

Table 6-8 Urinalysis in female rats

Group	Water for injection		CCA	CCA	CCA	CCA
Dose(mg/kg)	Day	Grade	10	100	300	1000
Occult blood	8w	0	8	7		
		1				
		2				
		3				
		4				
Urobilinogen	8w	0	1	1	1	
		1	7	7	6	
		2				
		3				
		4				

Values are expressed as the mean + S.D.
 Statistical analyses were not performed at 300 mg/kg.
 Not significantly different from water for injection.

Hematology

RBC	(10 ⁶ /mm ³)	Number of red blood cells
WBC	(10 ³ /mm ³)	Number of white blood cells
Ht	(%)	Hematocrit value
Hb	(g/dL)	Hemoglobin concentration
Plat.	(10 ³ /mm ³)	Number of blood platelets
MCV	(fL)	Mean corpuscular volume
MCH	(pg)	Mean corpuscular hemoglobin
MCHC	(g/dL)	Mean corpuscular hemoglobin concentration
Ret. (%)	(%)	Reticulocyte ratio
Hemogram		
Eosino.	(10 ³ /mm ³)	Number of eosinophilic leukocytes
Eosino.	(%)	Eosinophilic leukocyte ratio
Baso.	(10 ³ /mm ³)	Number of basophilic leukocytes
Baso.	(%)	Basophilic leukocyte ratio
Mono.	(10 ³ /mm ³)	Number of monocytes
Mono.	(%)	Monocyte ratio
Lymph.	(10 ³ /mm ³)	Number of lymphocytes
Lymph.	(%)	Lymphocyte ratio
Neutro.	(10 ³ /mm ³)	Number of neutrophilic leukocytes
Neutro.	(%)	Neutrophilic leukocyte ratio
LUC	(10 ³ /mm ³)	Number of large unstained cells
LUC	(%)	Large unstained cell ratio
Blood coagulation test		
PT	(Sec)	Prothrombin time
APTT	(Sec)	Activated partial thromboplastin time

Table 7-1 Hematology in male rats

Group	Dose (mg/kg)	N	Water for injection	CCA		CCA		CCA	
				10	8	100	5	300	5
RBC	(10 ⁶ /mm ³)	8	8.533±0.436	8.481±0.261	8.684±0.508	6.320±0.217			
WBC	(10 ³ /mm ³)	8	6.683±2.611	7.129±1.192	12.326±5.264*	14.240±1.565			
Ht	(%)	8	46.38±2.34	45.60±0.72	34.86±3.07**	30.10±0.67			
Hb	(g/dL)	8	15.93±0.61	15.71±0.26	10.58±1.08**	9.56±0.44			
Plat.	(10 ³ /mm ³)	8	1008.5±102.5	1053.1±113.1	2037.4±271.1**	3035.6±646.8			
MCV	(fL)	8	54.34±1.16	53.80±1.17	40.08±1.58**	47.64±2.03			
MCH	(pg)	8	18.70±0.55	18.56±0.62	12.16±0.67**	15.16±0.91			
MCHC	(g/dL)	8	34.39±0.80	34.45±0.46	30.34±0.55**	31.82±0.81			
Ret.	(%)	8	2.34±0.37	2.18±0.38	4.64±0.61**	6.68±2.58			
Eosino.	(10 ³ /mm ³)	8	0.084±0.045	0.073±0.041	0.062±0.033	0.012±0.004			
Eosino.	(%)	8	1.24±0.44	1.03±0.60	0.56±0.29*	0.08±0.04			
Baso.	(10 ³ /mm ³)	8	0.011±0.010	0.014±0.007	0.022±0.013	0.032±0.011			
Baso.	(%)	8	0.19±0.08	0.16±0.05	0.20±0.07	0.26±0.05			
Mono.	(10 ³ /mm ³)	8	0.143±0.063	0.136±0.056	0.428±0.215*	0.440±0.200			
Mono.	(%)	8	2.09±0.55	1.99±0.91	3.40±0.85*	3.06±1.15			
Lymph.	(10 ³ /mm ³)	8	4.945±2.231	5.380±0.964	7.71±3.015*	6.606±0.994			
Lymph.	(%)	8	72.95±6.74	75.36±3.79	65.02±11.99	46.64±7.38			
Neutro.	(10 ³ /mm ³)	8	1.433±0.476	1.443±0.333	3.810±2.690	6.604±1.550			
Neutro.	(%)	8	22.59±7.10	20.23±2.73	28.52±11.70	46.12±7.11			
IUC	(10 ³ /mm ³)	8	0.066±0.048	0.080±0.039	0.296±0.185**	0.540±0.166			
IUC	(%)	8	0.96±0.56	1.18±0.60	2.32±1.05**	3.86±1.42			
PT	(Sec)	8	12.19±2.36	11.23±2.34	9.28±1.09	7.94±0.30			
APTT	(Sec)	8	21.03±2.34	21.01±2.19	19.38±1.77	18.38±1.68			

