

Table 6-2 Urinalysis - Summary

B130235

Day: -12 Relative to Start Date

Sex: Female		Urine Color				
		Sampled	Normal	Colorless	Red	Other
0 mg/kg	N+ve	.	1	0	1	0
	Total	2	.	.	.	.
1 mg/kg	N+ve	.	2	0	0	0
	Total	2	.	.	.	.
10 mg/kg	N+ve	.	2	0	0	0
	Total	2	.	.	.	.
30 mg/kg	N+ve	.	2	0	0	0
	Total	2	.	.	.	.

Table 6-2 Urinalysis - Summary

B130235

Day: 25 Relative to Start Date

Sex: Male		Urine Color				
		Sampled	Normal	Colorless	Red	Other
0 mg/kg	N+ve	.	2	0	0	0
	Total	2	.	.	.	.
1 mg/kg	N+ve	.	2	0	0	0
	Total	2	.	.	.	.
10 mg/kg	N+ve	.	2	0	0	0
	Total	2	.	.	.	.
30 mg/kg	N+ve	.	2	0	0	0
	Total	2	.	.	.	.

Table 6-2 Urinalysis - Summary

B130235

Day: 25 Relative to Start Date

Sex: Female		Urine Color				
		Sampled	Normal	Colorless	Red	Other
0 mg/kg	N+ve	.	2	0	0	0
	Total	2	.	.	.	.
1 mg/kg	N+ve	.	2	0	0	0
	Total	2	.	.	.	.
10 mg/kg	N+ve	.	2	0	0	0
	Total	2	.	.	.	.
30 mg/kg	N+ve	.	2	0	0	0
	Total	2	.	.	.	.

Table 6-2 Urinalysis - Summary

B130235

Day(s) Relative to Start Date

Sex: Male		Urinalysis									
		Specific Gravity	Specific Gravity	Urine Volume (mL)	Urine Volume (mL)	Na (mmol)	Na (mmol)	K (mmol)	K (mmol)	Cl (mmol)	Cl (mmol)
		-12	25	-12	25	-12	25	-12	25	-12	25
0 mg/kg	Mean	1.0295	1.0215	77.0	78.5	4.163	2.870	6.663	6.433	5.555	2.414
	N	2	2	2	2	2	2	2	2	2	2
1 mg/kg	Mean	1.0210	1.0215	114.5	187.5	3.232	4.794	6.609	8.289	3.742	5.193
	N	2	2	2	2	2	2	2	2	2	2
10 mg/kg	Mean	1.0225	1.0120	102.5	255.5	5.399	7.378	8.952	10.527	6.081	7.494
	N	2	2	2	2	2	2	2	2	2	2
30 mg/kg	Mean	1.0215	1.0245	85.5	87.0	3.486	2.238	7.357	8.954	6.540	6.138
	N	2	2	2	2	2	2	2	2	2	2

Table 6-2 Urinalysis - Summary

B130235

Day(s) Relative to Start Date

Sex: Female		Urinalysis									
		Specific Gravity	Specific Gravity	Urine Volume (mL)	Urine Volume (mL)	Na (mmol)	Na (mmol)	K (mmol)	K (mmol)	Cl (mmol)	Cl (mmol)
		-12	25	-12	25	-12	25	-12	25	-12	25
0 mg/kg	Mean	1.0200	1.0180	93.5	143.5	2.300	3.364	5.253	7.357	3.634	3.364
	N	2	2	2	2	2	2	2	2	2	2
1 mg/kg	Mean	1.0330	1.0195	47.0	60.5	3.677	2.056	5.054	5.128	2.939	1.546
	N	2	2	2	2	2	2	2	2	2	2
10 mg/kg	Mean	1.0155	1.0125	145.5	131.5	7.683	4.007	8.375	7.284	6.851	2.890
	N	2	2	2	2	2	2	2	2	2	2
30 mg/kg	Mean	1.0330	1.0255	34.0	38.5	2.258	2.244	2.505	5.101	2.668	2.377
	N	2	2	2	2	2	2	2	2	2	2

