

Table 3-2 Food consumption (g/day) in female rats

Study No. : SBL101-003

Group	Water for injection	AAC		
		1	10	100
Day Pre				
	19.8± 0.8(6)	18.8± 1.3(6)	18.8± 2.1(6)	18.7± 1.4(6)
5	21.5± 2.3(6)	20.2± 3.3(6)	20.2± 1.2(6)	21.3± 2.3(6)
12	23.7± 3.4(6)	22.2± 2.6(6)	21.2± 2.5(6)	22.7± 2.5(6)
19	23.2± 2.0(6)	22.3± 2.7(6)	22.5± 2.6(6)	23.3± 2.6(6)
26	23.2± 2.9(6)	23.5± 2.4(6)	23.2± 0.8(6)	

Values are expressed as the mean ± S.D. (N).
 Not significantly different from Water for injection.

Gross ophthalmological examination

Grade

- 0 : No abnormal changes
- 1 : Slight
- 2 : Moderate
- 3 : Severe
- P : Non-graded change
- U : Unexamined

Table 4-1 Gross ophthalmological examination in male rats

Group	Dose (mg/kg)	Item	Grade	Water for injection	AAC	AAC	AAC	AAC
Pre	No abnormal changes			6	6	6	6	6
25	No abnormal changes			6	6	6	6	6

Numerals represent the number of animals.

Table 4-2 Gross ophthalmological examination in female rats

Group	Dose(mg/kg)	Item	Grade	Water for injection	AAC	AAC	AAC	AAC
Pre	No abnormal changes			6	6	6	6	6
25	No abnormal changes			6	6	6	6	6

Numerals represent the number of animals.

Slit-lamp examination

Grade

- 0 : No abnormal changes
- 1 : Slight
- 2 : Moderate
- 3 : Severe
- P : Non-graded change
- U : Unexamined

Table 4-3 Slit-lamp examination in male rats

Group	Dose (mg/kg)	Item	Grade	Water for injection	AAC	AAC	AAC	AAC
Pre	No abnormal changes			6	6	6	6	6
25	No abnormal changes			6	6	6	6	100

Numerals represent the number of animals.

Table 4-4 Slit-lamp examination in female rats

Group	Water for injection	AAC	AAC	AAC
Dose (mg/kg)		1	10	100
Day	Item	Grade		
Pre	No abnormal changes	6	6	6
25	No abnormal changes	6	6	6

Numerals represent the number of animals.

Fundusoscopic examination

Grade

- 0 : No abnormal changes
- 1 : Slight
- 2 : Moderate
- 3 : Severe
- P : Non-graded change
- U : Unexamined

Table 4-5 Funduscopic examination in male rats

Group	AAC	Water for injection	AAC	AAC	AAC
Dose (mg/kg)			1	10	100
Day	Item	Grade			
Pre	No abnormal changes	6	6	6	6
25	No abnormal changes	6		6	

Numerals represent the number of animals.

Table 4-6 Fundoscopic examination in female rats

Group	Dose(mg/kg)	Item	Grade	Water for injection	AAC	AAC	AAC	AAC
Pre	No abnormal changes			6	6	6	6	6
25	No abnormal changes			6	6	6	6	6
					1	10	100	

Numerals represent the number of animals.

Standard Urinalysis

Color	0 : Normal color					
	1 : Abnormal color					
		Protein	(mg/dL)	Glucose	(g/dL)	
		0 : -		0 : -		
		1 : ±		1 : +	0.1	
		2 : +	30	2 : ++	0.25	
		3 : ++	100	3 : +++	0.5	
		4 : +++	300<=	4 : ++++	1<=	
Ketone body	0 : -	Bilirubin	(mg/dL)	Occult blood		
	1 : ±	0 : -		0 : -		
	2 : +	1 : +	5	1 : ±		
	3 : ++	2 : ++	15	2 : +		
	4 : +++	3 : +++	40	3 : ++		
			80	4 : +++		
Urobilinogen	0 : ±		(Ehrlich unit/dL)			
	1 : +		0.1			
	2 : ++		1			
	3 : +++		2			
	4 : ++++		4			
			8<=			

Table 5-1 Urinalysis in male rats

Group	Dose(mg/kg)	Day	Grade	Water for injection	AAC	AAC	AAC	AAC
Color		26	0	6	6	6	10	100
			1					
PH		26	5					
			5.5					
			6	1			2	
			6.5				2	
			7	1			1	
			7.5	2	3		1	
			8	1	1		1	
			8.5	1	1		1	
			9					

Numerals represent the number of animals.
 Not significantly different from Water for injection.

