

Table 7 Organ Weight - Summary

B140965

Day(s) Relative to Start Date

Sex: Male		Organ Weight (Rat)											
		Final Body Weight (g)	Brain (g)	Brain Ratio (%)	Pituitary (mg)	Pituitary Ratio ($\times 10^{-3}\%$)	Thyroids (mg)	Thyroids Ratio ($\times 10^{-3}\%$)	Thymus (mg)	Thymus Ratio ($\times 10^{-3}\%$)	Submand GLs (g)	Submand GLs Ratio (%)	Lungs (g)
		29	29	29	29	29	29	29	29	29	29	29	29
0 mg/kg	Mean	353.23 I ¹	2.052 R ²	0.582 I ¹	14.28 I ¹	4.03 I ¹	30.90 I ¹	8.76 I ¹	614.7 I ¹	173.75 I ¹	0.692 I ¹	0.196 I ¹	1.445 I ¹
	SD	15.94	0.056	0.025	2.49	0.63	5.05	1.41	115.5	30.21	0.044	0.014	0.135
	N	6	6	6	6	6	6	6	6	6	6	6	6
0.5 mg/kg	Mean	355.05	2.077	0.585	13.03	3.67	33.28	9.40	621.8	175.13	0.635	0.179	1.432
	SD	11.29	0.073	0.023	1.55	0.38	3.65	1.26	89.2	24.89	0.062	0.017	0.108
	N	6	6	6	6	6	6	6	6	6	6	6	6
1 mg/kg	Mean	357.28	2.112	0.593	12.37	3.47	33.67	9.43	588.5	165.35	0.635	0.178	1.407
	SD	23.65	0.054	0.029	0.42	0.26	4.24	1.05	63.4	20.68	0.050	0.016	0.058
	N	6	6	6	6	6	6	6	6	6	6	6	6
10 mg/kg	Mean	347.80	1.908	0.548	13.57	3.89	34.10	9.82	553.0	159.32	0.608 d ³	0.175 d ³	1.377
	SD	14.32	0.193	0.039	2.01	0.50	2.33	0.76	45.5	15.84	0.040	0.007	0.133
	N	6	6	6	6	6	6	6	6	6	6	6	6

1 [I - Automatic Transformation: Identity]
 3 [d - Test: Dunnett 2 Sided p < 0.05]

2 [R - Automatic Transformation: Rank]

Table 7 Organ Weight - Summary

B140965

Day(s) Relative to Start Date

Sex: Male		Organ Weight (Rat)											
		Lungs Ratio (%)	Heart (g)	Heart Ratio (%)	Liver (g)	Liver Ratio (%)	Spleen (g)	Spleen Ratio (%)	Kidneys (g)	Kidneys Ratio (%)	Adrenals (mg)	Adrenals Ratio ($\times 10^{-3}\%$)	Testes (g)
		29	29	29	29	29	29	29	29	29	29	29	29
0 mg/kg	Mean	0.410 ¹	1.260 ¹	0.357 ¹	9.995 ¹	2.827 ¹	0.925 ¹	0.261 ¹	2.675 ¹	0.758 ¹	65.42 ¹	18.57 ¹	3.300 ¹
	SD	0.045	0.161	0.042	0.691	0.078	0.145	0.031	0.192	0.062	6.51	2.23	0.212
	N	6	6	6	6	6	6	6	6	6	6	6	6
0.5 mg/kg	Mean	0.403	1.362	0.383	9.902	2.790	0.790	0.222 ^{d3}	2.745	0.773	57.70	16.26	3.318
	SD	0.019	0.182	0.046	0.330	0.074	0.090	0.023	0.190	0.036	9.97	2.84	0.144
	N	6	6	6	6	6	6	6	6	6	6	6	6
1 mg/kg	Mean	0.395	1.270	0.355	9.890	2.764	0.695 ^{dd2}	0.195 ^{dd2}	2.605	0.732	65.63	18.41	3.305
	SD	0.033	0.183	0.037	0.918	0.093	0.084	0.027	0.101	0.056	2.23	0.78	0.338
	N	6	6	6	6	6	6	6	6	6	6	6	6
10 mg/kg	Mean	0.395	1.283	0.368	10.042	2.887	0.657 ^{dd2}	0.189 ^{dd2}	2.583	0.742	60.27	17.31	3.278
	SD	0.026	0.167	0.039	0.635	0.137	0.050	0.010	0.180	0.032	9.83	2.60	0.163
	N	6	6	6	6	6	6	6	6	6	6	6	6

