

Figure 1-1 Changes of body weight in rats
The water for injection group indicates the control group in study SBL101-003.

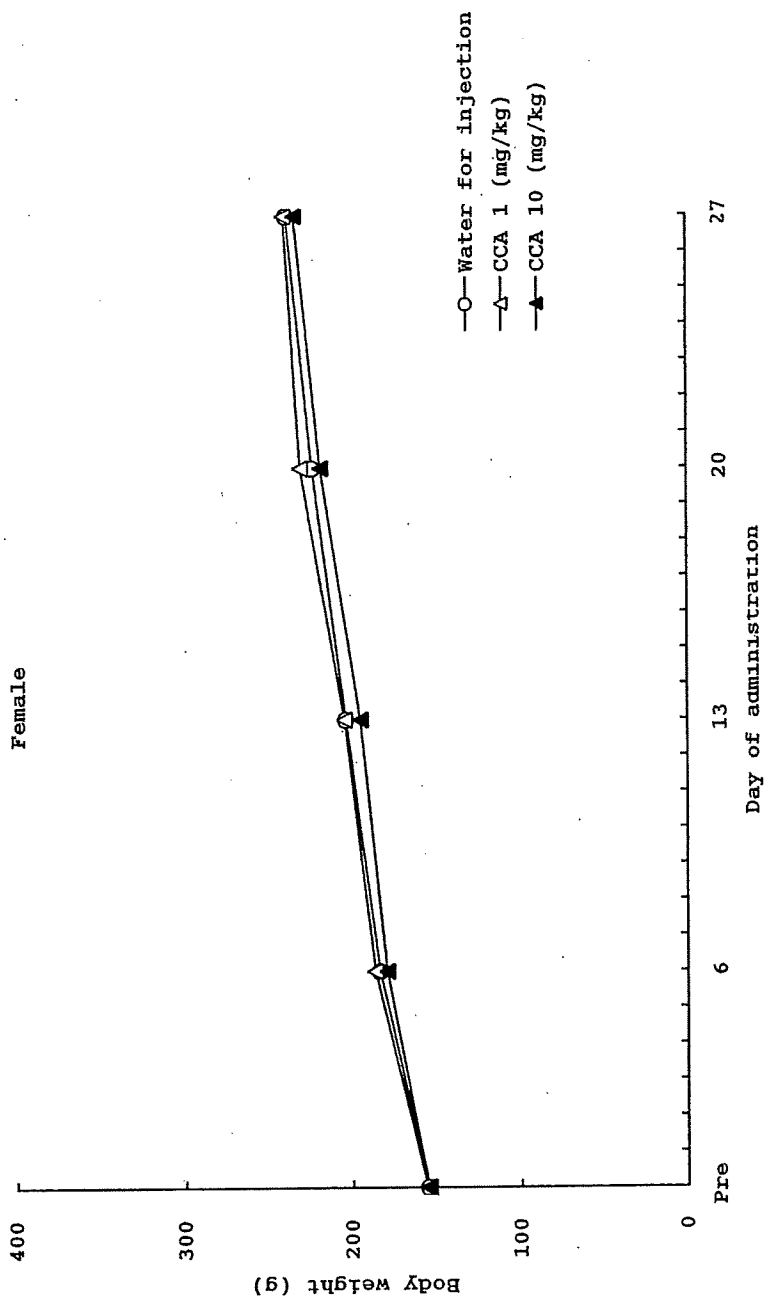


Figure 1-2 Changes of body weight in rats
The water for injection group indicates the control group in study SBL101-003.