- 938 -

Table 7 Hematology - Summary

B130235

Day(s) Relative to Start Date

Sex: Male		Hematology											
		Red Blood Cell Count (10 <sup>6</sup> /μL)	Red Blood Cell Count (10 <sup>6</sup> /μL)	Hemoglobin conc. (g/dL)	Hemoglobin conc. (g/dL)	Hematocrit (%)	Hematocrit (%)	MCV (fL)	MCV (fL)	MCH (pg)	MCH (pg)	MCHC (g/dL)	MCHC (g/dL)
		-6	28	-6	28	-6	28	-6	28	-6	28	-6	28
0 mg/kg	Mean	5.490	4.810	13.45	12.45	44.00	40.15	80.25	84.00	24.55	26.10	30.60	31.05
	N	2	2	2	2	2	2	2	2	2	2	2	2
1 mg/kg	Mean	5.340	5.150	12.85	12.60	43.50	43.20	81.60	84.10	24.15	24.55	29.55	29.15
	N	2	2	2	2	2	2	2	2	2	2	2	2
10 mg/kg	Mean	5.550	4.645	14.05	11.60	46.80	40.95	84.30	88.15	25.30	24.95	30.05	28.30
	N	2	2	2	2	2	2	2	2	2	2	2	2
30 mg/kg	Mean	5.350	4.240	13.25	10.60	44.65	37.00	83.35	87.25	24.75	25.00	29.70	28.65
	N	2	2	2	2	2	2	2	2	2	2	2	2

Table 7 Hematology - Summary

B130235

Day(s) Relative to Start Date

Sex: Male		Hematology											
		Platelet Count (10 <sup>3</sup> /μL)	Platelet Count (10 <sup>3</sup> /μL)	Reticulocyte (%)	Reticulocyte (%)	PT (sec)	PT (sec)	APTT (sec)	APTT (sec)	White Blood Cell Count (10 <sup>3</sup> /μL)	White Blood Cell Count (10 <sup>3</sup> /μL)	Lymphocyte (%)	Lymphocyte (%)
		-6	28	-6	28	-6	28	-6	28	-6	28	-6	28
0 mg/kg	Mean	368.0	269.5	0.680	0.960	8.85	9.25	22.00	22.30	6.395	7.780	44.45	40.55
	N	2	2	2	2	2	2	2	2	2	2	2	2
1 mg/kg	Mean	296.0	287.5	0.580	1.010	8.60	8.65	21.75	20.90	7.770	6.795	63.95	62.30
	N	2	2	2	2	2	2	2	2	2	2	2	2
10 mg/kg	Mean	399.0	477.5	0.920	2.085	9.00	8.50	22.25	21.10	7.805	9.475	51.05	40.70
	N	2	2	2	2	2	2	2	2	2	2	2	2
30 mg/kg	Mean	421.5	570.5	0.760	3.115	8.85	8.50	23.40	22.45	9.190	9.105	43.60	40.20
	N	2	2	2	2	2	2	2	2	2	2	2	2

Table 7 Hematology - Summary

B130235

Day(s) Relative to Start Date

Sex: Male		Hematology											
		Neutrophil	Neutrophil	Eosinophil	Eosinophil	Basophil	Basophil	Monocyte	Monocyte	Lymphocyte	Lymphocyte	Neutrophil	Neutrophil
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(10 <sup>3</sup> /μL)	(10 <sup>3</sup> /μL)	(10 <sup>3</sup> /μL)	(10 <sup>3</sup> /μL)
		-6	28	-6	28	-6	28	-6	28	-6	28	-6	28
0 mg/kg	Mean	50.65	53.25	1.05	0.55	0.00	0.00	3.85	5.65	2.830	2.415	3.285	4.820
	N	2	2	2	2	2	2	2	2	2	2	2	2
1 mg/kg	Mean	27.95	29.75	3.30	2.25	0.05	0.00	4.75	5.70	4.985	4.250	2.150	2.005
	N	2	2	2	2	2	2	2	2	2	2	2	2
10 mg/kg	Mean	44.20	55.35	0.70	0.40	0.00	0.00	4.05	3.55	3.980	3.805	3.470	5.295
	N	2	2	2	2	2	2	2	2	2	2	2	2
30 mg/kg	Mean	50.60	51.95	0.90	1.15	0.00	0.00	4.90	6.70	4.015	3.635	4.635	4.755
	N	2	2	2	2	2	2	2	2	2	2	2	2