Values are expressed as the mean ± S.D.
 Statistical analyses were not performed at 300 mg/kg.
 * p<0.05, ** p<0.01 : Significantly different from Water for injection.

Table 7-2 Hematology in female rats

Group	Dose (mg/kg)	N	Water for injection	CCA		CCA		CCA	
				10	8	100	7	300	0
RBC	(10 ⁶ /mm ³)		8.268±0.283	8.344±0.351	8.724±1.099				
WBC	(10 ³ /mm ³)		8.044±1.779	7.651±2.515	11.037±3.771				
Ht	(%)		44.96±1.85	44.81±1.85	37.36±4.15**				
Hb	(g/dL)		15.73±0.71	15.43±0.52	11.40±1.27**				
Plat.	(10 ³ /mm ³)		1090.1±79.5	1156.4±64.3	1926.6±207.2**				
MCV	(fL)		54.43±1.47	53.73±0.59	42.99±3.54**				
MCH	(pg)		19.03±0.57	18.54±0.44	13.16±1.50**				
MCHC	(g/dL)		34.96±0.50	34.49±0.63	30.54±1.05**				
Ret.	(%)		1.84±0.36	2.04±0.28	4.06±1.21**				
Eosino.	(10 ³ /mm ³)		0.099±0.029	0.120±0.090	0.016±0.014**				
Eosino.	(%)		1.26±0.36	1.46±1.00	0.016±0.011				
Baso.	(10 ³ /mm ³)		0.018±0.007	0.010±0.009	0.016±0.011				
Baso.	(%)		0.21±0.06	0.15±0.09	0.16±0.08				
Mono.	(10 ³ /mm ³)		0.189±0.100	0.156±0.074	0.456±0.243*				
Mono.	(%)		2.34±1.01	1.96±0.53	4.01±1.06**				
Lymph.	(10 ³ /mm ³)		6.014±1.165	5.490±1.748	5.179±2.028				
Lymph.	(%)		75.19±4.48	71.91±4.89	49.34±16.13**				
Neutro.	(10 ³ /mm ³)		1.640±0.722	1.789±0.727	4.950±3.085**				
Neutro.	(%)		19.96±5.12	23.48±5.34	42.80±16.33**				
LUC	(10 ³ /mm ³)		0.085±0.044	0.084±0.050	0.420±0.267**				
LUC	(%)		1.06±0.54	1.04±0.43	3.54±1.11**				
PT	(Sec)		7.55±0.25	7.70±0.29	7.80±0.71				
APTT	(Sec)		15.70±1.66	16.79±1.38	17.60±1.65				

Values are expressed as the mean ± S.D.
 Statistical analyses were not performed at 300 mg/kg.
 * P<0.05, ** P<0.01 : Significantly different from Water for injection.

Blood Chemistry

ASAT	(IU/L)	Aspartate aminotransferase
ALAT	(IU/L)	Alanine aminotransferase
ALP	(IU/L)	Alkaline phosphatase
G-GTP	(IU/L)	Gamma - glutamyl transpeptidase
T.Bil.	(mg/dL)	Total bilirubin
T.Prot.	(g/dL)	Total protein
Albumin	(g/dL)	Albumin
A/G		Albumin / Globulin
T.Chol.	(mg/dL)	Total cholesterol
TGL	(mg/dL)	Triglyceride
Glucose	(mg/dL)	Glucose
BUN	(mg/dL)	Blood urea nitrogen
Creat.	(mg/dL)	Creatinine
IP	(mg/dL)	Inorganic phosphorus
Ca	(mg/dL)	Calcium
Na	(mEq/L)	Sodium
K	(mEq/L)	Potassium
Cl	(mEq/L)	Chloride
Globlin	(g/dL)	Globlin

