

## Appendix 6

## Organ Weight

B120719

Sex: Male Day(s) Relative to Start Date

500 mg/kg	Organ Weights (Monkey)												
	Final Body Weight (Kg)	Brain (g)	Brain Ratio (%)	Pituitary (mg)	Pituitary Ratio (^3%)	Thyroid (L) (mg)	Thyroid (L)Ratio (^3%)	Thyroid (R) (mg)	Thyroid (R)Ratio (^3%)	Thyroids (mg)	Thyroids Ratio (^3%)	Thymus (g)	Thymus Ratio (^3%)
	11	11	11	11	11	11	11	11	11	11	11	11	11
10401	3.2	62.8	1.963	66	2.06	359	11.22	357	11.16	716	22.38	0.49	15.3
10402	2.8	62.8	2.243	63	2.25	260	9.29	267	9.54	527	18.82	0.67	23.9

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

Appendix 6 Organ Weight

B120719

Sex: Male Day(s) Relative to Start Date

500 mg/kg	Organ Weights (Monkey)												
	Submand. GL (L) (g)	Submand. GLs (L)Ratio (^3%)	Submand. GL (R) (g)	Submand. GLs (R)Ratio (^3%)	Submand. GLs (g)	Submand. GLs Ratio (^3%)	Lungs (g)	Lungs Ratio (%)	Heart (g)	Heart Ratio (%)	Liver (g)	Liver Ratio (%)	Spleen (g)
	11	11	11	11	11	11	11	11	11	11	11	11	11
10401	0.99	30.9	1.04	32.5	2.03	63.4	15.70	0.491	11.48	0.359	62.6	1.96	2.83
10402	1.26	45.0	1.22	43.6	2.48	88.6	15.93	0.569	11.23	0.401	71.0	2.54	2.05

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

## Appendix 6

## Organ Weight

B120719

Sex: Male Day(s) Relative to Start Date

500 mg/kg	Organ Weights (Monkey)												
	Spleen Ratio (%)	Pancreas (g)	Pancreas Ratio (%)	Kidney (L) (g)	Kidney (L) Ratio (%)	Kidney (R) (g)	Kidney (R) Ratio (%)	Kidneys (g)	Kidneys Ratio (%)	Adrenal (L) (mg)	Adrenal (L) Ratio (^-3%)	Adrenal (R) (mg)	Adrenal (R) Ratio (^-3%)
	11	11	11	11	11	11	11	11	11	11	11	11	11
10401	0.088	4.85	0.152	7.30	0.228	7.19	0.225	14.49	0.453	506	15.81	355	11.09
10402	0.073	4.73	0.169	7.50	0.268	7.44	0.266	14.94	0.534	492	17.57	415	14.82

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

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## Organ Weight

B120719

Sex: Male Day(s) Relative to Start Date

500 mg/kg	Organ Weights (Monkey)												
	Adrenals (mg)	Adrenals Ratio (^-3%)	Testis (L) (g)	Testis (L)Ratio (^-3%)	Testis (R) (g)	Testis (R)Ratio (^-3%)	Testes (g)	Testes Ratio (^-3%)	Prostate (g)	Prostate Ratio (^-3%)	Seminal vesicle (g)	Seminal ves. Ratio (^-3%)	Epididymis (L) (g)
	11	11	11	11	11	11	11	11	11	11	11	11	11
10401	861	26.91	1.13	35.3	1.03	32.2	2.16	67.5	0.91	28.4	1.67	52.2	0.64
10402	907	32.39	0.86	30.7	0.89	31.8	1.75	62.5	0.59	21.1	0.85	30.4	0.48

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

Appendix 6 Organ Weight

B120719

Sex: Male Day(s) Relative to Start Date

500 mg/kg	Organ Weights (Monkey)				
	Epididymis (L)Ratio (^3%)	Epididymis (R) (g)	Epididymis (R)Ratio (^3%)	Epididymides (g)	Epididymides Ratio (^3%)
	11	11	11	11	11
10401	20.0	0.53	16.6	1.17	36.6
10402	17.1	0.48	17.1	0.96	34.3

