

Table 6 Organ Weight - Summary

B120719

Day(s) Relative to Start Date

Sex: Female		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
50 mg/kg	Mean	0.350	13.46	0.620	23.85	0.970	37.31	12.170	0.4681	9.000	0.3462	58.70	2.258	2.540
	SD	-	-	-	-	-	-	-	-	-	-	-	-	-
	N	1	1	1	1	1	1	1	1	1	1	1	1	1
150 mg/kg	Mean	-	-	-	-	-	-	-	-	-	-	-	-	-
	SD	-	-	-	-	-	-	-	-	-	-	-	-	-
	N	-	-	-	-	-	-	-	-	-	-	-	-	-
500 mg/kg	Mean	-	-	-	-	-	-	-	-	-	-	-	-	-
	SD	-	-	-	-	-	-	-	-	-	-	-	-	-
	N	-	-	-	-	-	-	-	-	-	-	-	-	-

[MOR : Death or Moribundity.]

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

Table 6 Organ Weight - Summary

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Day(s) Relative to Start Date

Sex: Female		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
50 mg/kg	Mean	0.0977	4.200	0.1615	5.380	0.2069	5.380	0.2069	10.760	0.4138	486.0	18.692	369.0	14.192
	SD	-	-	-	-	-	-	-	-	-	-	-	-	-
	N	1	1	1	1	1	1	1	1	1	1	1	1	1
150 mg/kg	Mean	-	-	-	-	-	-	-	-	-	-	-	-	-
	SD	-	-	-	-	-	-	-	-	-	-	-	-	-
	N	-	-	-	-	-	-	-	-	-	-	-	-	-
500 mg/kg	Mean	-	-	-	-	-	-	-	-	-	-	-	-	-
	SD	-	-	-	-	-	-	-	-	-	-	-	-	-
	N	-	-	-	-	-	-	-	-	-	-	-	-	-

[MOR : Death or Moribundity.]

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

Table 6 Organ Weight - Summary

B120719

Day(s) Relative to Start Date

Sex: Female		Organ Weights (Monkey)									
		Adrenals (mg)	Adrenals Ratio (^-3%)	Ovary (L) (mg)	Ovary (L)Ratio (^-3%)	Ovary (R) (mg)	Ovary (R)Ratio (^-3%)	Ovaries (mg)	Ovaries Ratio (^-3%)	Uterus (g)	Uterus Ratio (^-3%)
		MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR	MOR
50 mg/kg	Mean	855.0	32.885	127.0	4.885	109.0	4.192	236.0	9.077	6.210	238.85
	SD	-	-	-	-	-	-	-	-	-	-
	N	1	1	1	1	1	1	1	1	1	1
150 mg/kg	Mean	-	-	-	-	-	-	-	-	-	-
	SD	-	-	-	-	-	-	-	-	-	-
	N	-	-	-	-	-	-	-	-	-	-
500 mg/kg	Mean	-	-	-	-	-	-	-	-	-	-
	SD	-	-	-	-	-	-	-	-	-	-
	N	-	-	-	-	-	-	-	-	-	-

[MOR : Death or Moribundity.]

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

Table 7 Necropsy - Summary

B120719

Removal Reason: Death	Male		Female	
	150 mg/kg	500 mg/kg	150 mg/kg	500 mg/kg
Number of Animals:	2	1	1	2
Necropsy Findings				
Present	2	1	1	2
Absent	0	0	0	0
Stomach				
Reddish Patch; mucosa, many	.	1	.	1
Colon				
Dark Reddish Patch; mucosa, many	.	.	.	2
Rectum				
Dark Reddish Patch; mucosa, many	.	.	.	2
Thymus				
Small	2	1	1	.
Adrenal				
Enlargement; bilateral	2	1	1	1
Whole Body				
Dehydration	.	.	.	2

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

Table 7 Necropsy - Summary

B120719

Removal Reason: Moribund sacrifice	Male		Female	
	150 mg/kg		50 mg/kg	
Number of Animals:	1		1	
Necropsy Findings				
Present	1		1	
Absent	0		0	
Stomach				
Reddish Patch; mucosa, many	1			
Thymus				
Small			1	
Adrenal				
Enlargement; bilateral	1		1	
Whole Body				
Dehydration	1		1	