Table 7 Hematology - Summary

B130235

Day(s) Relative to Start Date

Sex: Male		Hematology					
		Eosinophil (10 <sup>3</sup> /μL)	Eosinophil (10 <sup>3</sup> /μL)	Basophil (10 <sup>3</sup> /μL)	Basophil (10 <sup>3</sup> /μL)	Monocyte (10 <sup>3</sup> /μL)	Monocyte (10 <sup>3</sup> /μL)
		-6	28	-6	28	-6	28
0 mg/kg	Mean	0.060	0.045	0.000	0.000	0.220	0.500
	N	2	2	2	2	2	2
1 mg/kg	Mean	0.255	0.145	0.005	0.000	0.375	0.395
	N	2	2	2	2	2	2
10 mg/kg	Mean	0.050	0.030	0.000	0.000	0.305	0.345
	N	2	2	2	2	2	2
30 mg/kg	Mean	0.065	0.105	0.000	0.000	0.475	0.610
	N	2	2	2	2	2	2

Table 7 Hematology - Summary

B130235

Day(s) Relative to Start Date

Sex: Female		Hematology											
		Red Blood Cell Count (10 <sup>6</sup> /μL)	Red Blood Cell Count (10 <sup>6</sup> /μL)	Hemoglobin conc. (g/dL)	Hemoglobin conc. (g/dL)	Hematocrit (%)	Hematocrit (%)	MCV (fL)	MCV (fL)	MCH (pg)	MCH (pg)	MCHC (g/dL)	MCHC (g/dL)
		-6	28	-6	28	-6	28	-6	28	-6	28	-6	28
0 mg/kg	Mean	5.340	5.115	12.80	12.35	42.90	42.15	80.35	82.40	23.95	24.15	29.85	29.30
	N	2	2	2	2	2	2	2	2	2	2	2	2
1 mg/kg	Mean	5.595	5.220	13.45	12.75	44.90	43.05	80.25	82.40	24.05	24.40	29.95	29.65
	N	2	2	2	2	2	2	2	2	2	2	2	2
10 mg/kg	Mean	5.755	5.365	13.50	12.75	46.30	44.10	80.65	82.40	23.55	23.85	29.15	28.90
	N	2	2	2	2	2	2	2	2	2	2	2	2
30 mg/kg	Mean	5.395	3.795	13.20	9.40	43.80	33.65	81.20	88.65	24.50	24.75	30.15	27.95
	N	2	2	2	2	2	2	2	2	2	2	2	2

Table 7 Hematology - Summary

B130235

Day(s) Relative to Start Date

Sex: Female		Hematology											
		Platelet Count (10 <sup>3</sup> /μL)	Platelet Count (10 <sup>3</sup> /μL)	Reticulocyte (%)	Reticulocyte (%)	PT (sec)	PT (sec)	APTT (sec)	APTT (sec)	White Blood Cell Count (10 <sup>3</sup> /μL)	White Blood Cell Count (10 <sup>3</sup> /μL)	Lymphocyte (%)	Lymphocyte (%)
		-6	28	-6	28	-6	28	-6	28	-6	28	-6	28
0 mg/kg	Mean	407.5	395.5	0.805	1.130	8.65	8.50	22.80	23.35	8.565	8.955	37.80	49.35
	N	2	2	2	2	2	2	2	2	2	2	2	2
1 mg/kg	Mean	370.0	385.5	0.950	1.795	8.00	8.40	19.90	20.50	5.635	5.730	53.95	51.25
	N	2	2	2	2	2	2	2	2	2	2	2	2
10 mg/kg	Mean	474.5	470.5	0.860	1.660	8.20	8.25	23.50	23.80	10.050	9.900	45.00	44.25
	N	2	2	2	2	2	2	2	2	2	2	2	2
30 mg/kg	Mean	337.0	461.0	0.820	6.125	8.60	8.50	20.30	20.75	7.045	7.210	63.00	60.10
	N	2	2	2	2	2	2	2	2	2	2	2	2