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

Appendix 6 Organ Weight

B120719

Sex: Male Day(s) Relative to Start Date

150 mg/kg	Organ Weights (Monkey)												
	Final Body Weight (Kg)	Brain (g)	Brain Ratio (%)	Pituitary (mg)	Pituitary Ratio (^-3%)	Thyroid (L) (mg)	Thyroid (L)Ratio (^-3%)	Thyroid (R) (mg)	Thyroid (R)Ratio (^-3%)	Thyroids (mg)	Thyroids Ratio (^-3%)	Thymus (g)	Thymus Ratio (^-3%)
	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR
10301	2.8	-	-	-	-	-	-	-	-	-	-	-	-
10302	2.6	-	-	-	-	-	-	-	-	-	-	-	-
10303	3.1	63.8	2.058	65	2.10	244	7.87	245	7.90	489	15.77	0.55	17.7

[MOR : Death or Moribundity.]

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

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## Organ Weight

B120719

Sex: Male Day(s) Relative to Start Date

150 mg/kg	Organ Weights (Monkey)												
	Submand. GL (L) (g)	Submand. GLs (L)Ratio (^3%)	Submand. GL (R) (g)	Submand. GLs (R)Ratio (^3%)	Submand. GLs (g)	Submand. GLs Ratio (^3%)	Lungs (g)	Lungs Ratio (%)	Heart (g)	Heart Ratio (%)	Liver (g)	Liver Ratio (%)	Spleen (g)
	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR
10301	-	-	-	-	-	-	-	-	-	-	-	-	-
10302	-	-	-	-	-	-	-	-	-	-	-	-	-
10303	0.96	31.0	0.98	31.6	1.94	62.6	15.66	0.505	10.17	0.328	58.4	1.88	1.60

[MOR : Death or Moribundity.]

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

Appendix 6 Organ Weight

B120719

Sex: Male Day(s) Relative to Start Date

150 mg/kg	Organ Weights (Monkey)												
	Spleen Ratio (%)	Pancreas (g)	Pancreas Ratio (%)	Kidney (L) (g)	Kidney (L) Ratio (%)	Kidney (R) (g)	Kidney (R) Ratio (%)	Kidneys (g)	Kidneys Ratio (%)	Adrenal (L) (mg)	Adrenal (L) Ratio (^-3%)	Adrenal (R) (mg)	Adrenal (R) Ratio (^-3%)
	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR
10301	-	-	-	-	-	-	-	-	-	-	-	-	-
10302	-	-	-	-	-	-	-	-	-	-	-	-	-
10303	0.052	3.18	0.103	6.70	0.216	7.19	0.232	13.89	0.448	365	11.77	308	9.94

[MOR : Death or Moribundity.]

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

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## Organ Weight

B120719

Sex: Male Day(s) Relative to Start Date

150 mg/kg	Organ Weights (Monkey)												
	Adrenals (mg)	Adrenals Ratio (^3%)	Testis (L) (g)	Testis (L)Ratio (^3%)	Testis (R) (g)	Testis (R)Ratio (^3%)	Testes (g)	Testes Ratio (^3%)	Prostate (g)	Prostate Ratio (^3%)	Seminal vesicle (g)	Seminal ves. Ratio (^3%)	Epididymis (L) (g)
	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR
10301	-	-	-	-	-	-	-	-	-	-	-	-	-
10302	-	-	-	-	-	-	-	-	-	-	-	-	-
10303	673	21.71	2.25	72.6	2.35	75.8	4.60	148.4	2.19	70.6	3.19	102.9	0.58

[MOR : Death or Moribundity.]

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

Appendix 6 Organ Weight

B120719

Sex: Male Day(s) Relative to Start Date

150 mg/kg	Organ Weights (Monkey)				
	Epididymis (L)Ratio (^3%)	Epididymis (R) (g)	Epididymis (R)Ratio (^3%)	Epididymides (g)	Epididymides Ratio (^3%)
	MOR	MOR	MOR	MOR	MOR
10301	-	-	-	-	-
10302	-	-	-	-	-
10303	18.7	0.62	20.0	1.20	38.7

[MOR : Death or Moribundity.]