Table 8-1 Blood chemistry in male rats

Group	Dose (mg/kg)	N	Water for injection	CCA		CCA		CCA		CCA	
				10	8	100	5	300	5	1000	0
ASAT (IU/L)	231.1±138.2			251.0±157.2		167.2±73.6		225.2±73.5			
ALAT (IU/L)	76.5±72.2			108.4±93.3		47.2±34.9		35.4±20.3			
ALP (IU/L)	544.8±127.1			457.0±59.9		409.8±82.4*		559.6±166.1			
G-GTP (IU/L)	1.8±0.7			1.8±0.7		2.4±1.1		5.8±1.9			
T.Bil. (mg/dL)	0.060±0.021			0.046±0.017		0.018±0.013**		0.028±0.013			
T.Prot. (g/dL)	5.61±0.31			5.48±0.33		4.98±0.38**		4.68±0.55			
Albumin (g/dL)	4.16±0.30			3.99±0.22		3.04±0.19**		2.60±0.35			
A/G	2.953±0.627			2.715±0.325		1.615±0.358**		1.250±0.115			
T.Chol. (mg/dL)	47.5±6.1			44.9±3.5		60.0±24.4		71.6±17.2			
TGL (mg/dL)	14.8±7.0			14.5±1.4		19.4±2.4*		20.0±6.5			
Glucose (mg/dL)	122.0±20.6			126.1±11.9		141.6±8.4		160.4±14.6			
BUN (mg/dL)	21.75±2.65			21.28±2.50		37.38±21.41**		105.94±77.09			
Creat. (mg/dL)	0.208±0.018			0.206±0.020		0.224±0.078		0.310±0.178			
IP (mg/dL)	8.283±0.508			8.020±0.445		9.752±0.615**		12.222±2.524			
Ca (mg/dL)	9.31±0.39			9.43±0.31		8.86±0.34		7.46±1.17			
Na. (mEq/L)	144.8±1.0			144.9±0.8		148.2±0.8**		144.0±5.2			
K (mEq/L)	4.23±0.37			4.29±0.26		4.92±1.01		5.66±1.28			
Cl (mEq/L)	108.6±0.7			109.0±1.5		107.6±2.5		108.0±4.3			
Globlin (g/dL)	1.45±0.23			1.49±0.20		1.94±0.36**		2.08±0.25			

Values are expressed as the mean ± S.D.

Statistical analyses were not performed at 300 mg/kg.

* P<0.05, ** P<0.01 : Significantly different from Water for injection.

Table 8-2 Blood chemistry in female rats

Group	Dose(mg/kg)	Water for injection	CCA		CCA		CCA	
			10	8	100	7	300	0
ASAT (IU/L)		194.6±46.1	183.0±71.8		177.6±43.2			1000
ALAT (IU/L)		52.6±13.3	56.6±29.2		51.4±18.4			0
ALP (IU/L)		329.9±57.5	299.5±60.1		469.0±102.4**			
G-GTP (IU/L)		2.4±1.2	2.9±0.8		3.6±1.6			
T.Bil. (mg/dL)		0.063±0.012	0.056±0.019		0.033±0.015**			
T.Prot. (g/dL)		5.95±0.18	5.88±0.25		4.94±0.24**			
Albumin (g/dL)		4.40±0.17	4.39±0.31		2.90±0.17**			
A/G		2.868±0.347	3.005±0.524		1.430±0.164**			
T.Chol. (mg/dL)		53.5±9.1	53.5±14.5		64.6±16.6			
TGL (mg/dL)		10.9±3.5	12.9±5.8		18.1±6.6*			
Glucose (mg/dL)		115.3±12.4	106.0±13.1		143.7±28.2*			
BUN (mg/dL)		29.74±5.30	30.28±5.39		47.54±18.38*			
Creat. (mg/dL)		0.274±0.057	0.279±0.038		0.229±0.050			
IP (mg/dL)		7.724±0.679	7.454±0.854		8.760±0.652*			
Ca (mEq/L)		9.38±0.23	9.24±0.30		8.53±0.32**			
Na (mEq/L)		142.1±1.0	142.4±1.1		143.7±1.5*			
K (mEq/L)		4.05±0.35	4.15±0.31		4.67±0.37**			
Cl (mEq/L)		106.5±1.7	107.3±1.2		106.0±2.1			
Globulin (g/dL)		1.55±0.15	1.49±0.20		2.04±0.19**			

Values are expressed as the mean ± S.D.

Statistical analyses were not performed at 300 mg/kg.