Table 7 Hematology - Summary

B130235

Day(s) Relative to Start Date

Sex: Female		Hematology											
		Neutrophil	Neutrophil	Eosinophil	Eosinophil	Basophil	Basophil	Monocyte	Monocyte	Lymphocyte	Lymphocyte	Neutrophil	Neutrophil
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(10 <sup>3</sup> /μL)	(10 <sup>3</sup> /μL)	(10 <sup>3</sup> /μL)	(10 <sup>3</sup> /μL)
		-6	28	-6	28	-6	28	-6	28	-6	28	-6	28
0 mg/kg	Mean	56.50	42.10	1.85	3.25	0.00	0.05	3.85	5.25	3.240	4.310	4.835	3.840
	N	2	2	2	2	2	2	2	2	2	2	2	2
1 mg/kg	Mean	41.60	43.35	0.45	0.75	0.00	0.00	4.00	4.65	3.030	2.945	2.355	2.475
	N	2	2	2	2	2	2	2	2	2	2	2	2
10 mg/kg	Mean	48.95	48.80	1.95	1.80	0.00	0.00	4.10	5.15	4.560	4.330	4.885	4.895
	N	2	2	2	2	2	2	2	2	2	2	2	2
30 mg/kg	Mean	33.80	34.95	0.20	0.60	0.00	0.00	3.00	4.35	4.580	4.545	2.245	2.310
	N	2	2	2	2	2	2	2	2	2	2	2	2

Table 7 Hematology - Summary

B130235

Day(s) Relative to Start Date

Sex: Female		Hematology					
		Eosinophil (10 <sup>3</sup> /μL)	Eosinophil (10 <sup>3</sup> /μL)	Basophil (10 <sup>3</sup> /μL)	Basophil (10 <sup>3</sup> /μL)	Monocyte (10 <sup>3</sup> /μL)	Monocyte (10 <sup>3</sup> /μL)
		-6	28	-6	28	-6	28
0 mg/kg	Mean	0.160	0.330	0.000	0.005	0.330	0.470
	N	2	2	2	2	2	2
1 mg/kg	Mean	0.025	0.045	0.000	0.000	0.225	0.265
	N	2	2	2	2	2	2
10 mg/kg	Mean	0.185	0.165	0.000	0.000	0.420	0.510
	N	2	2	2	2	2	2
30 mg/kg	Mean	0.015	0.040	0.000	0.000	0.205	0.315
	N	2	2	2	2	2	2

Table 8 Blood Chemistry - Summary

B130235

Day(s) Relative to Start Date

Sex: Male		Blood Chemistry											
		ASAT (U/L)	ASAT (U/L)	ALAT (U/L)	ALAT (U/L)	LDH (U/L)	LDH (U/L)	ALP (U/L)	ALP (U/L)	Creatine Kinase (U/L)	Creatine Kinase (U/L)	Total Bilirubin (mg/dL)	Total Bilirubin (mg/dL)
		-6	28	-6	28	-6	28	-6	28	-6	28	-6	28
0 mg/kg	Mean	34.0	29.0	36.0	35.5	321.5	269.5	1023.0	1020.0	101.0	38.0	0.20	0.15
	N	2	2	2	2	2	2	2	2	2	2	2	2
1 mg/kg	Mean	40.5	28.0	52.0	37.5	333.5	230.0	1005.5	789.5	102.5	46.0	0.15	0.10
	N	2	2	2	2	2	2	2	2	2	2	2	2
10 mg/kg	Mean	50.0	35.5	62.0	51.5	355.5	332.0	1135.5	953.5	161.5	74.5	0.25	0.10
	N	2	2	2	2	2	2	2	2	2	2	2	2
30 mg/kg	Mean	33.5	36.5	35.0	52.0	283.0	295.0	1034.5	852.0	71.0	122.5	0.10	0.05
	N	2	2	2	2	2	2	2	2	2	2	2	2