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

Table 7 Necropsy - Summary

B120719

Removal Reason: Scheduled sacrifice	Male		Female		
	0 mg/kg	50 mg/kg	0 mg/kg	50 mg/kg	150 mg/kg
Number of Animals:	3	3	3	2	2
Necropsy Findings					
Present	1	0	1	2	1
Absent	2	3	2	0	1
Lungs (And Bronchus)					
Brownish Change	1	.	0	.	.
Cyst	0	.	1	.	.
Thymus					
Small	.	.	.	2	.
Adrenal					
Enlargement; bilateral	.	.	.	2	1

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

Table 7 Necropsy - Summary

B120719

Removal Reason: Intermittent scheduled sacrifice	Male	Female
	500 mg/kg	500 mg/kg
Number of Animals:	2	1
Necropsy Findings		
Present	2	0
Absent	0	1
Adrenal		
Enlargement; bilateral	2	.

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

Table 7 Necropsy - Summary Death and Moribundity B120719

Removal Reason: ALL	Male		Female		
	150 mg/kg	500 mg/kg	50 mg/kg	150 mg/kg	500 mg/kg
Number of Animals:	3	1	1	1	2
Necropsy Findings					
Present	3	1	1	1	2
Stomach					
Reddish Patch; mucosa, many	1	1	.	.	1
Colon					
Dark Reddish Patch; mucosa, many	2
Rectum					
Dark Reddish Patch; mucosa, many	2
Thymus					
Small	2	1	1	1	.
Adrenal					
Enlargement; bilateral	3	1	1	1	1
Whole Body					
Dehydration	1	.	1	.	2

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

Table 8 Cerebrospinal Fluid Concentrations

B120719

<Male>

Dose (mg/kg)	Animal No.	Cerebrospinal fluid concentration of P092 (ng/mL)
0	10101	BLQ
	10102	BLQ
	10103	BLQ
50	10201	BLQ
	10202	BLQ
	10203	BLQ
150	10301	59.1
	10302	BLQ
	10303	BLQ
500/250	10401	BLQ
	10402	BLQ
	10403	209

<Female>

Dose (mg/kg)	Animal No.	Cerebrospinal fluid concentration of P092 (ng/mL)
0	50101	BLQ
	50102	BLQ
	50103	BLQ
50	50201	BLQ
	50202	BLQ
	50203	BLQ
150	50301	BLQ
	50302	BLQ
	50303	199
500/250	50401	BLQ
	50402	BLQ
	50403	BLQ

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

Table 8 Cerebrospinal Fluid Concentrations

B120719

<Single Oral Dose>

Dose (mg/kg)	Animal No.	Cerebrospinal Fluid concentration of P092 (ng/mL)		
		1 h	4 h	24 h
500	60101	BLQ	BLQ	BLQ
	60102	BLQ	BLQ	BLQ
	60103	BLQ	BLQ	BLQ

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

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	-52 a.m.	-51 a.m.	-50 a.m.	-49 a.m.	-48 a.m.	-47 a.m.	-46 a.m.	-45 a.m.	-44 a.m.
1	m	10101	No Abnormalities Detected		X	X	X	X	X	X	X	X	X
		10102	No Abnormalities Detected		X	X	X	X	X	X	X	X	X
		10103	No Abnormalities Detected		X	X	X	X	X	X	X	X	X

Severity Codes: X = Present

Group 1 - 0 mg/kg Group 2 - 50 mg/kg Group 3 - 150 mg/kg Group 4 - 500 mg/kg

Time 10 , 2h after dosing;

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

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	-43	-42	-41	-40	-39	-38	-37	-36	-35
					a.m.								
1	m	10101	No Abnormalities Detected		X	X	X	X	X	X	X	X	X
		10102	No Abnormalities Detected		X	X	X	X	X	X	X	X	X
		10103	No Abnormalities Detected		X	X	X	X	X	X	X	X	X

Severity Codes: X = Present

Group 1 - 0 mg/kg Group 2 - 50 mg/kg Group 3 - 150 mg/kg Group 4 - 500 mg/kg

Time 10 , 2h after dosing;

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

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	Day numbers relative to Start Date								
					-34 a.m.	-33 a.m.	-32 a.m.	-31 a.m.	-30 a.m.	-29 a.m.	-28 a.m.	-27 a.m.	-26 a.m.
1	m	10101	No Abnormalities Detected		X	X	X	X	X	X	X	X	X
		10102	No Abnormalities Detected		X	X	X	X	X	X	X	X	X
		10103	No Abnormalities Detected		X	X	X	X	X	X	X	X	X