1 [1 - Automatic Transformation: Identity]
 3 [d - Test: Dunnett 2 Sided p < 0.05]

2 [dd - Test: Dunnett 2 Sided p < 0.01]

Table 7

Organ Weight - Summary

B140965

Day(s) Relative to Start Date

Sex: Male		Organ Weight (Rat)		
		Testes Ratio (%)	Prostate (g)	Prostate Ratio (%)
		29	29	29
0 mg/kg	Mean	0.938 ¹	0.570 ¹	0.162 ¹
	SD	0.097	0.088	0.028
	N	6	6	6
0.5 mg/kg	Mean	0.935	0.555	0.157
	SD	0.032	0.093	0.027
	N	6	6	6
1 mg/kg	Mean	0.925	0.498	0.141
	SD	0.077	0.074	0.031
	N	6	6	6
10 mg/kg	Mean	0.945	0.492	0.141
	SD	0.073	0.107	0.029
	N	6	6	6

1 [I - Automatic Transformation: Identity]

Table 7 Organ Weight - Summary

B140965

Day(s) Relative to Start Date

Sex: Female		Organ Weight (Rat)										
		Final Body Weight (g)	Brain (g)	Brain Ratio (%)	Pituitary (mg)	Pituitary Ratio ($\times 10^{-3}\%$)	Thyroids (mg)	Thyroids Ratio ($\times 10^{-3}\%$)	Thymus (mg)	Thymus Ratio ($\times 10^{-3}\%$)	Submand. GLs (g)	Submand. GLs Ratio (%)
		29	29	29	29	29	29	29	29	29	29	29
0 mg/kg	Mean	206.87 ¹	1.845 ¹	0.894 ^{R2}	13.17 ¹	6.38 ¹	25.87 ¹	12.53 ¹	419.3 ¹	203.43 ¹	0.413 ¹	0.200 ¹
	SD	12.38	0.033	0.051	0.88	0.53	3.85	1.88	1020	5189	0.044	0.016
	N	6	6	6	6	6	6	6	6	6	6	6
0.5 mg/kg	Mean	210.33	1.875	0.891	15.97 ^{d3}	7.57 ^{d3}	25.10	11.94	458.3	217.28	0.405	0.193
	SD	9.06	0.091	0.008	2.41	0.96	3.64	1.68	76.2	30.33	0.031	0.012
	N	6	6	6	6	6	6	6	6	6	6	6
1 mg/kg	Mean	214.18	1.880	0.880	13.40	6.25	25.37	11.88	432.0	200.87	0.458	0.214
	SD	12.46	0.064	0.049	1.45	0.52	0.81	0.92	63.8	20.98	0.045	0.014
	N	6	6	6	6	6	6	6	6	6	6	6
10 mg/kg	Mean	215.95	1.865	0.866	14.47	6.69	25.80	11.92	495.0	229.56	0.402	0.186
	SD	12.51	0.034	0.060	2.22	0.81	3.62	1.15	63.4	30.36	0.049	0.021
	N	6	6	6	6	6	6	6	6	6	6	6

1 [I - Automatic Transformation: Identity]
 3 [d - Test: Dunnett 2 Sided p < 0.05]

2 [R - Automatic Transformation: Rank]