Table 8 Blood Chemistry - Summary

B130235

Day(s) Relative to Start Date

Sex: Male		Blood Chemistry											
		Urea Nitrogen (mg/dL)	Urea Nitrogen (mg/dL)	Creatinine (mg/dL)	Creatinine (mg/dL)	Glucose (mg/dL)	Glucose (mg/dL)	Total Cholesterol (mg/dL)	Total Cholesterol (mg/dL)	Phospholipid (mg/dL)	Phospholipid (mg/dL)	Triglyceride (mg/dL)	Triglyceride (mg/dL)
		-6	28	-6	28	-6	28	-6	28	-6	28	-6	28
0 mg/kg	Mean	16.65	17.95	1.00	0.95	76.0	72.5	111.5	116.0	175.0	166.5	26.0	31.5
	N	2	2	2	2	2	2	2	2	2	2	2	2
1 mg/kg	Mean	16.40	17.50	0.80	0.85	75.5	76.0	73.5	74.5	122.0	122.0	34.5	34.5
	N	2	2	2	2	2	2	2	2	2	2	2	2
10 mg/kg	Mean	21.15	18.00	1.25	1.25	80.5	77.5	96.5	89.0	148.5	132.0	24.5	49.5
	N	2	2	2	2	2	2	2	2	2	2	2	2
30 mg/kg	Mean	16.40	15.35	1.10	0.90	89.5	76.5	77.0	73.5	135.5	123.5	44.0	43.0
	N	2	2	2	2	2	2	2	2	2	2	2	2

- 948 -

Table 8 Blood Chemistry - Summary

B130235

Day(s) Relative to Start Date

Sex: Male		Blood Chemistry											
		Total Protein (g/dL)	Total Protein (g/dL)	A/G Ratio	A/G Ratio	Albumin (%)	Albumin (%)	Alpha1 Globulin (%)	Alpha1 Globulin (%)	Alpha2 Globulin (%)	Alpha2 Globulin (%)	Beta Globulin (%)	Beta Globulin (%)
		-6	28	-6	28	-6	28	-6	28	-6	28	-6	28
0 mg/kg	Mean	8.25	7.90	1.505	1.380	60.05	58.00	3.55	3.50	10.60	11.15	14.20	13.95
	N	2	2	2	2	2	2	2	2	2	2	2	2
1 mg/kg	Mean	7.90	7.90	1.600	1.515	61.45	60.15	3.05	3.45	10.45	9.10	11.60	12.15
	N	2	2	2	2	2	2	2	2	2	2	2	2
10 mg/kg	Mean	8.50	7.80	1.465	1.055	59.40	50.75	3.30	4.15	9.95	9.70	14.10	17.10
	N	2	2	2	2	2	2	2	2	2	2	2	2
30 mg/kg	Mean	8.45	7.90	1.475	1.190	59.50	54.10	3.20	3.10	10.25	10.45	14.70	16.85
	N	2	2	2	2	2	2	2	2	2	2	2	2



Table 8 Blood Chemistry - Summary

B130235

Day(s) Relative to Start Date

Sex: Male		Blood Chemistry											
		Gamma Globulin (%)	Gamma Globulin (%)	Albumin (g/dL)	Albumin (g/dL)	Alpha1 Globulin (g/dL)	Alpha1 Globulin (g/dL)	Alpha2 Globulin (g/dL)	Alpha2 Globulin (g/dL)	Beta Globulin (g/dL)	Beta Globulin (g/dL)	Gamma Globulin (g/dL)	Gamma Globulin (g/dL)
		-6	28	-6	28	-6	28	-6	28	-6	28	-6	28
0 mg/kg	Mean	11.60	13.40	4.95	4.58	0.29	0.28	0.87	0.88	1.17	1.10	0.96	1.06
	N	2	2	2	2	2	2	2	2	2	2	2	2
1 mg/kg	Mean	13.45	15.15	4.86	4.76	0.24	0.27	0.83	0.72	0.92	0.96	1.06	1.20
	N	2	2	2	2	2	2	2	2	2	2	2	2
10 mg/kg	Mean	13.25	18.30	5.05	3.98	0.28	0.32	0.85	0.76	1.20	1.33	1.13	1.41
	N	2	2	2	2	2	2	2	2	2	2	2	2
30 mg/kg	Mean	12.35	15.50	5.03	4.28	0.27	0.25	0.87	0.83	1.24	1.33	1.04	1.22
	N	2	2	2	2	2	2	2	2	2	2	2	2