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

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Organ Weight

B120719

Sex: Male Day(s) Relative to Start Date

500 mg/kg	Organ Weights (Monkey)												
	Final Body Weight (Kg)	Brain (g)	Brain Ratio (%)	Pituitary (mg)	Pituitary Ratio (^-3%)	Thyroid (L) (mg)	Thyroid (L)Ratio (^-3%)	Thyroid (R) (mg)	Thyroid (R)Ratio (^-3%)	Thyroids (mg)	Thyroids Ratio (^-3%)	Thymus (g)	Thymus Ratio (^-3%)
	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR
10403	2.5	-	-	-	-	-	-	-	-	-	-	-	-

[MOR : Death or Moribundity.]

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

Appendix 6 Organ Weight

B120719

Sex: Male Day(s) Relative to Start Date

500 mg/kg	Organ Weights (Monkey)												
	Submand. GL (L) (g)	Submand. GLs (L)Ratio (^3%)	Submand. GL (R) (g)	Submand. GLs (R)Ratio (^3%)	Submand. GLs (g)	Submand. GLs Ratio (^3%)	Lungs (g)	Lungs Ratio (%)	Heart (g)	Heart Ratio (%)	Liver (g)	Liver Ratio (%)	Spleen (g)
	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR
10403	-	-	-	-	-	-	-	-	-	-	-	-	-

[MOR : Death or Moribundity.]

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

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## Organ Weight

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Sex: Male Day(s) Relative to Start Date

500 mg/kg	Organ Weights (Monkey)												
	Spleen Ratio (%)	Pancreas (g)	Pancreas Ratio (%)	Kidney (L) (g)	Kidney (L)Ratio (%)	Kidney (R) (g)	Kidney (R)Ratio (%)	Kidneys (g)	Kidneys Ratio (%)	Adrenal (L) (mg)	Adrenal (L)Ratio (^3%)	Adrenal (R) (mg)	Adrenal (R)Ratio (^3%)
	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR
10403	-	-	-	-	-	-	-	-	-	-	-	-	-

[MOR : Death or Moribundity.]

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

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Organ Weight

B120719

Sex: Male Day(s) Relative to Start Date

500 mg/kg	Organ Weights (Monkey)												
	Adrenals (mg)	Adrenals Ratio (^-3%)	Testis (L) (g)	Testis (L)Ratio (^-3%)	Testis (R) (g)	Testis (R)Ratio (^-3%)	Testes (g)	Testes Ratio (^-3%)	Prostate (g)	Prostate Ratio (^-3%)	Seminal vesicle (g)	Seminal ves. Ratio (^-3%)	Epididymis (L) (g)
	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR
10403	-	-	-	-	-	-	-	-	-	-	-	-	-

[MOR : Death or Moribundity.]

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

Sex: Male Day(s) Relative to Start Date

500 mg/kg	Organ Weights (Monkey)				
	Epididymis (L)Ratio (^~3%)	Epididymis (R) (g)	Epididymis (R)Ratio (^~3%)	Epididymides (g)	Epididymides Ratio (^~3%)
	MOR	MOR	MOR	MOR	MOR
10403	-	-	-	-	-

[MOR : Death or Moribundity.]

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

## Appendix 6

## Organ Weight

B120719

Sex: Female Day(s) Relative to Start Date

0 mg/kg	Organ Weights (Monkey)												
	Final Body Weight (Kg)	Brain (g)	Brain Ratio (%)	Pituitary (mg)	Pituitary Ratio (^-3%)	Thyroid (L) (mg)	Thyroid (L)Ratio (^-3%)	Thyroid (R) (mg)	Thyroid (R)Ratio (^-3%)	Thyroids (mg)	Thyroids Ratio (^-3%)	Thymus (g)	Thymus Ratio (^-3%)
	15	15	15	15	15	15	15	15	15	15	15	15	15
50101	3.5	64.2	1.834	64	1.83	273	7.80	189	5.40	462	13.20	2.71	77.4
50102	2.9	69.3	2.390	60	2.07	141	4.86	142	4.90	283	9.76	2.25	77.6
50103	2.8	63.9	2.282	62	2.21	88	3.14	84	3.00	172	6.14	1.64	58.6