Table 7 Organ Weight - Summary

B140965

Day(s) Relative to Start Date

Sex: Female		Organ Weight (Rat)										
		Lungs	Lungs Ratio (%)	Heart	Heart Ratio (%)	Liver	Liver Ratio (%)	Spleen	Spleen Ratio (%)	Kidneys	Kidneys Ratio (%)	Adrenals
		(g)	(%)	(mg)								
		29	29	29	29	29	29	29	29	29	29	29
0 mg/kg	Mean	0.995 ¹	0.482 ¹	0.767 ¹	0.371 ¹	5.758 ¹	2.781 ¹	0.440 ¹	0.213 ¹	1.613 ¹	0.781 ¹	57.88 ¹
	SD	0.034	0.019	0.068	0.025	0.512	0.114	0.049	0.021	0.145	0.064	5.71
	N	6	6	6	6	6	6	6	6	6	6	6
0.5 mg/kg	Mean	1.003	0.477	0.807	0.383	6.300	2.998	0.488	0.232	1.603	0.763	65.78
	SD	0.059	0.023	0.086	0.028	0.497	0.242	0.040	0.013	0.083	0.034	3.16
	N	6	6	6	6	6	6	6	6	6	6	6
1 mg/kg	Mean	0.998	0.466	0.815	0.381	6.078	2.837	0.487	0.227	1.618	0.758	64.93
	SD	0.092	0.028	0.074	0.033	0.507	0.142	0.042	0.010	0.155	0.083	7.88
	N	6	6	6	6	6	6	6	6	6	6	6
10 mg/kg	Mean	1.073	0.498	0.822	0.380	6.163	2.852	0.490	0.227	1.635	0.757	67.55 ^{d2}
	SD	0.042	0.023	0.083	0.030	0.465	0.077	0.092	0.041	0.160	0.064	6.88
	N	6	6	6	6	6	6	6	6	6	6	6

1 [I - Automatic Transformation: Identity]

2 [d - Test: Dunnett 2 Sided p < 0.05]

Table 7

Organ Weight - Summary

B140965

Day(s) Relative to Start Date

Sex: Female		Organ Weight (Rat)		
		Adrenals Ratio ($\times 10^{-3}\%$)	Ovaries (mg)	Ovaries Ratio ($\times 10^{-3}\%$)
		29	29	29
0 mg/kg	Mean	27.94 1 ¹	78.63 1 ¹	37.89 1 ¹
	SD	1.56	12.57	4.60
	N	6	6	6
0.5 mg/kg	Mean	31.32	91.50	43.54
	SD	1.98	11.40	5.32
	N	6	6	6
1 mg/kg	Mean	30.31	85.90	40.00
	SD	3.18	15.73	6.13
	N	6	6	6
10 mg/kg	Mean	31.34	92.32	42.70
	SD	3.45	12.75	4.85
	N	6	6	6

1 [1 - Automatic Transformation: Identity]

Table 8

Necropsy - Summary

B140965

Removal Reason: Scheduled sacrifice	Male				Female			
	0 mg/kg	0.5 mg/kg	1 mg/kg	10 mg/kg	0 mg/kg	0.5 mg/kg	1 mg/kg	10 mg/kg
Number of Animals:	6	6	6	6	6	6	6	6
Necropsy Findings								
Present	2	0	0	2	0	0	0	2
Absent	4	6	6	4	6	6	6	4
Kidney								
Depressed patch; unilateral	1
Dilatation; pelvis, unilateral	1
Brain								
Defect; cerebrum, partial	.	.	.	1
Skin								
neck; Crust	1
Tail								
Crust	.	.	.	1	.	.	.	1

Table 9

Histopathology - Summary

B140965

Removal Reason: Scheduled sacrifice	Male				Female			
	0 mg/kg	0.5 mg/kg	1 mg/kg	10 mg/kg	0 mg/kg	0.5 mg/kg	1 mg/kg	10 mg/kg
Number of Animals:	6	6	6	6	6	6	6	6
Tongue								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	6	.	.	6	6	.	.	6
Esophagus								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	6	.	.	6	6	.	.	6
Stomach								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	6	.	.	6	6	.	.	6
Duodenum								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	6	.	.	6	6	.	.	6
Jejunum								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	6	.	.	6	6	.	.	6
Ileum								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	6	.	.	6	6	.	.	6
Cecum								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	6	.	.	6	6	.	.	6
Colon								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	6	.	.	6	6	.	.	6
Rectum								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	6	.	.	6	6	.	.	6
Liver								
Examined	6	6	6	6	6	6	6	6
No Visible Lesions	5	6	6	2	6	6	6	0
Cell infiltration; inflammatory, focal	1	0	0	0	0	0	0	0
.... minimal	1	0	0	0	0	0	0	0
Vacuolation; bile ductal epithelium	0	0	0	4	0	0	0	6
.... minimal	0	0	0	4	0	0	0	6
Pancreas								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	6	.	.	6	6	.	.	6
Submandibular Gland								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	6	.	.	6	6	.	.	6