- 950 -

Table 8 Blood Chemistry - Summary

B130235

Day(s) Relative to Start Date

Sex: Male		Blood Chemistry									
		Ca (mg/dL)	Ca (mg/dL)	Inorganic Phosphorus (mg/dL)	Inorganic Phosphorus (mg/dL)	Na (mmol/L)	Na (mmol/L)	K (mmol/L)	K (mmol/L)	Cl (mmol/L)	Cl (mmol/L)
		-6	28	-6	28	-6	28	-6	28	-6	28
0 mg/kg	Mean	10.65	10.45	4.15	4.80	153.5	153.0	5.45	5.25	112.0	110.0
	N	2	2	2	2	2	2	2	2	2	2
1 mg/kg	Mean	10.55	10.50	6.70	6.35	152.5	152.5	5.40	5.40	110.0	109.5
	N	2	2	2	2	2	2	2	2	2	2
10 mg/kg	Mean	10.20	9.75	5.65	5.55	155.0	152.5	5.50	5.25	111.0	108.5
	N	2	2	2	2	2	2	2	2	2	2
30 mg/kg	Mean	10.45	9.70	5.70	5.90	154.5	151.5	5.00	5.55	111.5	111.0
	N	2	2	2	2	2	2	2	2	2	2

Table 8 Blood Chemistry - Summary

B130235

Day(s) Relative to Start Date

Sex: Female		Blood Chemistry											
		ASAT (U/L)	ASAT (U/L)	ALAT (U/L)	ALAT (U/L)	LDH (U/L)	LDH (U/L)	ALP (U/L)	ALP (U/L)	Creatine Kinase (U/L)	Creatine Kinase (U/L)	Total Bilirubin (mg/dL)	Total Bilirubin (mg/dL)
		-6	28	-6	28	-6	28	-6	28	-6	28	-6	28
0 mg/kg	Mean	39.5	27.0	58.0	39.0	341.5	275.5	593.0	584.0	70.0	82.0	0.20	0.15
	N	2	2	2	2	2	2	2	2	2	2	2	2
1 mg/kg	Mean	33.5	30.0	48.0	43.5	269.5	271.0	567.0	548.5	37.5	44.0	0.15	0.05
	N	2	2	2	2	2	2	2	2	2	2	2	2
10 mg/kg	Mean	28.5	23.0	35.5	30.0	243.0	205.5	550.0	584.5	61.0	30.5	0.15	0.05
	N	2	2	2	2	2	2	2	2	2	2	2	2
30 mg/kg	Mean	28.5	33.0	31.0	37.5	265.0	274.0	453.5	409.0	49.0	86.0	0.20	0.05
	N	2	2	2	2	2	2	2	2	2	2	2	2

- 952 -

Table 8 Blood Chemistry - Summary

B130235

Day(s) Relative to Start Date

Sex: Female		Blood Chemistry											
		Urea Nitrogen (mg/dL)	Urea Nitrogen (mg/dL)	Creatinine (mg/dL)	Creatinine (mg/dL)	Glucose (mg/dL)	Glucose (mg/dL)	Total Cholesterol (mg/dL)	Total Cholesterol (mg/dL)	Phospholipid (mg/dL)	Phospholipid (mg/dL)	Triglyceride (mg/dL)	Triglyceride (mg/dL)
		-6	28	-6	28	-6	28	-6	28	-6	28	-6	28
0 mg/kg	Mean	15.05	15.40	0.90	0.85	78.0	89.0	131.0	137.0	185.0	171.5	29.0	21.5
	N	2	2	2	2	2	2	2	2	2	2	2	2
1 mg/kg	Mean	15.85	16.50	0.85	0.80	79.5	96.0	104.0	99.0	168.5	146.5	58.5	51.5
	N	2	2	2	2	2	2	2	2	2	2	2	2
10 mg/kg	Mean	14.25	14.05	0.75	0.75	80.5	83.0	106.0	109.5	171.0	171.0	50.0	39.5
	N	2	2	2	2	2	2	2	2	2	2	2	2
30 mg/kg	Mean	16.20	15.50	1.05	0.85	90.0	87.5	133.0	106.0	190.0	139.0	30.5	27.5
	N	2	2	2	2	2	2	2	2	2	2	2	2