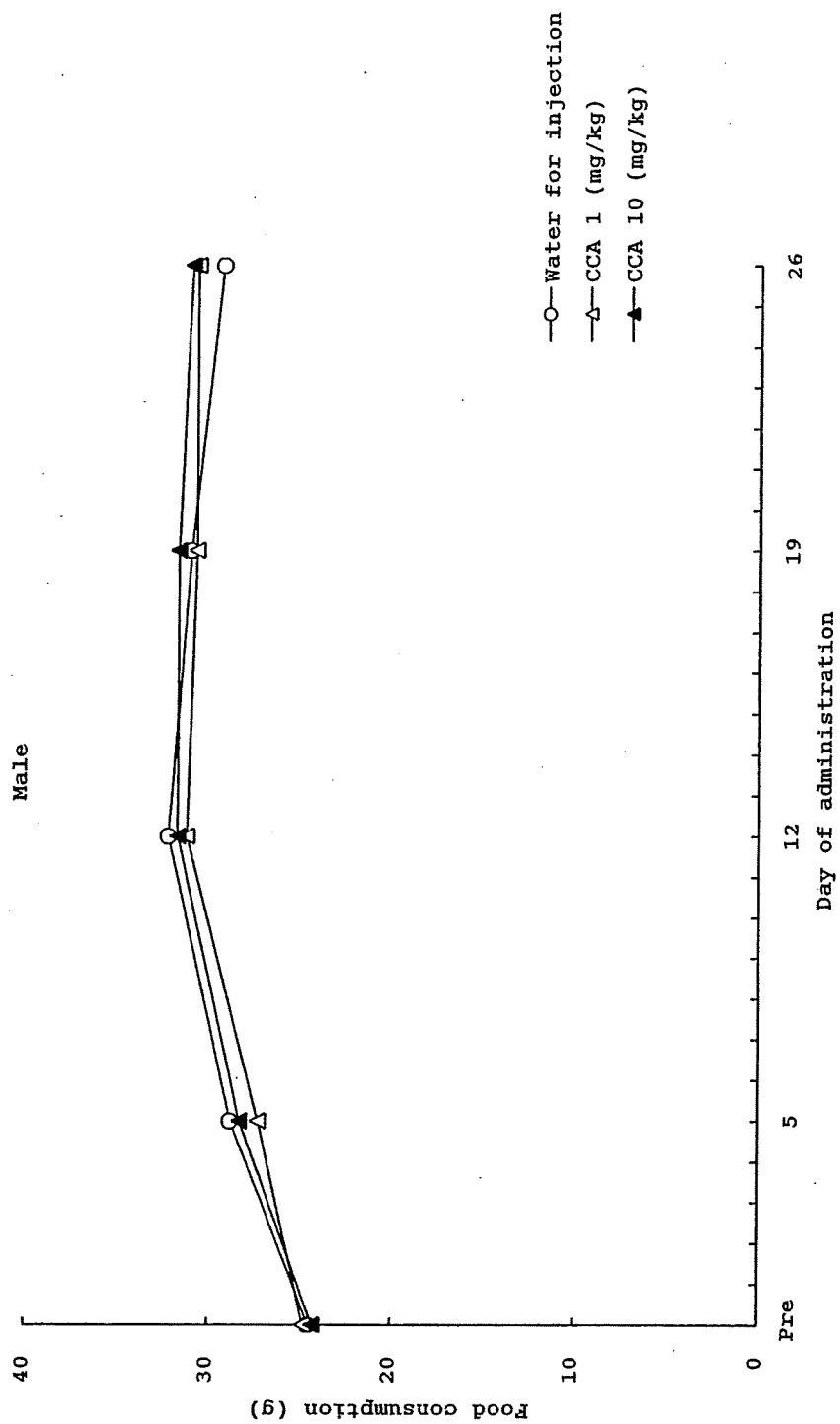


Figure 2-1 Changes of food consumption in rats
The water for injection group indicates the control group in study SBL101-003.