Severity Codes: X = Present

Group 1 - 0 mg/kg Group 2 - 50 mg/kg Group 3 - 150 mg/kg Group 4 - 500 mg/kg

Time 10 , 2h after dosing;

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

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	-25	-24	-23	-22	-21	-20	-19	-18	-17
					a.m.								
1	m	10101	No Abnormalities Detected		X	X	X	X	X	X	X	X	X
		10102	No Abnormalities Detected		X	X	X	X	X	X	X	X	X
		10103	No Abnormalities Detected		X	X	X	X	X	X	X	X	X

Severity Codes: X = Present

Group 1 - 0 mg/kg Group 2 - 50 mg/kg Group 3 - 150 mg/kg Group 4 - 500 mg/kg

Time 10 , 2h after dosing;

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

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	-16 a.m.	-15 a.m.	-14 a.m.	-13 a.m.	-12 a.m.	-11 a.m.	-10 a.m.	-9 a.m.	-8 a.m.
1	m	10101	No Abnormalities Detected		X	X	X	X	X	X	X	X	X
		10102	No Abnormalities Detected		X	X	X	X	X	X	X	X	X
		10103	No Abnormalities Detected		X	X	X	X	X	X	X	X	X

Severity Codes: X = Present

Group 1 - 0 mg/kg Group 2 - 50 mg/kg Group 3 - 150 mg/kg Group 4 - 500 mg/kg

Time 10 , 2h after dosing;

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

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	-7 a.m.	-6 a.m.	-5 a.m.	-4 a.m.	-3 a.m.	-2 a.m.	-1 a.m.
1	m	10101	No Abnormalities Detected		X	X	X	X	X	X	X
		10102	No Abnormalities Detected		X	X	X	X	X	X	X
		10103	No Abnormalities Detected		X	X	X	X	X	X	X

Severity Codes: X = Present

Group 1 - 0 mg/kg Group 2 - 50 mg/kg Group 3 - 150 mg/kg Group 4 - 500 mg/kg

Time 10 , 2h after dosing;

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

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	Day numbers relative to Start Date								
					-52 a.m.	-51 a.m.	-50 a.m.	-49 a.m.	-48 a.m.	-47 a.m.	-46 a.m.	-45 a.m.	-44 a.m.
2	m	10201	No Abnormalities Detected		X	X	X	X	X	X	X	X	X
		10202	No Abnormalities Detected		X	X	X	X	X	X	X	X	X
		10203	No Abnormalities Detected		X	X	X	X	X	X	X	X	X

Severity Codes: X = Present

Group 1 - 0 mg/kg Group 2 - 50 mg/kg Group 3 - 150 mg/kg Group 4 - 500 mg/kg

Time 10, 2h after dosing;

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

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	-43	-42	-41	-40	-39	-38	-37	-36	-35
					a.m.								
2	m	10201	No Abnormalities Detected		X	X	X	X	X	X	X	X	X
		10202	No Abnormalities Detected		X	X	X	X	X	X	X	X	X
		10203	No Abnormalities Detected		X	X	X	X	X	X	X	X	X

Severity Codes: X = Present

Group 1 - 0 mg/kg Group 2 - 50 mg/kg Group 3 - 150 mg/kg Group 4 - 500 mg/kg

Time 10 , 2h after dosing;

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

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	-34	-33	-32	-31	-30	-29	-28	-27	-26
					a.m.								
2	m	10201	No Abnormalities Detected		X	X	X	X	X	X	X	X	X
		10202	No Abnormalities Detected		X	X	X	X	X	X	X	X	X
		10203	No Abnormalities Detected		X	X	X	X	X	X	X	X	X

Severity Codes: X = Present

Group 1 - 0 mg/kg Group 2 - 50 mg/kg Group 3 - 150 mg/kg Group 4 - 500 mg/kg

Time 10 , 2h after dosing;

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

Day numbers relative to Start Date

Group	Sex	Animal	Clinical Sign	Site	-25	-24	-23	-22	-21	-20	-19	-18	-17
					a.m.								
2	m	10201	No Abnormalities Detected		X	X	X	X	X	X	X	X	X
		10202	No Abnormalities Detected		X	X	X	X	X	X	X	X	X
		10203	No Abnormalities Detected		X	X	X	X	X	X	X	X	X

Severity Codes: X = Present

Group 1 - 0 mg/kg Group 2 - 50 mg/kg Group 3 - 150 mg/kg Group 4 - 500 mg/kg

Time 10 , 2h after dosing;

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