Table 4-1 Body weight (g) in male rats

Study No. : SBL94-83

Group Dose(mg/kg)	Water for injection	CCA 10	CCA 100	CCA 300	CCA 1000
Day Pre	190.3± 4.6(8)	190.0± 4.6(8)	189.1± 4.1(8)	184.0± 5.2(8)	190.4± 4.0(8)
6	212.3±17.0(8)	212.5±24.7(8)	210.0±12.8(8)	202.6±14.4(8)	
13	246.9±25.9(8)	255.6±22.4(8)	229.9±14.8(8)	224.1±21.3(8)	
20	271.8±32.3(8)	280.6±29.3(8)	254.0±22.0(8)	234.4±30.5(7)	
25				250.6±25.0(5)	
27	290.0±31.1(8)	304.0±31.0(8)	278.4±24.6(8)		
34	309.3±36.2(8)	322.1±31.3(8)	292.0±30.1(8)		
41	326.4±38.1(8)	339.8±32.5(8)	306.0±34.4(7)		
48	341.1±38.2(8)	353.6±35.7(8)	312.1±47.2(7)		
53	347.6±40.4(8)	354.9±41.2(8)	319.8±44.8(6)		

Values are expressed as the mean ± S.D. (N).
Statistical analyses were not performed at 300 mg/kg.
Not significantly different from Water for injection.

Table 4-2 Body weight (g) in female rats

Study No. : SBL94-83

Group / Dose(mg/kg)	Water for injection	CCA 10	CCA 100	CCA 300	CCA 1000
Day Pre	149.4± 3.7(8)	149.3± 3.9(8)	150.1± 3.7(8)	143.9± 2.7(8)	149.5± 4.1(8)
6	153.9± 8.0(8)	157.8± 7.4(8)	154.5± 5.8(8)	149.9±13.9(7)	
13	173.1± 8.3(8)	180.5± 5.8(8)	168.5± 9.8(8)	161.5±12.8(4)	
20	183.5±11.7(8)	186.4±14.6(8)	184.6±10.7(8)		
27	190.3±13.5(8)	201.0±20.8(8)	205.8±13.2(8)		
34	200.8±11.6(8)	209.0±23.7(8)	218.6±14.1(8)		
41	210.0±13.4(8)	216.6±21.8(8)	225.5±18.8(8)		
48	215.0±14.0(8)	219.6±20.1(8)	225.8±16.5(8)		
53	218.4±12.7(8)	222.6±21.9(8)	232.3±13.8(7)		

Values are expressed as the mean ± S.D. (N).
Statistical analyses were not performed at 300 mg/kg.
Not significantly different from Water for injection.

Table 4-3 Body weight gain (g) in male rats

Study No. : SBL94-83

Group	Water for injection	CCA	CCA	CCA	CCA
Dose(mg/kg)		10	100	300	1000
Day 6	22.0±13.8(8)	22.5±22.3(8)	20.9±12.6(8)	18.6±15.9(8)	
13	34.6±11.3(8)	43.1±11.0(8)	19.9± 7.1(8)*	21.5±10.0(8)	
20	24.9± 9.6(8)	25.0±13.8(8)	24.1±12.6(8)	6.4±22.7(7)	
25				2.0± 8.7(5)	
27	18.3± 8.0(8)	23.4±10.7(8)	24.4± 7.6(8)		
34	19.3±10.0(8)	18.1± 3.3(8)	13.6±13.4(8)		
41	17.1± 5.4(8)	17.6± 8.2(8)	9.9± 7.9(7)		
48	14.8± 4.1(8)	13.9±11.5(8)	6.1±15.6(7)		
53	6.5± 8.3(8)	1.3± 6.9(8)	-7.5±22.5(6)		

