dL	g/dL
IU/L	IU/L
mmol/L	mmol/L

Measurement/Statistics

<u>Measurement</u>	<u>Descriptive</u>
Chemistry - Sodium	Mean
	Standard Deviation
	Count (N)

Appendix 05b - Chemistry by parameter**PR1000 - 28 Day Repeated Dose Study in the Rat**

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

<u>Measurement</u>	<u>Descriptive</u>
Chemistry - Potassium	Mean Standard Deviation Count (N)
Chemistry - Creatin- ine	Mean Standard Deviation Count (N)
Chemistry - Albumin	Mean Standard Deviation Count (N)
Chemistry - ALP	Mean Standard Deviation Count (N)
Chemistry - Glucose	Mean Standard Deviation Count (N)
Chemistry - Calcium	Mean Standard Deviation Count (N)
Chemistry - AST	Mean Standard Deviation Count (N)
Chemistry - ALT	Mean Standard Deviation Count (N)

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Key Page**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
4	4 - High Dose	Dose	1000 mg/kg/day

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