* P<0.05, ** P<0.01 : Significantly different from Water for injection.

Gross Autopsy Findings

Grade

- 0 : No abnormal changes
- 1 : Slight
- 2 : Moderate
- 3 : Marked
- P : Non-graded changes

Table 9-1 Gross autopsy findings in male rats

Study No. : SBL94-83

Findings	Group		Water for injection						CCA										
	Dose (mg/kg)		0		1		2		3		10		300		1000				
	Grade		P	0	1	2	3	P	0	1	2	3	P	0	1	2	3	P	
Abdominal cavity																			
Ascites			8	0	8	0	5	0	4	0	4	0	4	0	4	0	4	0	1
Thoracic cavity																			
Hydrothorax			8	0	8	0	5	0	4	0	4	0	4	0	4	0	4	0	1
Spleen																			
White focus			8	0	8	0	5	0	4	0	4	0	4	0	4	0	4	0	1
Thymus																			
Small size			8	0	8	0	4	1	2	1	2	3	3	1	2	3	3	0	3
Lung																			
Black focus			7	1	8	0	5	0	5	0	5	0	5	0	5	0	5	0	0
Stomach																			
Black focus, mucosa, glandular stomach			8	0	8	0	5	0	2	0	2	0	2	0	2	0	2	0	3
Jejunum																			
Black content			8	0	8	0	5	0	4	0	4	0	4	0	4	0	4	0	1
Liver																			
Red			7	1	8	0	5	0	5	0	5	0	5	0	5	0	5	0	0
Abnormal lobulation																			
White focus			7	1	8	0	5	0	5	0	5	0	5	0	5	0	5	0	0
Kidney																			
Enlargement			8	0	8	0	3	2	2	2	2	3	3	2	2	3	3	0	3
White focus																			
Discoloration			8	0	8	0	5	0	4	0	4	0	4	0	4	0	4	0	1
Urinary bladder																			
Urine content			8	0	8	0	3	2	2	2	3	3	3	2	2	3	3	0	3
Testis																			
Small size			7	1	8	0	5	0	5	0	5	0	5	0	5	0	5	0	0
Epididymis																			
Small size			7	1	8	0	5	0	5	0	5	0	5	0	5	0	5	0	0
Seminal vesicle																			
Small size			8	0	8	0	5	0	4	0	4	0	4	0	4	0	4	0	1

Numerals represent the number of animals.

Table 9-2 Gross autopsy findings in male rats

Findings	Group			Water for injection			CCA			CCA			CCA							
	Dose (mg/kg)			Grade			10			100			300			1000				
	0	1	2	3	P	0	1	2	3	P	0	1	2	3	P	0	1	2	3	P
Prostate Small size	8				0	8				0	5				0	4				1
Subcutaneous tissue Edema	8				0	8				0	5				0	4				1
Lymph node (Mediastinal) Enlargement	8				0	8				0	1				4	2				3
Lymph node (Renal) Enlargement	8				0	8				0	1				4	3				2
Skeletal muscle (back) White	8				0	8				0	0				5	0				5
Application site (subcutaneous tissue) White	8				0	8				0	0				5	0				5

Numerals represent the number of animals.

Table 9-3 Gross autopsy findings in female rats

Findings	Group	Dose(mg/kg) Grade	Water for injection			CCA			CCA			CCA					
			0	1	2	3	P	0	1	2	3	P	0	1	2	3	P
Abdominal cavity			8	0	8	0	6	1									
Adhesion, abdominal organs			8	0	8	0	6	1									
Lung			8	0	8	0	6	1									
Black focus			8	0	8	0	6	1									
Stomach			8	0	8	0	5	2									
Black focus, mucosa, glandular stomach			8	0	8	0	5	2									
Lymph node (Mediastinal)			8	0	8	0	1	6									
Enlargement			8	0	8	0	1	6									
Lymph node (Renal)			8	0	8	0	1	6									
Enlargement			8	0	8	0	1	6									
Lymph node (Lumbar)			8	0	8	0	6	1									
Enlargement			8	0	8	0	6	1									
Skeletal muscle(back)			8	0	8	0	0	7									
White			8	0	8	0	0	7									
Application site(subcutaneous tissue)			8	0	8	0	0	7									
White			8	0	8	0	0	7									

Numerals represent the number of animals.