Table 9

Histopathology - Summary

B140965

Removal Reason: Scheduled sacrifice	Male				Female			
	0 mg/kg	0.5 mg/kg	1 mg/kg	10 mg/kg	0 mg/kg	0.5 mg/kg	1 mg/kg	10 mg/kg
Number of Animals:	6	6	6	6	6	6	6	6
Sublingual Gland								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	6	.	.	6	6	.	.	6
Parotid Gland								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	6	.	.	6	6	.	.	5
Cell infiltration; lymphocyte, focal	0	.	.	0	0	.	.	1
.... minimal	0	.	.	0	0	.	.	1
Trachea								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	6	.	.	6	6	.	.	6
Lungs (And Bronchus)								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	5	.	.	6	6	.	.	4
Osseous metaplasia	1	.	.	0	0	.	.	1
Cell infiltration; inflammatory, focal	0	.	.	0	0	.	.	1
.... minimal	0	.	.	0	0	.	.	1
Thymus								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	6	.	.	6	6	.	.	6
Spleen								
Examined	6	6	6	6	6	6	6	6
No Visible Lesions	6	6	6	2	6	6	6	0
Vacuolation; macrophage, marginal zone	0	0	0	4	0	0	0	6
.... minimal	0	0	0	4	0	0	0	6
Bone Marrow (Femur)								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	6	.	.	6	6	.	.	6
Bone Marrow (Sternum)								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	6	.	.	6	6	.	.	6
Mandibular Lymph Node								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	6	.	.	6	6	.	.	6
Mesenteric Lymph Node								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	6	.	.	6	6	.	.	6
Inguinal Lymph Node								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	6	.	.	6	6	.	.	6

Table 9

Histopathology - Summary

B140965

Removal Reason: Scheduled sacrifice	Male				Female			
	0 mg/kg	0.5 mg/kg	1 mg/kg	10 mg/kg	0 mg/kg	0.5 mg/kg	1 mg/kg	10 mg/kg
Number of Animals:	6	6	6	6	6	6	6	6
Heart								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	6	.	.	6	6	.	.	6
Aorta								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	6	.	.	6	6	.	.	6
Kidney								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	4	.	.	5	5	.	.	4
Scar	1	.	.	1	0	.	.	0
.... minimal	1	.	.	1	0	.	.	0
Cell infiltration; lymphocyte, focal	0	.	.	0	1	.	.	1
.... minimal	0	.	.	0	1	.	.	1
Basophilic tubule	1	.	.	0	0	.	.	1
.... minimal	1	.	.	0	0	.	.	1
Dilatation; pelvis	1	.	.	0	0	.	.	0
.... minimal	1	.	.	0	0	.	.	0
Urinary Bladder								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	6	.	.	6	6	.	.	6
Testis								
Examined	6	0	0	6
No Visible Lesions	6	.	.	6
Epididymis								
Examined	6	0	0	6
No Visible Lesions	6	.	.	5
Cell infiltration; lymphocyte, focal	0	.	.	1
.... minimal	0	.	.	1
Prostate								
Examined	6	0	0	6
No Visible Lesions	3	.	.	2
Cell infiltration; lymphocyte, focal	3	.	.	4
.... minimal	3	.	.	4
Seminal Vesicle								
Examined	6	0	0	6
No Visible Lesions	6	.	.	6
Ovary								
Examined	6	0	0	6
No Visible Lesions	6	.	.	6

Table 9

Histopathology - Summary

B140965

Removal Reason: Scheduled sacrifice	Male				Female			
	0 mg/kg	0.5 mg/kg	1 mg/kg	10 mg/kg	0 mg/kg	0.5 mg/kg	1 mg/kg	10 mg/kg
Number of Animals:	6	6	6	6	6	6	6	6
Uterus								
Examined	6	0	0	6
No Visible Lesions	6	.	.	6
Vagina								
Examined	6	0	0	6
No Visible Lesions	6	.	.	6
Mammary Gland								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	6	.	.	6	6	.	.	6
Pituitary								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	4	.	.	6	6	.	.	6
Cyst	2	.	.	0	0	.	.	0
Thyroid								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	6	.	.	5	6	.	.	5
Ectopic thymic tissue	0	.	.	1	0	.	.	1
Parathyroid								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	6	.	.	6	6	.	.	6
Adrenal								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	6	.	.	6	6	.	.	6
Brain								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	6	.	.	5	6	.	.	6
Porencephaly	0	.	.	1	0	.	.	0
Spinal Cord								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	6	.	.	6	6	.	.	6
Optic Nerve								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	6	.	.	6	6	.	.	6
Sciatic Nerve								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	6	.	.	6	6	.	.	6
Eyeball								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	6	.	.	6	6	.	.	5
Retinal dysplasia	0	.	.	0	0	.	.	1

