

Appendix 4 Hematology

B120719

Sex: Female Day(s) Relative to Start Date

500 mg/kg	Hematology											
	Hematocrit	Hematocrit	Hematocrit	Hematocrit	Hematocrit	Hematocrit	MCV	MCV	MCV	MCV	MCV	MCV
	(%)	(%)	(%)	(%)	(%)	(%)	(fL)	(fL)	(fL)	(fL)	(fL)	(fL)
	-46	-4	5	10	11	14	-46	-4	5	10	11	14
50401	40.9	42.7	75.2	77.8
50402	45.9	43.8	61.4 ! ¹	.	.	.	77.9	79.6	80.4 ! ²	.	.	.
50403	40.7	40.9	.	.	39.3	.	83.4	82.8	.	.	83.3	.

[Day 5 and 10 : Moribundity.]

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

1 [RC:Re-analysis due to sample outside of the assay range]

2 [RC:The value was re-calculated due to re-analysis of RBC and HCT after dilution.]

Appendix 4 Hematology

B120719

Sex: Female Day(s) Relative to Start Date

500 mg/kg	Hematology											
	MCH	MCH	MCH	MCH	MCH	MCH	MCHC	MCHC	MCHC	MCHC	MCHC	MCHC
	(pg)	(pg)	(pg)	(pg)	(pg)	(pg)	(g/dL)	(g/dL)	(g/dL)	(g/dL)	(g/dL)	(g/dL)
	-46	-4	5	10	11	14	-46	-4	5	10	11	14
50401	23.0	23.0	30.6	29.5
50402	24.4	24.5	26.3 ! ¹	.	.	.	31.4	30.8	32.7 ! ²	.	.	.
50403	24.4	25.1	.	.	24.4	.	29.2	30.3	.	.	29.3	.

[Day 5 and 10 : Moribundity.]

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

1 [RC:The value was re-calculated due to re-analysis of RBC after dilution.]

2 [RC:The value was re-calculated due to re-analysis of HCT after dilution.]

Appendix 4 Hematology

B120719

Sex: Female Day(s) Relative to Start Date

500 mg/kg	Hematology											
	Reticulocyte	Reticulocyte	Reticulocyte	Reticulocyte	Reticulocyte	Reticulocyte						
	(%)	(%)	(%)	(%)	(%)	(%)	(10 ⁹ /L)					
	-46	-4	5	10	11	14	-46	-4	5	10	11	14
50401	0.39	0.57	21.2	31.3
50402	0.44	1.31	1.20	.	.	.	25.9	72.1	91.7 ¹	.	.	.
50403	1.09	0.42	.	.	0.77	.	53.2	20.7	.	.	36.3	.

[Day 5 and 10 : Moribundity.]

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

1 [RC:The value was re-calculated due to re-analysis of RBC after dilution.]

Appendix 4 Hematology

B120719

Sex: Female Day(s) Relative to Start Date

500 mg/kg	Hematology											
	Platelet Count (10 ³ /uL)	PT (sec)										
	-46	-4	5	10	11	14	-46	-4	5	10	11	14
50401	502	457	8.1	8.6
50402	461	376	653	.	.	.	9.9	9.6	9.6	.	.	.
50403	293	252	.	.	297	.	8.5	8.7	.	.	8.3	.

[Day 5 and 10 : Moribundity.]

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

Appendix 4 Hematology

B120719

Sex: Female Day(s) Relative to Start Date

500 mg/kg	Hematology											
	APTT (sec)	APTT (sec)	APTT (sec)	APTT (sec)	APTT (sec)	APTT (sec)	White Blood Cell Count (10 ³ /uL)					
	-46	-4	5	10	11	14	-46	-4	5	10	11	14
50401	20.8	22.6	9.63	10.42
50402	19.2	20.5	27.3	.	.	.	9.10	7.80	9.23	.	.	.
50403	20.1	21.1	.	.	19.9	.	5.27	5.11	.	.	7.20	.

[Day 5 and 10 : Moribundity.]