Table 9-4 Gross autopsy findings in male rats (Interim deaths)

Findings	Group			Water for injection			CCA			CCA			CCA					
	Dose (mg/kg)			Grade			10			100			300			1000		
	0	1	2	0	1	2	0	1	2	0	1	2	0	1	2	0	1	2
External findings																		
Trace of reddish rhinorrhea							3	0	2							1	8	0
Prolapse, penis							2	1	3							0	8	0
Abdominal cavity							2	1	2							1	8	0
Ascites							3	0	2							1	8	0
Adhesion, abdominal organs																		
Thoracic cavity							3	0	0							3	8	0
Hydrothorax																		
Spleen							2	1	3							0	8	0
White focus																		
Thymus							3	0	3							0	2	6
Edema							2	1	2							1	8	0
Small size							3	0	3							0	6	2
Red																		
Lung							3	0	2							1	8	0
White focus																		
Black focus							3	0	2							1	8	0
Stomach																		
Black focus, mucosa, glandular stomach							3	0	3							0	6	2
Jejunum							2	1	2							1	8	0
Black content																		
Ileum							2	1	2							1	8	0
Black content																		
Cecum							2	1	2							1	8	0
Black content																		
Colon							2	1	2							1	8	0
Black content																		
Rectum							3	0	2							1	8	0
Black content																		

Numerals represent the number of animals.

Table 9-5 Gross autopsy findings in male rats (Interim deaths)

Study No. : SBL94-83

Findings	Group	Water for injection						CCA								
		Dose (mg/kg)		Grade		CCA		100		300		1000				
		0	1	2	3	P	0	1	2	3	P	0	1	2	3	P
Liver																
White focus							3				0	0				3
Adhesion, interlobar							3				0	2				0
Kidney							1				2	2				0
Enlargement							3				0	2				0
White focus							1				2	2				0
Discoloration							2				1	2				0
Urinary bladder							3				0	2				0
Urine content							2				1	3				0
White material content							3				0	2				0
Red, mucosa/serosa							2				1	3				0
Ureter							2				1	3				0
Dilatation							3				0	2				0
Seminal vesicle							3				0	2				0
Small size							3				0	2				0
Prostate							3				0	2				0
Small size							3				0	2				0
Adrenal							3				0	2				0
Defect, right							2				1	2				6
Subcutaneous tissue							2				1	2				6
Edema							2				1	2				6
Lymph node (Mediastinal)							2				1	3				0
Enlargement							3				0	1				0
Diaphragm							2				1	3				0
White focus							3				0	1				0
Lymph node (Renal)							2				1	3				0
Enlargement							1				2	0				0
Skeletal muscle (back)							1				2	0				0
White							3				3	8				0

Numerals represent the number of animals.

Table 9-6 Gross autopsy findings in male rats (Interim deaths)

Study No. : SBL94-83

Findings	Group	Water for injection			CCA			CCA			CCA						
		0	1	2	3	P	0	1	2	3	P	0	1	2	3	P	
Dose(mg/kg)																	
Grade																	
							10										1000
Skeletal muscle(back)																	
Black																	
Abdominal cavity/thoracic cavity																	
White focus, peritoneum/pleura																	
Black focus, peritoneum/pleura																	
Application site(subcutaneous tissue)																	
White																	
White focus																	
Edema																	
Black																	
Induration																	

Numerals represent the number of animals.

Table 9-7 Gross autopsy findings in female rats (Interim deaths)

Study No. : SBL94-83

Findings	Group	Water for injection			CCA			CCA			CCA							
		Dose (mg/kg)	Grade	0	1	2	3	P	0	1	2	3	P	0	1	2	3	P
External findings																		
Soiled hair				0	1	2	3	P	0	1	2	3	P	0	1	2	3	P
Abdominal cavity																		
Ascites																		
Thoracic cavity																		
Hydrothorax																		
Spleen																		
Small size																		
White focus																		
Thymus																		
Edema																		
Small size																		
Lung																		
White focus																		
Black focus																		
Stomach																		
White focus, serosa, forestomach																		
Black focus, mucosa, glandular stomach																		
Jejunum																		
Black content																		
Ileum																		
Black content																		
Cecum																		
Black content																		
Colon																		
Black content																		
Liver																		
White focus																		
Black focus																		

Numerals represent the number of animals.