Table 9 Histopathology - Summary

B140965

Removal Reason: Scheduled sacrifice	Male				Female			
	0 mg/kg	0.5 mg/kg	1 mg/kg	10 mg/kg	0 mg/kg	0.5 mg/kg	1 mg/kg	10 mg/kg
Number of Animals:	6	6	6	6	6	6	6	6
Eyeball (Continued...)								
.... minimal	0	.	.	0	0	.	.	1
Harderian Gland								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	6	.	.	6	6	.	.	6
Femoral Muscle								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	6	.	.	6	6	.	.	6
Femur								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	6	.	.	6	6	.	.	6
Sternum								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	6	.	.	6	6	.	.	6
Skin								
Examined	6	0	0	6	6	0	0	6
No Visible Lesions	6	.	.	5	6	.	.	5
Crust	0	.	.	1	0	.	.	1
.... minimal	0	.	.	1	0	.	.	1
Acanthosis; focal	0	.	.	0	0	.	.	1
.... minimal	0	.	.	0	0	.	.	1
Administered Site (Tail)								
Examined	6	6	6	6	6	6	6	6
No Visible Lesions	6	6	6	0	6	6	6	0
Cell infiltration; inflammatory, perivascular	0	0	0	6	0	0	0	6
.... minimal	0	0	0	6	0	0	0	6
Proliferation; intima, vascular wall	0	0	0	6	0	0	0	6
.... minimal	0	0	0	0	0	0	0	2
.... mild	0	0	0	5	0	0	0	3
.... moderate	0	0	0	1	0	0	0	1
Thrombus	0	0	0	0	0	0	0	1
.... mild	0	0	0	0	0	0	0	1
Tail								
Examined	0	0	0	1	0	0	0	1
Ulcer	.	.	.	1	.	.	.	1
.... mild	.	.	.	0	.	.	.	1
.... moderate	.	.	.	1	.	.	.	0
Crust	.	.	.	1	.	.	.	1
.... mild	.	.	.	0	.	.	.	1

Table 9 Histopathology - Summary

B140965

Removal Reason: Scheduled sacrifice	Male				Female			
	0 mg/kg	0.5 mg/kg	1 mg/kg	10 mg/kg	0 mg/kg	0.5 mg/kg	1 mg/kg	10 mg/kg
Number of Animals:	6	6	6	6	6	6	6	6
Tail (Continued...) moderate	.	.	.	1	.	.	.	0

Table 10 Blood Concentration of P092

B140965

<1st Dose, Male>

Dose (mg/kg)	Animal No.	Blood concentration of P092 (ng/mL)						C ₀ (ng/mL)	t _{1/2} (h)	AUC _{0-24h} (ng·h/mL)
		0.083 h	1 h	2 h	4 h	8 h	24 h			
0.5	20101	177.1	53.24	50.68	36.83	20.90	13.55	197.5	12.0	651.7
	20102	168.2	67.58	43.19	28.88	22.36	16.52	182.7	27.3	663.6
	20103	153.7	66.61	42.75	26.17	17.17	12.39	165.8	21.3	561.0
	Mean	166.3	62.48	45.54	30.63	20.14	14.15	182.0	20.2	625.4
	SD	11.8	8.01	4.46	5.54	2.68	2.13	15.9	7.7	56.1
1	20201	217.7	111.6	79.06	55.30	44.30	22.39	231.3	15.6	1132
	20202	193.9	127.0	82.73	73.45	51.76	37.04	201.5	20.1	1385
	20203	241.2	127.1	86.64	62.46	48.46	37.18	255.6	29.8	1352
	Mean	217.6	121.9	82.81	63.74	48.17	32.20	229.5	21.8	1290
	SD	23.7	8.9	3.79	9.14	3.74	8.50	27.1	7.3	138
10	20301	765.7	462.3	348.8	367.8	278.6	243.3	801.5	40.0	7218
	20302	730.5	452.8	408.3	332.4	251.0	192.1	762.8	20.2	6487
	20303	786.2	457.3	281.8	301.2	230.2	225.2	825.7	62.5	6296
	Mean	760.8	457.5	346.3	333.8	253.3	220.2	796.7	40.9	6667
	SD	28.2	4.8	63.3	33.3	24.3	26.0	31.7	21.2	487

