

GRA309 - 01/00

Provantis 12.0.1 EDSVC

1/16/2026 9:19:00AM

Generalized Results - Group Summary by Mixed Parameter / Time (Groups Across Top)

For Study:	PR1000
Title:	28 Day Repeated Dose Study in the Rat
Requested By:	Danielle Gardner
Job Number:	31661
Base Day is Day:	1
Start Period:	Day -7 Relative to Start Date
End Period:	Day 29 Relative to Start Date
Subject Reference:	Subject Name
Subjects Excluded:	None
Groups:	All
Measurements:	Sodium, Potassium, Creatinine, Albumin, Alkaline Phosphatase, Glucose, Calcium, Aspartate Aminotransferase, Alanine Aminotransferase
Selected for Duplicate Results:	First value
Analysis by Sex:	Split
Style:	Portrait - Groups across the top
Exclusion Profile:	None

Table 05b - Chemistry - by Parameter

PR1000 - 28 Day Repeated Dose Study in the Rat

Sex: Male			0 mg/kg/day	100 mg/kg/day	500 mg/kg/day	1000 mg/kg/day
Day(s) Relative to Start Date						
Sodium (mmol/L)	-7	Mean	145.5	145.0	140.9	145.6
		SD	0.7	5.8	1.5	2.2
		N	10	10	10	10
	1	Mean	145.5	145.2	140.9	145.6
		SD	0.7	5.7	1.4	2.3
		N	10	10	10	10
	15	Mean	145.4	143.7	143.4	140.8
		SD	1.9	0.8	1.3	1.2
		N	10	10	10	10
	29	Mean	144.9	143.0	141.1	139.3
		SD	1.4	1.4	1.4	1.0
		N	10	9	10	8
Potassium (mmol/L)	-7	Mean	5.93	6.08	5.46	5.73
		SD	0.08	0.37	0.11	0.11
		N	10	10	10	10
	1	Mean	5.95	6.07	5.49	5.74
		SD	0.36	0.38	0.10	0.11
		N	10	10	10	10
	15	Mean	6.16	5.84	5.28	5.53
		SD	1.52	0.87	0.87	0.40
		N	10	10	10	10
	29	Mean	6.19	6.17	6.20	6.61
		SD	1.14	1.00	1.18	1.18
		N	10	9	10	8
Creatinine (μ mol/L)	-7	Mean	64.8	45.8	61.0	61.0
		SD	5.4	10.6	1.2	1.2
		N	10	10	10	10
	1	Mean	64.8	45.7	61.1	53.5
		SD	5.2	10.5	10.5	10.6
		N	10	10	10	10
	15	Mean	57.4	46.6	61.6	60.2
		SD	22.8	10.6	12.5	24.7
		N	10	10	10	10
	29	Mean	57.3	46.0	62.5	61.4
		SD	20.0	10.1	24.1	24.1
		N	10	9	10	8

Table 05b - Chemistry - by Parameter

PR1000 - 28 Day Repeated Dose Study in the Rat

Sex: Male			0 mg/kg/day	100 mg/kg/day	500 mg/kg/day	1000 mg/kg/day
Day(s) Relative to Start Date						
Albumin (g/dL)	-7	Mean	39.51	42.00	38.00	40.51
		SD	0.70	4.21	4.19	0.70
		N	10	10	10	10
	1	Mean	39.50	42.00	37.99	40.49
		SD	0.70	4.20	4.19	0.70
		N	10	10	10	10
	15	Mean	37.85	39.84	34.30	40.91
		SD	2.94	5.00	4.26	6.25
		N	10	10	10	10
	29	Mean	36.20	38.72	34.14	39.79
		SD	6.15	7.82	5.64	5.87
		N	10	9	10	8
Alkaline Phosp'tase (IU/L)	-7	Mean	133.7	181.7	139.7	134.0
		SD	0.8	69.6	10.2	1.2
		N	10	10	10	10
	1	Mean	133.6	181.6	139.6	134.0
		SD	1.0	69.7	10.5	1.5
		N	10	10	10	10
	15	Mean	131.1	157.5	140.6	146.6
		SD	23.7	49.0	47.9	45.0
		N	10	10	10	10
	29	Mean	128.3	150.7	143.1	135.3
		SD	47.1	42.5	48.6	41.5
		N	10	9	10	8
Glucose (mmol/L)	-7	Mean	6.54	5.84	6.40	6.46
		SD	0.13	0.50	0.13	0.16
		N	10	10	10	10
	1	Mean	6.56	5.83	6.40	6.46
		SD	0.11	0.52	0.14	0.15
		N	10	10	10	10
	15	Mean	6.77	6.19	6.34	6.79
		SD	1.02	0.93	0.79	0.97
		N	10	10	10	10
	29	Mean	6.40	6.39	6.39	6.89
		SD	0.96	0.92	0.60	0.92
		N	10	9	10	8