Table 5-2 Urinalysis in male rats

Group	Water for injection	AAC	AAC	AAC
Dose(mg/kg)	Day	Grade		
Protein	26	0		
	1		2	
	2	4		4
	3	1		
	4	1		
Glucose	26	0	6	6
	1			
	2			
	3			
	4			

Numerals represent the number of animals.
 Not significantly different from Water for injection.

Table 5-3 Urinalysis in male rats

Group	Dose(mg/kg)	Day	Grade	Water for injection	AAC	AAC	AAC
Ketone body	26	0	2	5	4	10	100
		1	3	1	2		
		2	1	1			
		3					
		4					
Bilirubin	26	0	5	6	6		
		1	1				
		2					
		3					

Numerals represent the number of animals.
 Not significantly different from Water for injection.

Table 5-4 Urinalysis in male rats

Group	Dose (mg/kg)	Day	Grade	Water for injection	AAC	AAC	AAC
Occult blood		26	0	3	4	5	
			1	1	1	1	
			2	1			
			3	1	1		
			4				
Urobilinogen		26	0	3	6	5	
			1	3		1	
			2				
			3				
			4				

Numerals represent the number of animals.
 Not significantly different from Water for injection.

Table 5-5 Urinalysis in female rats

Group	Water for injection	AAC	AAC	AAC
Dose (mg/kg)	Day	Grade		
Color	26	0	6	6
		1		
pH	26	5		
		5.5		
		6		
		6.5	1	1
		7	1	1
		7.5	3	2
		8	1	2
		8.5	2	2
		9	1	1

Numerals represent the number of animals.
 Not significantly different from Water for injection.

Table 5-6 Urinalysis in female rats

Group	Dose(mg/kg)	Day	Grade	Water for injection	AAC	AAC	AAC
Protein	26	0	3	2	4	10	100
			2	2	2		
			2	1	2		
			3				
			4				
Glucose	26	0	6	6	6		
			1				
			2				
			3				
			4				

Numerals represent the number of animals.
 Not significantly different from Water for injection.

Table 5-7 Urinalysis in female rats

Group	Dose(mg/kg)	Day	Grade	Water for Injection	AAC	AAC	AAC
Ketone body	26	6	0	6	5	1	100
			1	6	5	1	10
			2	6	5	1	10
			3	6	5	1	10
			4	6	5	1	10
Bilirubin	26	6	0	6	6	6	6
			1	6	6	6	6
			2	6	6	6	6
			3	6	6	6	6

Numerals represent the number of animals.
 Not significantly different from Water for Injection.

Table 5-8 Urinalysis in female rats

Group	Dose (mg/kg)	Day	Grade	Water for injection	AAC	AAC	AAC	AAC
Occult blood	26	0	3		1	10	100	
		1	1	2	2	2		
		2	2	2	2	3		
		3				1		
		4						
Urobilinogen	26	0	4		5	6		
		1	2		1			
		2						
		3						
		4						

Numerals represent the number of animals.
 Not significantly different from Water for injection.

Hematology

RBC	(10 ⁶ /mm ³)	Erythrocyte count
WBC	(10 ³ /mm ³)	Leukocyte count
Ht	(%)	Hematocrit value
Hb	(g/dL)	Hemoglobin concentration
Plat.	(10 ³ /mm ³)	Platelet count
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)	Eosinophil count
Eosino.	(%)	Eosinophil ratio
Baso.	(10 ³ /mm ³)	Basophil count
Baso.	(%)	Basophil ratio
Mono.	(10 ³ /mm ³)	Monocyte count
Mono.	(%)	Monocyte ratio
Lymph.	(10 ³ /mm ³)	Lymphocyte count
Lymph.	(%)	Lymphocyte ratio
Neutro.	(10 ³ /mm ³)	Neutrophil count
Neutro.	(%)	Neutrophil ratio
LUC	(10 ³ /mm ³)	Large unstained cell count
LUC	(%)	Large unstained cell ratio
Blood coagulation test		
PT	(Sec)	Prothrombin time
APTT	(Sec)	Activated partial thromboplastin time