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

Appendix 4 Hematology

B120719

Sex: Female Day(s) Relative to Start Date

500 mg/kg	Hematology											
	Lymphocyte	Lymphocyte	Lymphocyte	Lymphocyte	Lymphocyte	Lymphocyte	Neutrophil	Neutrophil	Neutrophil	Neutrophil	Neutrophil	Neutrophil
	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
	-46	-4	5	10	11	14	-46	-4	5	10	11	14
50401	54.5	53.5	42.9	43.6
50402	64.7	67.9	34.1	.	.	.	29.9	27.0	53.9	.	.	.
50403	56.7	59.9	.	.	49.3	.	40.5	38.1	.	.	46.3	.

[Day 5 and 10 : Moribundity.]

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

Appendix 4 Hematology

B120719

Sex: Female Day(s) Relative to Start Date

500 mg/kg	Hematology											
	Eosinophil	Eosinophil	Eosinophil	Eosinophil	Eosinophil	Eosinophil	Basophil	Basophil	Basophil	Basophil	Basophil	Basophil
	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
	-46	-4	5	10	11	14	-46	-4	5	10	11	14
50401	0.3	0.6	0.0	0.0
50402	1.6	1.5	0.1	.	.	.	0.1	0.1	0.1	.	.	.
50403	0.0	0.0	.	.	0.1	.	0.0	0.0	.	.	0.1	.

[Day 5 and 10 : Moribundity.]

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

Appendix 4 Hematology

B120719

Sex: Female Day(s) Relative to Start Date

500 mg/kg	Hematology											
	Monocyte	Monocyte	Monocyte	Monocyte	Monocyte	Monocyte	Lymphocyte	Lymphocyte	Lymphocyte	Lymphocyte	Lymphocyte	Lymphocyte
	(%)	(%)	(%)	(%)	(%)	(%)	(10 ³ /uL)					
	-46	-4	5	10	11	14	-46	-4	5	10	11	14
50401	2.3	2.3	5.25	5.57
50402	3.7	3.5	11.8	.	.	.	5.89	5.30	3.15	.	.	.
50403	2.8	2.0	.	.	4.2	.	2.99	3.06	.	.	3.55	.

[Day 5 and 10 : Moribundity.]

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

Appendix 4 Hematology

B120719

Sex: Female Day(s) Relative to Start Date

500 mg/kg	Hematology											
	Neutrophil (10 ³ /uL)	Eosinophil (10 ³ /uL)										
	-46	-4	5	10	11	14	-46	-4	5	10	11	14
50401	4.13	4.55	0.03	0.06
50402	2.71	2.10	4.97	.	.	.	0.15	0.12	0.01	.	.	.
50403	2.13	1.95	.	.	3.33	.	0.00	0.00	.	.	0.01	.

[Day 5 and 10 : Moribundity.]

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

Appendix 4 Hematology

B120719

Sex: Female Day(s) Relative to Start Date

500 mg/kg	Hematology											
	Basophil (10 ³ /uL)	Monocyte (10 ³ /uL)										
	-46	-4	5	10	11	14	-46	-4	5	10	11	14
50401	0.00	0.00	0.22	0.24
50402	0.01	0.01	0.01	.	.	.	0.34	0.27	1.09	.	.	.
50403	0.00	0.00	.	.	0.01	.	0.15	0.10	.	.	0.30	.

[Day 5 and 10 : Moribundity.]

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

Appendix 5 Blood Chemistry

B120719

Sex: Male Day(s) Relative to Start Date

0 mg/kg	Blood Chemistry											
	ASAT	ASAT	ASAT	ASAT	ALAT	ALAT	ALAT	ALAT	LDH	LDH	LDH	LDH
	(U/L)	(U/L)	(U/L)	(U/L)	(U/L)	(U/L)	(U/L)	(U/L)	(U/L)	(U/L)	(U/L)	(U/L)
	-46	-4	11	14	-46	-4	11	14	-46	-4	11	14
10101	27	28	.	28	18	16	.	21	224	240	.	239
10102	44	31	.	36	41	24	.	41	221	208	.	298
10103	80	34	.	34	57	33	.	38	512	263	.	291