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

Table 4-4 Body weight gain (g) in female rats

Study No. : SBL94-83

Group	Water for injection	CCA	CCA	CCA	CCA
Dose(mg/kg)		10	100	300	1000
Day 6	4.5± 7.7(8)	8.5± 5.7(8)	4.4± 5.8(8)	6.6±12.5(7)	
13	19.3± 6.6(8)	22.8± 6.1(8)	14.0± 6.5(8)	5.3± 4.0(4)	
20	10.4± 6.3(8)	5.9± 9.5(8)	16.1± 2.7(8)		
27	6.8± 6.2(8)	14.6± 7.9(8)*	21.1± 3.1(8)**		
34	10.5± 5.5(8)	8.0± 5.6(8)	12.9± 5.0(8)		
41	9.3± 4.2(8)	7.6± 4.4(8)	6.9± 6.5(8)		
48	5.0± 4.4(8)	3.0± 3.9(8)	0.3± 8.1(8)		
53	3.4± 2.8(8)	3.0± 4.8(8)	3.3± 8.8(7)		

Values are expressed as the mean ± S.D. (N).
Statistical analyses were not performed at 300 mg/kg.
* $P<0.05$, ** $P<0.01$: 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 5-1 Gross ophthalmological examination in male rats Study No. : SBL94-83

Group			Water for injection	CCA	CCA	CCA	CCA
Dose(mg/kg) Week	Item	Grade		10	100	300	1000
Pre	No abnormal changes		8	8	8	8	8
4w	No abnormal changes					5	
8w	No abnormal changes		8		5		

Numerals represent the number of animals.

Table 5-2 Gross ophthalmological examination in female rats Study No. : SBL94-83

Group			Water for injection	CCA	CCA	CCA	CCA
Dose(mg/kg)				10	100	300	1000
Week	Item	Grade					
Pre	No abnormal changes		8	8	8	8	8
8w	No abnormal changes		8		7		

Numerals represent the number of animals.

Funduscopic examination

Grade

0 : No abnormal changes

1 : Slight

2 : Moderate

3 : Severe

P : Non-graded change

U : Unexamined

Table 5-3 Funduscopic examination in male rats Study No. : SBL94-83

Group			Water for injection	CCA	CCA	CCA	CCA
Dose(mg/kg)				10	100	300	1000
Week	Item	Grade					
Pre	No abnormal changes		8	8	8	8	8
4w	No abnormal changes					5	
8w	No abnormal changes		8		5		

Numerals represent the number of animals.

Table 5-4 Funduscopic examination in female rats

Study No. : SBL94-83

Group			Water for injection	CCA	CCA	CCA	CCA
Dose(mg/kg)				10	100	300	1000
Week	Item	Grade					
Pre	No abnormal changes		8	8	8	8	8
8w	No abnormal changes		8		7		

Numerals represent the number of animals.

Number of Animals

Study No. : SBL94-83

Item : Urinalysis
Sex : Male

Group Week /Dose(mg/kg)	Water for injection	CCA 10	CCA 100	CCA 300	CCA 1000
4w				5	
8w	8	8	7		

Number of Animals

Study No. : SBL94-83

Item : Urinalysis
Sex : Female

Group Week /Dose(mg/kg)	Water for injection	CCA 10	CCA 100	CCA 300	CCA 1000
8w	8	8	7		

Standard Urinalysis

Color
0 : Normal color
1 : Abnormal color

Protein		(mg/dL)
0	−	
1	±	
2	∓	30
3	++	100
4	+++	300<=

Glucose		(g/dL)
0	−	
1	±	0.1
2	∓	0.25
3	++	0.5
4	+++	1<=

Ketone body		(mg/dL)
0	−	
1	±	5
2	∓	15
3	++	40
4	+++	80

Bilirubin	
0	−
1	+
2	++
3	+++

Occult blood	
0	−
1	±
2	∓
3	++
4	+++

Urobilinogen		(Ehrlich unit/dL)
0	±	0.1
1	∓	1
2	++	2
3	+++	4
4	++++	8<=

Table 6-1 Urinalysis in male rats

Study No. : SBL94-83

Group			Water for injection	CCA	CCA	CCA	CCA
Dose(mg/kg)	Day	Grade		10	100	300	1000
Color	4w	0				5	
		1					
	8w	0	8	8	7		
		1					
pH	4w	5					
		5.5					
		6					
		6.5					
		7				4	
		7.5				1	
		8					
		8.5					
		9					
	8w	5					
		5.5					
		6		1			
		6.5	1	1	2		
		7	3	4	3		
		7.5	2	2	1		
		8	1				
		8.5	1		1		
		9					