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

## Appendix 6

## Organ Weight

B120719

Sex: Female Day(s) Relative to Start Date

0 mg/kg	Organ Weights (Monkey)												
	Submand. GL (L) (g)	Submand. GLs (L)Ratio (^3%)	Submand. GL (R) (g)	Submand. GLs (R)Ratio (^3%)	Submand. GLs (g)	Submand. GLs Ratio (^3%)	Lungs (g)	Lungs Ratio (%)	Heart (g)	Heart Ratio (%)	Liver (g)	Liver Ratio (%)	Spleen (g)
	15	15	15	15	15	15	15	15	15	15	15	15	15
50101	1.12	32.0	1.16	33.1	2.28	65.1	14.34	0.410	12.21	0.349	61.6	1.76	7.73
50102	0.80	27.6	0.79	27.2	1.59	54.8	13.45	0.464	10.12	0.349	45.0	1.55	5.02
50103	0.58	20.7	0.58	20.7	1.16	41.4	13.54	0.484	8.60	0.307	48.7	1.74	2.04

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

Appendix 6 Organ Weight

B120719

Sex: Female Day(s) Relative to Start Date

0 mg/kg	Organ Weights (Monkey)												
	Spleen Ratio (%)	Pancreas (g)	Pancreas Ratio (%)	Kidney (L) (g)	Kidney (L) Ratio (%)	Kidney (R) (g)	Kidney (R) Ratio (%)	Kidneys (g)	Kidneys Ratio (%)	Adrenal (L) (mg)	Adrenal (L) Ratio (^-3%)	Adrenal (R) (mg)	Adrenal (R) Ratio (^-3%)
	15	15	15	15	15	15	15	15	15	15	15	15	15
50101	0.221	5.76	0.165	5.91	0.169	6.03	0.172	11.94	0.341	295	8.43	256	7.31
50102	0.173	4.74	0.163	4.86	0.168	4.81	0.166	9.67	0.333	276	9.52	252	8.69
50103	0.073	4.57	0.163	4.67	0.167	4.50	0.161	9.17	0.328	246	8.79	199	7.11

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

Sex: Female Day(s) Relative to Start Date

0 mg/kg	Organ Weights (Monkey)									
	Adrenals (mg)	Adrenals Ratio ( <sup>^</sup> -3%)	Ovary (L) (mg)	Ovary (L)Ratio ( <sup>^</sup> -3%)	Ovary (R) (mg)	Ovary (R)Ratio ( <sup>^</sup> -3%)	Ovaries (mg)	Ovaries Ratio ( <sup>^</sup> -3%)	Uterus (g)	Uterus Ratio ( <sup>^</sup> -3%)
	15	15	15	15	15	15	15	15	15	15
50101	551	15.74	209	5.97	337	9.63	546	15.60	8.67	247.7
50102	528	18.21	165	5.69	147	5.07	312	10.76	3.48	120.0
50103	445	15.89	143	5.11	115	4.11	258	9.21	3.84	137.1

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

Appendix 6 Organ Weight

B120719

Sex: Female Day(s) Relative to Start Date

50 mg/kg	Organ Weights (Monkey)												
	Final Body Weight (Kg)	Brain (g)	Brain Ratio (%)	Pituitary (mg)	Pituitary Ratio (^-3%)	Thyroid (L) (mg)	Thyroid (L)Ratio (^-3%)	Thyroid (R) (mg)	Thyroid (R)Ratio (^-3%)	Thyroids (mg)	Thyroids Ratio (^-3%)	Thymus (g)	Thymus Ratio (^-3%)
	15	15	15	15	15	15	15	15	15	15	15	15	15
50202	2.5	57.2	2.288	65	2.60	290	11.60	274	10.96	564	22.56	0.37	14.8
50203	2.6	60.3	2.319	64	2.46	178	6.85	189	7.27	367	14.12	0.17	6.5

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