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

Appendix 5 Blood Chemistry

B120719

Sex: Male Day(s) Relative to Start Date

0 mg/kg	Blood Chemistry											
	Gamma GT (U/L)	Gamma GT (U/L)	Gamma GT (U/L)	Gamma GT (U/L)	ALP (U/L)	ALP (U/L)	ALP (U/L)	ALP (U/L)	Creatine Kinase (U/L)	Creatine Kinase (U/L)	Creatine Kinase (U/L)	Creatine Kinase (U/L)
	-46	-4	11	14	-46	-4	11	14	-46	-4	11	14
10101	126	118	.	111	2532	2633	.	2868	150	273	.	93
10102	134	119	.	92	1900	1533	.	1641	90	98	.	104
10103	96	128	.	103	2024	2603	.	3040	654	77	.	96

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

Appendix 5 Blood Chemistry

B120719

Sex: Male Day(s) Relative to Start Date

0 mg/kg	Blood Chemistry											
	Total Bilirubin (mg/dL)	Total Bilirubin (mg/dL)	Total Bilirubin (mg/dL)	Total Bilirubin (mg/dL)	Urea Nitrogen (mg/dL)	Urea Nitrogen (mg/dL)	Urea Nitrogen (mg/dL)	Urea Nitrogen (mg/dL)	Creatinine (mg/dL)	Creatinine (mg/dL)	Creatinine (mg/dL)	Creatinine (mg/dL)
	-46	-4	11	14	-46	-4	11	14	-46	-4	11	14
10101	0.2	0.1	.	0.2	21.5	19.8	.	19.7	0.9	0.9	.	0.9
10102	0.2	0.2	.	0.1	16.3	18.9	.	18.0	0.8	0.7	.	0.7
10103	0.2	0.2	.	0.2	24.5	22.8	.	23.4	0.8	0.8	.	0.8

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

Appendix 5 Blood Chemistry

B120719

Sex: Male Day(s) Relative to Start Date

0 mg/kg	Blood Chemistry											
	Glucose (mg/dL)	Glucose (mg/dL)	Glucose (mg/dL)	Glucose (mg/dL)	Total Cholesterol (mg/dL)	Total Cholesterol (mg/dL)	Total Cholesterol (mg/dL)	Total Cholesterol (mg/dL)	Phospholipid (mg/dL)	Phospholipid (mg/dL)	Phospholipid (mg/dL)	Phospholipid (mg/dL)
	-46	-4	11	14	-46	-4	11	14	-46	-4	11	14
10101	80	85	.	90	157	153	.	152	203	210	.	212
10102	99	104	.	103	139	126	.	117	199	185	.	181
10103	87	80	.	91	115	112	.	109	147	160	.	153

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

Appendix 5 Blood Chemistry

B120719

Sex: Male Day(s) Relative to Start Date

0 mg/kg	Blood Chemistry											
	Triglyceride (mg/dL)	Triglyceride (mg/dL)	Triglyceride (mg/dL)	Triglyceride (mg/dL)	Total Protein (g/dL)	Total Protein (g/dL)	Total Protein (g/dL)	Total Protein (g/dL)	Ca (mg/dL)	Ca (mg/dL)	Ca (mg/dL)	Ca (mg/dL)
	-46	-4	11	14	-46	-4	11	14	-46	-4	11	14
10101	15	30	.	24	7.8	7.5	.	7.8	11.4	11.1	.	10.1
10102	24	23	.	31	7.8	7.6	.	7.6	12.3	11.8	.	10.9
10103	21	30	.	31	7.5	7.3	.	7.4	9.9	9.7	.	9.4

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

Appendix 5 Blood Chemistry

B120719

Sex: Male Day(s) Relative to Start Date

0 mg/kg	Blood Chemistry											
	Inorganic Phosphorus (mg/dL)	Inorganic Phosphorus (mg/dL)	Inorganic Phosphorus (mg/dL)	Inorganic Phosphorus (mg/dL)	Na (mmol/L)	Na (mmol/L)	Na (mmol/L)	Na (mmol/L)	K (mmol/L)	K (mmol/L)	K (mmol/L)	K (mmol/L)
	-46	-4	11	14	-46	-4	11	14	-46	-4	11	14
10101	6.5	6.7	.	5.8	160	157	.	152	5.5	5.1	.	4.5
10102	6.4	6.9	.	5.7	165	160	.	158	6.3	6.2	.	4.8
10103	5.2	6.6	.	5.6	152	152	.	149	4.6	5.2	.	4.3