Table 10 Blood Concentration of P092

B140965

<1st Dose, Female>

Dose (mg/kg)	Animal No.	Blood concentration of P092 (ng/mL)						C ₀ (ng/mL)	t _{1/2} (h)	AUC _{0-24h} (ng·h/mL)
		0.083 h	1 h	2 h	4 h	8 h	24 h			
0.5	60101	94.12	53.63	36.53	25.87	16.52	12.69	99.04	16.9	501.7
	60102	85.26	38.49	25.31	20.39	12.92	11.45	91.62	22.3	403.3
	60103	100.9	41.95	30.62	17.79	13.64	11.94	109.2	41.7	426.4
	Mean	93.43	44.69	30.82	21.35	14.36	12.03	99.95	27.0	443.8
	SD	7.84	7.93	5.61	4.12	1.90	0.62	8.83	13.0	51.5
1	60201	132.1	64.06	47.30	32.87	22.90	20.82	141.0	17.5	698.4
	60202	111.2	63.41	46.01	29.42	22.28	16.77	117.0	27.6	635.5
	60203	102.7	49.65	36.71	28.41	22.68	18.43	109.7	36.2	618.0
	Mean	115.3	59.04	43.34	30.23	22.62	18.67	122.6	27.1	650.6
	SD	15.1	8.14	5.78	2.34	0.31	2.04	16.4	9.4	42.3
10	60301	546.3	314.2	234.9	208.6	197.6	183.3	574.3	116.3	5019
	60302	601.8	353.0	267.4	209.5	191.9	250.4	631.6	36.2	5617
	60303	534.4	329.6	219.7	153.4	137.0	156.4	558.3	20.6	4017
	Mean	560.8	332.3	240.7	190.5	175.5	196.7	588.1	57.7	4884
	SD	36.0	19.5	24.4	32.1	33.5	48.4	38.5	51.3	808

Table 10 Blood Concentration of P092

B140965

<2nd Dose, Male>		
Dose (mg/kg)	Animal No.	Blood concentration of P092 (ng/mL)
		Pre
0.5	20101	BLQ
	20102	BLQ
	20103	BLQ
	Mean	BLQ
	SD	NC
1	20201	6.779
	20202	5.120
	20203	BLQ
	Mean	BLQ
	SD	NC
10	20301	70.09
	20302	90.70
	20303	49.07
	Mean	69.95
	SD	20.82

<2nd Dose, Female>		
Dose (mg/kg)	Animal No.	Blood concentration of P092 (ng/mL)
		Pre
0.5	60101	BLQ
	60102	BLQ
	60103	BLQ
	Mean	BLQ
	SD	NC
1	60201	6.767
	60202	BLQ
	60203	BLQ
	Mean	BLQ
	SD	NC
10	60301	91.21
	60302	153.0
	60303	43.50
	Mean	95.90
	SD	54.90

BLQ: Below the lower limit of quantification (< 5 ng/mL)