Findings	Group	Dose (mg/kg) Grade	Water for injection									CCA															
			0			1			2			3			P			10			300			1000			
Kidney Enlargement			0	1	2	3	P	0	1	2	3	P	0	1	2	3	P	0	1	2	3	P	0	1	2	3	P
Discoloration			1	0	2	6	8	1	0	2	6	8	1	0	2	6	8	1	0	2	6	8	1	0	2	6	8
White			1	0	7	1	8	1	0	7	1	8	1	0	7	1	8	1	0	7	1	8	1	0	7	1	8
Cyst			1	0	6	2	8	1	0	6	2	8	1	0	6	2	8	1	0	6	2	8	1	0	6	2	8
Red focus			1	0	5	3	8	1	0	5	3	8	1	0	5	3	8	1	0	5	3	8	1	0	5	3	8
Rough surface			1	0	6	2	8	1	0	6	2	8	1	0	6	2	8	1	0	6	2	8	1	0	6	2	8
Urinary bladder			1	0	7	1	8	1	0	7	1	8	1	0	7	1	8	1	0	7	1	8	1	0	7	1	8
Urine content			1	0	6	2	8	1	0	6	2	8	1	0	6	2	8	1	0	6	2	8	1	0	6	2	8
Adrenal			1	0	6	2	8	1	0	6	2	8	1	0	6	2	8	1	0	6	2	8	1	0	6	2	8
White focus			1	0	7	1	8	1	0	7	1	8	1	0	7	1	8	1	0	7	1	8	1	0	7	1	8
Black focus			1	0	7	1	8	1	0	7	1	8	1	0	7	1	8	1	0	7	1	8	1	0	7	1	8
Subcutaneous tissue			1	0	3	5	1	1	0	3	5	1	1	0	3	5	1	1	0	3	5	1	1	0	3	5	1
Edema			0	1	6	2	8	0	1	6	2	8	0	1	6	2	8	0	1	6	2	8	0	1	6	2	8
Skeletal muscle (back)			1	0	6	2	8	1	0	6	2	8	1	0	6	2	8	1	0	6	2	8	1	0	6	2	8
White			1	0	4	4	1	1	0	4	4	1	1	0	4	4	1	1	0	4	4	1	1	0	4	4	1
Brown			1	0	6	2	8	1	0	6	2	8	1	0	6	2	8	1	0	6	2	8	1	0	6	2	8
Black			1	0	4	4	1	1	0	4	4	1	1	0	4	4	1	1	0	4	4	1	1	0	4	4	1
Abdominal cavity/thoracic cavity			1	0	5	3	8	1	0	5	3	8	1	0	5	3	8	1	0	5	3	8	1	0	5	3	8
White focus, peritoneum/pleura			0	1	5	3	8	0	1	5	3	8	0	1	5	3	8	0	1	5	3	8	0	1	5	3	8
Application site (subcutaneous tissue)			1	0	7	1	8	1	0	7	1	8	1	0	7	1	8	1	0	7	1	8	1	0	7	1	8
White			1	0	3	5	0	1	0	3	5	0	1	0	3	5	0	1	0	3	5	0	1	0	3	5	0
White focus			1	0	7	1	8	1	0	7	1	8	1	0	7	1	8	1	0	7	1	8	1	0	7	1	8
Edema			1	0	3	5	0	1	0	3	5	0	1	0	3	5	0	1	0	3	5	0	1	0	3	5	0

Numerals represent the number of animals.

Table 9-9 Gross autopsy findings in female rats (Interim deaths)

Findings	Group	Water for injection									CCA											
		0			1			2			3			100			300			1000		
Dose (mg/kg)	Grade	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
Application site (subcutaneous tissue)																						
Black																						
Black focus																						
Brown focus																						
Induration																						

Numerals represent the number of animals.

Organ weight

Submand.
Epididy.
Sem. Vesic.

-R
-L
-R&L

Submandibular gland
Epididymis
Seminal vesicle

(Right)
(Left)
(Right and Left)