Table 05b - Chemistry - by Parameter

PR1000 - 28 Day Repeated Dose Study in the Rat

Sex: Male			0 mg/kg/day	100 mg/kg/day	500 mg/kg/day	1000 mg/kg/day
Day(s) Relative to Start Date						
Calcium (mmol/L)	-7	Mean	2.968	3.734	3.060	3.014
		SD	0.062	1.080	0.063	0.062
		N	10	10	10	10
	1	Mean	2.972	3.735	3.060	3.015
		SD	0.064	1.081	0.063	0.065
		N	10	10	10	10
	15	Mean	2.473	3.201	2.732	3.118
		SD	1.110	1.360	1.143	1.273
		N	10	10	10	10
	29	Mean	2.939	4.036	2.701	3.056
		SD	1.151	0.756	1.344	1.446
		N	10	9	10	8
AST (IU/L)	-7 [a]	Mean	63.2	66.0	56.9 ***	66.0
		SD	4.3	4.3	2.0	0.0
		N	10	10	10	10
	1 [a]	Mean	62.9	66.0	56.9 ***	65.9
		SD	4.1	4.3	2.1	2.1
		N	10	10	10	10
	15 [a]	Mean	59.7	62.9	67.1	62.6
		SD	21.4	23.1	19.4	15.4
		N	10	10	10	10
	29 [a]	Mean	65.1	63.7	71.1	59.3
		SD	13.1	16.7	11.8	20.6
		N	10	9	10	8
ALT (IU/L)	-7 [c]	Mean	70.01	70.00	70.01	70.00
		SD	5.01	5.00	4.99	5.00
		N	10	10	10	10
	1 [c]	Mean	70.00	80.00 ***	90.00 ***	100.07 ***
		SD	5.00	4.99	4.99	5.05
		N	10	10	10	10
	15 [c]	Mean	69.98	200.00 ***	300.05 ***	400.01 ***
		SD	4.98	7.99	9.95	11.00
		N	10	10	10	10
	29 [c]	Mean	70.01	419.09 ***	799.99 ***	999.10 ***
		SD	5.00	10.15	15.01	14.83
		N	10	9	10	8

Table 05b - Chemistry - by Parameter

PR1000 - 28 Day Repeated Dose Study in the Rat

Sex: Female			0 mg/kg/day	100 mg/kg/day	500 mg/kg/day	1000 mg/kg/day
Day(s) Relative to Start Date						
Sodium (mmol/L)	-7	Mean	146.0	145.9	146.1	148.1
		SD	2.1	1.4	1.4	1.9
		N	10	10	10	10
	1	Mean	146.0	145.2	147.0	148.0
		SD	1.3	5.7	4.9	6.0
		N	10	10	10	10
	15	Mean	145.6	144.3	142.6	141.1
		SD	1.3	1.6	1.3	1.3
		N	10	10	10	10
	29	Mean	144.8	143.0	140.9	138.8
		SD	1.7	1.1	1.5	1.5
		N	10	10	10	10
Potassium (mmol/L)	-7	Mean	5.27	5.82	5.68	5.95
		SD	1.06	0.18	1.19	0.20
		N	10	10	10	10
	1	Mean	5.81	5.81	5.68	5.96
		SD	0.16	0.19	0.19	0.20
		N	10	10	10	10
	15	Mean	5.46	6.12	6.12	6.03
		SD	0.98	1.04	1.32	0.90
		N	10	10	10	10
	29	Mean	5.22	5.57	5.81	5.84
		SD	1.11	1.37	1.27	1.30
		N	10	10	10	10
Creatinine (μ mol/L)	-7	Mean	61.0	65.0	60.8	68.7
		SD	0.0	5.3	6.1	2.4
		N	10	10	10	10
	1	Mean	64.8	61.1	60.9	68.8
		SD	5.4	10.7	12.0	15.1
		N	10	10	10	10
	15	Mean	64.8	63.1	63.3	69.8
		SD	23.9	10.7	11.5	21.3
		N	10	10	10	10
	29	Mean	65.3	65.5	65.9	70.5
		SD	26.2	11.0	22.9	22.1
		N	10	10	10	10