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

Appendix 5 Blood Chemistry

B120719

Sex: Male Day(s) Relative to Start Date

0 mg/kg	Blood Chemistry											
	Cl	Cl	Cl	Cl	A/G Ratio	A/G Ratio	A/G Ratio	A/G Ratio	Albumin	Albumin	Albumin	Albumin
	(mmol/L)	(mmol/L)	(mmol/L)	(mmol/L)					(%)	(%)	(%)	(%)
	-46	-4	11	14	-46	-4	11	14	-46	-4	11	14
10101	113	110	.	107	1.46	1.54	.	1.48	59.4	60.7	.	59.7
10102	114	112	.	107	1.48	1.34	.	1.42	59.7	57.2	.	58.6
10103	109	111	.	108	1.74	1.66	.	1.67	63.5	62.4	.	62.6

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

Appendix 5 Blood Chemistry

B120719

Sex: Male Day(s) Relative to Start Date

0 mg/kg	Blood Chemistry											
	Albumin (g/dL)	Albumin (g/dL)	Albumin (g/dL)	Albumin (g/dL)	Alpha1 Globulin (%)	Alpha1 Globulin (%)	Alpha1 Globulin (%)	Alpha1 Globulin (%)	Alpha2 Globulin (%)	Alpha2 Globulin (%)	Alpha2 Globulin (%)	Alpha2 Globulin (%)
	-46	-4	11	14	-46	-4	11	14	-46	-4	11	14
10101	4.6	4.5	.	4.7	3.1	3.7	.	3.4	8.6	8.8	.	8.5
10102	4.7	4.4	.	4.5	3.5	3.1	.	3.5	10.0	10.8	.	10.1
10103	4.8	4.6	.	4.6	2.2	2.6	.	3.2	12.3	13.1	.	13.1

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

Appendix 5 Blood Chemistry

B120719

Sex: Male Day(s) Relative to Start Date

0 mg/kg	Blood Chemistry											
	Beta Globulin (%)	Beta Globulin (%)	Beta Globulin (%)	Beta Globulin (%)	Gamma Globulin (%)	Gamma Globulin (%)	Gamma Globulin (%)	Gamma Globulin (%)	Alpha1 Globulin (g/dL)	Alpha1 Globulin (g/dL)	Alpha1 Globulin (g/dL)	Alpha1 Globulin (g/dL)
	-46	-4	11	14	-46	-4	11	14	-46	-4	11	14
10101	16.9	15.5	.	14.7	12.0	11.3	.	13.7	0.2	0.3	.	0.3
10102	14.7	15.2	.	14.2	12.1	13.7	.	13.6	0.3	0.2	.	0.3
10103	10.4	8.8	.	8.3	11.6	13.1	.	12.8	0.2	0.2	.	0.2

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]

Appendix 5 Blood Chemistry

B120719

Sex: Male Day(s) Relative to Start Date

0 mg/kg	Blood Chemistry											
	Alpha2 Globulin (g/dL)	Alpha2 Globulin (g/dL)	Alpha2 Globulin (g/dL)	Alpha2 Globulin (g/dL)	Beta Globulin (g/dL)	Beta Globulin (g/dL)	Beta Globulin (g/dL)	Beta Globulin (g/dL)	Gamma Globulin (g/dL)	Gamma Globulin (g/dL)	Gamma Globulin (g/dL)	Gamma Globulin (g/dL)
	-46	-4	11	14	-46	-4	11	14	-46	-4	11	14
10101	0.7	0.7	.	0.7	1.3	1.2	.	1.1	0.9	0.8	.	1.1
10102	0.8	0.8	.	0.8	1.1	1.2	.	1.1	0.9	1.0	.	1.0
10103	0.9	1.0	.	1.0	0.8	0.6	.	0.6	0.9	1.0	.	0.9

[Dose level was changed from 500 mg/kg to 250 mg/kg on Day 5.]