Numerals represent the number of animals.
Statistical analyses were not performed at 300 mg/kg.
Not significantly different from Water for injection.

Table 6-2 Urinalysis in male rats

Study No. : SBL94-83

Group			Water for injection	CCA	CCA	CCA	CCA
Dose(mg/kg)				10	100	300	1000
	Day	Grade					
Protein	4w	0					
		1					
		2					
		3				4	
		4				1	
	8w	0	2	1	1		
		1		2			
		2	5	4	4		
		3	1	1	1		
		4			1		
Glucose	4w	0				1	
		1					
		2				2	
		3					
		4				2	
	8w	0	8	8	6		
		1					
		2					
		3					
		4			1		

Numerals represent the number of animals.
Statistical analyses were not performed at 300 mg/kg.
Not significantly different from Water for injection.

Table 6-3 Urinalysis in male rats

Study No. : SBL94-83

Group			Water for injection	CCA	CCA	CCA	CCA
Dose(mg/kg)				10	100	300	1000
	Day	Grade					
Ketone body	4w	0				4	
		1				1	
		2					
		3					
		4					
	8w	0	5	4	4		
		1		3	3		
		2	3	1			
		3					
		4					
Bilirubin	4w	0				3	
		1				2	
		2					
		3					
	8w	0	8	8	4		
		1			3		
		2					
		3					

Numerals represent the number of animals.
Statistical analyses were not performed at 300 mg/kg.
Not significantly different from Water for injection.

Table 6-4 Urinalysis in male rats

Study No. : SBL94-83

Group			Water for injection	CCA	CCA	CCA	CCA
Dose(mg/kg)				10	100	300	1000
	Day	Grade					
Occult blood	4w	0				4	
		1				1	
		2					
		3					
		4					
	8w	0	5	7	5		
		1	1	1	1		
		2	1				
		3					
		4	1		1		
Urobilinogen	4w	0				1	
		1				4	
		2					
		3					
		4					
	8w	0	5	2	3		
		1	3	6	4		
		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.

Table 6-5 Urinalysis in female rats

Study No. : SBL94-83

Group			Water for injection	CCA	CCA	CCA	CCA
Dose(mg/kg)				10	100	300	1000
	Day	Grade					
Color	8w	0	8	8	7		
		1					
pH	8w	5					
		5.5	1				
		6	2		1		
		6.5	3	1			
		7	1	4	3		
		7.5		3	2		
		8	1		1		
		8.5					
		9					

Numerals represent the number of animals.
Statistical analyses were not performed at 300 mg/kg.
Not significantly different from Water for injection.

Table 6-6 Urinalysis in female rats

Study No. : SBL94-83

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

Numerals represent the number of animals.
Statistical analyses were not performed at 300 mg/kg.
Not significantly different from Water for injection.

Table 6-7 Urinalysis in female rats

Study No. : SBL94-83

Group			Water for injection	CCA	CCA	CCA	CCA
Dose(mg/kg)				10	100	300	1000
	Day	Grade					
Ketone body	8w	0	1	1	6*		
		1	7	7	1		
		2					
		3					
		4					
Bilirubin	8w	0	8	8	4		
		1			3		
		2					
		3					

Numerals represent the number of animals.
Statistical analyses were not performed at 300 mg/kg.
* P<0.05 : Significantly different from Water for injection.