Table 05b - Chemistry - by Parameter

PR1000 - 28 Day Repeated Dose Study in the Rat

Sex: Female			0 mg/kg/day	100 mg/kg/day	500 mg/kg/day	1000 mg/kg/day
Day(s) Relative to Start Date						
Albumin (g/dL)	-7	Mean	38.99	39.50	41.00	39.99
		SD	3.99	0.70	1.01	1.39
		N	10	10	10	10
	1	Mean	39.49	42.99	41.01	40.01
		SD	0.72	0.79	0.90	1.41
		N	10	10	10	10
	15	Mean	41.36	43.53	41.88	37.50
		SD	3.17	8.44	7.31	7.62
		N	10	10	10	10
	29	Mean	43.21	40.41	41.68	37.69
		SD	6.18	6.35	6.34	8.10
		N	10	10	10	10
Alkaline Phosp'tase (IU/L)	-7	Mean	135.6	134.0	135.0	134.4
		SD	0.7	1.5	1.5	1.3
		N	10	10	10	10
	1	Mean	134.1	138.3	135.1	134.4
		SD	1.4	1.5	1.4	1.6
		N	10	10	10	10
	15	Mean	139.8	152.4	139.5	131.7
		SD	21.1	43.2	44.5	46.1
		N	10	10	10	10
	29	Mean	145.5	148.4	143.1	151.9
		SD	43.5	51.5	43.6	51.4
		N	10	10	10	10
Glucose (mmol/L)	-7	Mean	6.27	6.41	6.35	6.56
		SD	0.07	0.10	0.07	0.05
		N	10	10	10	10
	1	Mean	6.39	6.51	6.30	6.55
		SD	0.11	0.03	0.00	0.05
		N	10	10	10	10
	15	Mean	6.42	6.62	6.66	6.42
		SD	0.79	0.87	1.02	0.85
		N	10	10	10	10
	29	Mean	6.39	6.64	7.00	7.01
		SD	0.91	0.94	1.07	0.90
		N	10	10	10	10

Table 05b - Chemistry - by Parameter

PR1000 - 28 Day Repeated Dose Study in the Rat

Sex: Female			0 mg/kg/day	100 mg/kg/day	500 mg/kg/day	1000 mg/kg/day
Day(s) Relative to Start Date						
Calcium (mmol/L)	-7	Mean	3.016	3.037	3.084	3.060
		SD	0.226	0.033	0.031	0.089
		N	10	10	10	10
	1	Mean	3.037	3.150	3.084	3.059
		SD	0.032	0.127	0.029	0.055
		N	10	10	10	10
	15	Mean	3.725	3.616	3.070	2.682
		SD	1.210	1.274	1.294	1.357
		N	10	10	10	10
	29	Mean	2.963	2.815	2.999	2.634
		SD	1.498	1.383	1.310	1.268
		N	10	10	10	10
AST (IU/L)	-7 [a]	Mean	61.6	63.1	66.0 **	55.5 ***
		SD	4.1	4.1	0.0	1.3
		N	10	10	10	10
	1 [a]	Mean	63.0	63.7	66.0	55.5 *
		SD	4.2	5.1	5.8	6.3
		N	10	10	10	10
	15 [a]	Mean	65.0	67.4	59.8	66.0
		SD	23.5	17.2	24.9	13.2
		N	10	10	10	10
	29 [a]	Mean	58.9	59.2	59.3	73.5
		SD	12.1	18.2	15.8	28.4
		N	10	10	10	10
ALT (IU/L)	-7 [c]	Mean	66.00	64.99 ***	65.01 ***	64.99 ***
		SD	1.09	0.12	0.10	0.11
		N	10	10	10	10
	1 [c]	Mean	64.99	65.66	67.49	72.04 ***
		SD	2.79	0.11	0.97	5.01
		N	10	10	10	10
	15 [c]	Mean	65.00	100.01 ***	179.99 ***	250.00 ***
		SD	4.20	2.00	4.00	4.99
		N	10	10	10	10
	29 [c]	Mean	65.00	200.00 ***	299.49 ***	451.50 ***
		SD	2.80	7.10	2.10	8.70
		N	10	10	10	10