NC: Not calculated

Table 10 Blood Concentration of P092

B140965

<4th Dose, Male>

Dose (mg/kg)	Animal No.	Blood concentration of P092 (ng/mL)							C ₀ (ng/mL)	t _{1/2} (h)	AUC _{0-24h} (ng·h/mL)
		pre	0.083 h	1 h	2 h	4 h	8 h	24 h			
0.5	20101	5.034	74.90	41.32	26.46	25.20	26.42	18.52	79.04	42.3	608.0
	20102	BLQ	97.98	34.37	24.24	18.84	20.20	10.86	107.7	20.8	468.2
	20103	BLQ	72.32	27.50	21.28	19.78	13.13	9.891	78.93	20.8	367.5
	Mean	BLQ	81.73	34.40	23.99	21.27	19.92	13.09	88.56	28.0	481.2
	SD	NC	14.13	6.91	2.60	3.43	6.65	4.73	16.58	12.4	120.8
1	20201	8.830	145.2	66.11	51.66	57.45	38.50	32.38	155.9	25.5	1036
	20202	6.371	136.7	60.71	51.74	42.43	33.48	33.11	147.1	32.3	937.2
	20203	BLQ	88.03	40.42	40.16	41.17	30.90	18.08	94.46	18.9	724.1
	Mean	5.067	123.3	55.75	47.85	47.02	34.29	27.86	132.5	25.6	899.1
	SD	4.557	30.8	13.55	6.66	9.06	3.86	8.47	33.2	6.7	159.4
10	20301	88.09	633.8	347.2	308.0	340.7	335.3	290.9	669.3	84.7	7842
	20302	138.0	752.0	358.0	314.1	343.5	343.9	302.6	804.3	101.7	8114
	20303	97.09	633.2	258.4	218.5	266.4	246.5	241.6	686.7	180.1	6118
	Mean	107.7	673.0	321.2	280.2	316.9	308.6	278.4	720.1	122.2	7358
	SD	26.6	68.4	54.7	53.5	43.7	53.9	32.4	73.4	50.9	1082

BLQ: Below the lower limit of quantification (< 5 ng/mL)

NC: Not calculated

Table 10 Blood Concentration of P092

B140965

<4th Dose, Female>

Dose (mg/kg)	Animal No.	Blood concentration of P092 (ng/mL)							C ₀ (ng/mL)	t _{1/2} (h)	AUC _{0-24h} (ng·h/mL)
		pre	0.083 h	1 h	2 h	4 h	8 h	24 h			
0.5	60101	BLQ	81.65	28.17	23.94	24.35	21.35	16.54	89.91	39.2	526.3
	60102	BLQ	47.58	18.64	15.63	17.43	14.92	11.98	51.79	40.0	364.6
	60103	BLQ	50.85	18.75	10.86	16.07	11.05	13.83	55.66	29.1	331.3
	Mean	BLQ	60.03	21.85	16.81	19.28	15.77	14.12	65.79	36.1	407.4
	SD	NC	18.80	5.47	6.62	4.44	5.20	2.29	20.98	6.1	104.3
1	60201	8.592	120.3	49.67	42.32	38.15	29.93	28.59	130.3	34.7	819.1
	60202	6.253	96.11	39.38	31.25	35.50	31.75	21.79	104.2	28.7	735.3
	60203	BLQ	88.29	39.02	33.65	29.02	22.66	18.25	95.06	27.8	595.6
	Mean	BLQ	101.6	42.69	35.74	34.22	28.11	22.88	109.9	30.4	716.7
	SD	NC	16.7	6.05	5.82	4.70	4.81	5.25	18.3	3.8	112.9
10	60301	155.3	594.9	341.4	391.2	357.8	353.9	336.2	625.6	220.7	8539
	60302	144.7	776.7	322.8	395.7	320.4	355.6	259.6	840.9	43.3	7920
	60303	65.77	565.6	241.4	205.2	228.9	260.7	260.9	610.9	89.8	6228
	Mean	121.9	645.7	301.9	330.7	302.4	323.4	285.6	692.5	117.9	7562
	SD	48.9	114.4	53.2	108.7	66.3	54.3	43.9	128.8	92.0	1196

BLQ: Below the lower limit of quantification (< 5 ng/mL)

NC: Not calculated

Key Page

Code	Description
10	Before dosing
10	After dosing

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	Day numbers relative to Start Date																	
					1 BD	1 T10	2 Day	3 Day	4 Day	5 Day	6 Day	7 Day	8 BD	8 T10	9 Day	10 Day	11 Day	12 Day	13 Day	14 Day	15 BD	15 T10
m		10101	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		10102	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		10103	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		10104	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		10105	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
		10106	No Abnormalities Detected		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Verity Codes: X = Present

Group 1 - 0 mg/kg Group 2 - 0.5 mg/kg Group 3 - 1 mg/kg Group 4 - 10 mg/kg