Table 10-1 Organ weight in male rats

Study No. : SBL94-83

Group	Dose(mg/kg)	N	Water for injection	CCA		
				10	100	300
Pituitary	(mg)		11.51±1.20	9.94±1.51	8.20±1.08	
Thyroid-R	(mg)		9.56±2.61	8.42±0.61	6.76±3.99	
Thyroid-L	(mg)		8.79±1.95	7.24±2.72	7.24±2.72	
Thyroid-R&L	(mg)		17.20±2.88	17.32±1.41	14.00±5.93	
Adrenal-R	(mg)		27.14±3.77	29.58±2.66	33.42±10.68	
Adrenal-L	(mg)		29.84±4.50	31.74±1.84	39.46±3.06	
Adrenal-R&L	(mg)		56.98±7.96	61.32±4.17	72.88±11.78	
Testis-R	(mg)		1456.5±358.0	1474.2±89.4	1334.6±191.5	
Testis-L	(mg)		1524.3±343.6	1455.8±84.9	1320.2±122.5	
Testis-R&L	(mg)		2980.8±676.5	2930.0±170.8	2654.8±310.1	
Thymus	(mg)		255.9±79.6	226.6±45.8	149.8±88.5	
Submand.-R	(mg)		289.1±37.1	248.0±18.7	191.4±20.8	
Submand.-L	(mg)		293.0±39.2	249.8±24.1	182.4±22.3	
Submand.-R&L	(mg)		582.1±76.1	497.8±41.1	373.8±43.0	
Spleen	(mg)		543.5±88.2	964.0±137.4**	753.8±355.9	
Brain	(mg)		2024.4±97.9	1954.0±59.8	1853.8±70.7	
Heart	(mg)		1170.6±135.7	1216.4±134.2	1001.2±121.4	
Lung	(mg)		1105.6±103.6	1074.6±57.3	955.4±83.8	
Liver	(g)		8.576±1.205	10.232±1.137*	9.112±0.514	
Kidney-R	(mg)		1367.9±135.1	1936.4±608.6*	1914.0±138.8	
Kidney-L	(mg)		1340.4±117.8	2003.2±611.5*	1887.0±216.6	
Kidney-R&L	(mg)		2708.3±244.7	3939.6±1218.6*	3801.0±333.3	
Epididy.-R	(mg)		520.5±90.6	491.8±61.7	291.0±52.4	
Epididy.-L	(mg)		525.0±81.7	505.4±49.3	277.8±43.6	
Epididy.-R&L	(mg)		1045.5±161.1	997.2±108.9	568.8±95.9	
Sem. Vesic.	(mg)		1141.3±320.5	799.4±204.1	472.2±174.4	
Prostate	(mg)		895.5±213.6	652.0±72.4	341.8±89.3	

Values are expressed as the mean ± S.D.

Statistical analyses were not performed at 300 mg/kg.

* P<0.05 , ** P<0.01 : Significantly different from Water for injection.

Table 10-2 Organ weight in female rats

Study No. : SBL94-83

Group	Water for injection	CCA	CCA	CCA	CCA
Dose (mg/kg)	N	10	100	300	1000
Pituitary (mg)	8	14.14±1.95	12.41±2.25		
Thyroid-R (mg)		7.11±1.23	7.53±0.83		
Thyroid-L (mg)		6.14±1.86	6.06±0.89		
Thyroid-R&L (mg)		13.25±2.83	13.59±1.68		
Adrenal-R (mg)		31.53±5.23	37.47±6.74		
Adrenal-L (mg)		34.14±5.64	38.49±6.70		
Adrenal-R&L (mg)		65.66±10.76	75.96±13.11		
Ovary-R (mg)		32.69±5.42	28.63±10.07		
Ovary-L (mg)		31.74±5.91	26.69±8.99		
Ovary-R&L (mg)		64.43±9.16	55.31±18.86		
Thymus (mg)		231.3±52.4	158.6±52.6*		
Submand.-R (mg)		189.4±19.8	181.1±12.0		
Submand.-L (mg)		184.5±18.8	186.3±10.5		
Submand.-R&L (mg)		373.9±37.9	367.3±31.1		
Spleen (mg)		380.3±49.2	404.1±73.8		
Brain (mg)		1868.6±49.5	1868.0±48.8		
Heart (mg)		783.5±35.3	827.5±88.3		
Lung (mg)		847.8±55.6	864.9±65.5		
Liver (g)		5.473±0.330	5.813±0.716		
Kidney-R (mg)		850.1±68.9	867.3±80.1		
Kidney-L (mg)		813.6±57.1	1265.1±127.4**		
Kidney-R&L (mg)		1663.8±119.7	1244.0±180.8**		
Uterus (mg)		363.9±73.6	1716.8±135.7		
			2509.1±291.7**		
			252.0±108.0		

Values are expressed as the mean ± S.D.

Statistical analyses were not performed at 300 mg/kg.

* P<0.05, ** P<0.01 : Significantly different from Water for injection.