Table 05b - Chemistry - by Parameter

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>Measurement</u>	<u>Marker</u>
3	-7	3	Male	AST	***
		<i>Comment:</i>	Anova & Dunnett, 2-Sided: *** = $p < 0.001$		
3	1	3	Male	AST	***
		<i>Comment:</i>	Anova & Dunnett, 2-Sided: *** = $p < 0.001$		
3	1	2	Male	ALT	***
		<i>Comment:</i>	Anova & Dunnett, 2-Sided: *** = $p < 0.001$		
3	15	2	Male	ALT	***
		<i>Comment:</i>	Anova & Dunnett, 2-Sided: *** = $p < 0.001$		
3	29	2	Male	ALT	***
		<i>Comment:</i>	Anova & Dunnett, 2-Sided: *** = $p < 0.001$		
3	1	3	Male	ALT	***
		<i>Comment:</i>	Anova & Dunnett, 2-Sided: *** = $p < 0.001$		
3	15	3	Male	ALT	***
		<i>Comment:</i>	Anova & Dunnett, 2-Sided: *** = $p < 0.001$		
3	29	3	Male	ALT	***
		<i>Comment:</i>	Anova & Dunnett, 2-Sided: *** = $p < 0.001$		
3	1	4	Male	ALT	***
		<i>Comment:</i>	Anova & Dunnett, 2-Sided: *** = $p < 0.001$		
3	15	4	Male	ALT	***
		<i>Comment:</i>	Anova & Dunnett, 2-Sided: *** = $p < 0.001$		
3	29	4	Male	ALT	***
		<i>Comment:</i>	Anova & Dunnett, 2-Sided: *** = $p < 0.001$		
6	-7	3	Female	AST	**
		<i>Comment:</i>	Anova & Dunnett, 2-Sided: ** = $p < 0.01$		
6	-7	4	Female	AST	***
		<i>Comment:</i>	Anova & Dunnett, 2-Sided: *** = $p < 0.001$		
6	1	4	Female	AST	*
		<i>Comment:</i>	Anova & Dunnett, 2-Sided: * = $p < 0.05$		
6	-7	2	Female	ALT	***
		<i>Comment:</i>	Anova & Dunnett, 2-Sided: *** = $p < 0.001$		
6	15	2	Female	ALT	***
		<i>Comment:</i>	Anova & Dunnett, 2-Sided: *** = $p < 0.001$		
6	29	2	Female	ALT	***
		<i>Comment:</i>	Anova & Dunnett, 2-Sided: *** = $p < 0.001$		
6	-7	3	Female	ALT	***
		<i>Comment:</i>	Anova & Dunnett, 2-Sided: *** = $p < 0.001$		
6	15	3	Female	ALT	***
		<i>Comment:</i>	Anova & Dunnett, 2-Sided: *** = $p < 0.001$		
6	29	3	Female	ALT	***
		<i>Comment:</i>	Anova & Dunnett, 2-Sided: *** = $p < 0.001$		

Table 05b - Chemistry - by Parameter

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>Measurement</u>	<u>Marker</u>
6	-7	4	Female	ALT	***
		<i>Comment:</i> Anova & Dunnett, 2-Sided: *** = $p < 0.001$			
6	1	4	Female	ALT	***
		<i>Comment:</i> Anova & Dunnett, 2-Sided: *** = $p < 0.001$			
6	15	4	Female	ALT	***
		<i>Comment:</i> Anova & Dunnett, 2-Sided: *** = $p < 0.001$			
6	29	4	Female	ALT	***
		<i>Comment:</i> Anova & Dunnett, 2-Sided: *** = $p < 0.001$			

Table 05b - Chemistry - by Parameter

PR1000 - 28 Day Repeated Dose Study in the Rat

Key Page

Measurement Descriptions

<u>Headings Used</u>	<u>Description</u>
Sodium	Sodium
Potassium	Potassium
Creatinine	Creatinine
Albumin	Albumin
Alkaline Phosph'tase	Alkaline Phosphatase
Glucose	Glucose
Calcium	Calcium
AST	Aspartate Aminotransferase
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>	<u>Comparative</u>	Arithmetic <u>/Adjusted</u>	<u>Transformation</u>
Sodium	Mean Standard Deviation Count (N)			
Potassium	Mean Standard Deviation Count (N)			
Creatinine	Mean Standard Deviation Count (N)			
Albumin	Mean Standard Deviation Count (N)			
Alkaline Phosphatase	Mean Standard Deviation Count (N)			
Glucose	Mean Standard Deviation Count (N)			

Table 05b - Chemistry - by Parameter

PR1000 - 28 Day Repeated Dose Study in the Rat

Key Page

Measurement/Statistics (Continued)

<u>Measurement</u>	<u>Descriptive</u>	<u>Comparative</u>	<u>Arithmetic</u> <u>/Adjusted</u>	<u>Transformation</u>
Calcium	Mean Standard Deviation Count (N)			
Aspartate Aminotransferase	Mean Standard Deviation Count (N)	Anova & Dunnett's 2 Sided	Arithmetic	Identity (No Transformation)
Alanine Aminotransferase	Mean Standard Deviation Count (N)	AnCova & Dunnett's 2 Sided	Arithmetic	Identity (No Transformation)

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

Pairwise Comparisons

<u>Group</u>	<u>Vs</u>	<u>Group</u>
1		2
1		3
1		4

Table 05b - Chemistry - by Parameter

PR1000 - 28 Day Repeated Dose Study in the Rat

End of Print