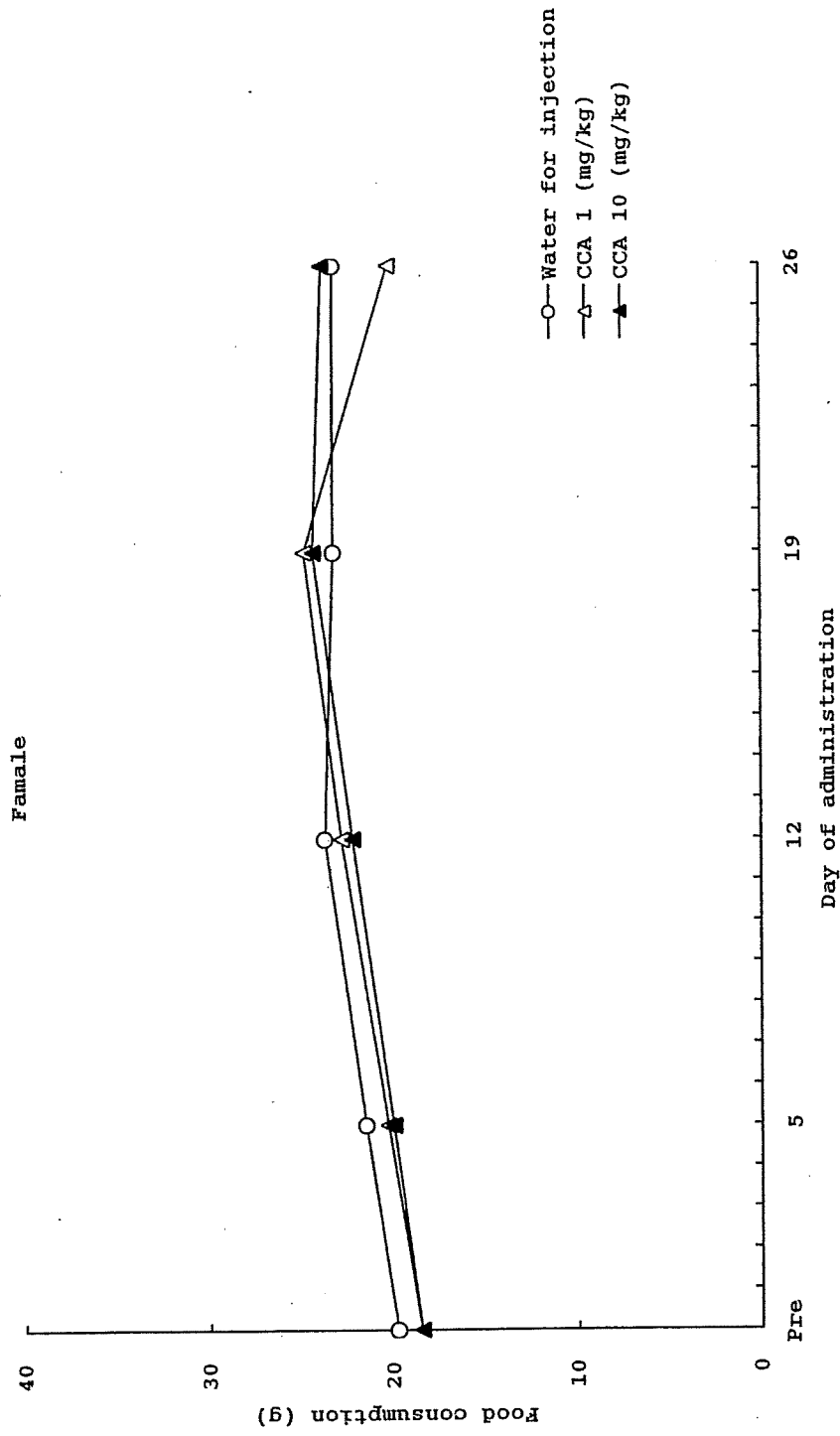


Figure 2-2 Changes of food consumption in rats
The water for injection group indicates the control group in study SBL101-003.

Table 1-1 Clinical signs in male rats (Administration site)

Group	Number of animals	Item	Day of administration (Before administration)																												
			0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
Water for injection	6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CCA (1 mg/kg)	6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
CCA (10 mg/kg)	6	Crust	0	0	0	0	0	0	3	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	

Numerals represent the number of animals.

Table 1-2 Clinical signs in female rats (Administration site)

Group	Number of animals	Item	Day of administration (Before administration)																												
			0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
Water for Injection	6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CCA(1 mg/kg)	6		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CCA (10 mg/kg)	6	Crust	0	0	0	0	0	3	4	5	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6

Numerals represent the number of animals.

Table 2-1 Body weight (g) in male rats

Group	Water for injection	CCA		CCA
		1	10	
Day Pre	195.7± 8.6(6)	197.0± 7.5(6)	197.3± 5.6(6)	
6	253.5±13.8(6)	254.2±12.8(6)	255.0±10.1(6)	
13	307.3±23.9(6)	308.7±17.2(6)	306.3±11.1(6)	
20	345.8±29.2(6)	347.2±24.7(6)	341.5±16.2(6)	
27	378.7±35.0(6)	378.8±31.2(6)	372.2±16.5(6)	

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

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

Group	Water for injection	CCA	
		1	10
Day Pre	155.0± 7.5(6)	155.7± 5.3(6)	155.0± 6.5(6)
6	183.7±11.6(6)	186.5±10.3(6)	179.5± 9.6(6)
13	203.8±17.4(6)	204.5±13.4(6)	195.0±15.1(6)
20	223.7±17.7(6)	231.0±19.7(6)	218.8±15.0(6)
27	239.2±20.4(6)	240.7±22.2(6)	234.3±16.5(6)

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

Table 2-3 Body weight gain (g) in male rats

Group	Water for injection	CCA	
		1	10
Day 6	57.8± 9.1(6)	57.2± 6.2(6)	57.7± 5.6(6)
13	53.8±13.2(6)	54.5± 7.7(6)	51.3± 2.8(6)
20	38.5± 7.4(6)	38.5± 8.7(6)	35.2± 5.9(6)
27	32.8± 6.8(6)	31.7± 7.5(6)	30.7± 3.2(6)

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

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

Group	Water for injection	CCA	
		1	10
Day 6	28.7 ± 5.7 (6)	30.8 ± 6.1 (6)	24.5 ± 6.5 (6)
13	20.2 ± 7.9 (6)	18.0 ± 4.6 (6)	15.5 ± 7.5 (6)
20	19.8 ± 2.7 (6)	26.5 ± 7.5 (6)	23.8 ± 5.5 (6)
27	15.5 ± 4.8 (6)	9.7 ± 3.7 (6)*	15.5 ± 2.6 (6)

Values are expressed as the mean ± S.D. (N).

* P<0.05 : 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	Water for injection	CCA	CCA
Dose (mg/kg)		1	10
Day	Grade		
Pre	No abnormal changes	6	6
25	No abnormal changes	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	CCA	CCA
Pre		No abnormal changes		6	6	6
25		No abnormal changes		6	6	6
					1	10

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)	Day	Item	Grade	Water for injection	CCA	CCA
Pre			No abnormal changes		6	6	6
25			No abnormal changes		6	6	6

Numerals represent the number of animals.

Table 4-4 Slit-lamp examination in female rats

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

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

Numerals represent the number of animals.

Table 4-6 Funduscopic examination in female rats

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

Numerals represent the number of animals.

Standard Urinalysis

Color 0 : Normal color
 1 : Abnormal color

Protein 0 : -
 1 : ±
 2 : +
 3 : ++
 4 : +++

(mg/dL)
 30
 100
 300<=

Glucose 0 : -
 1 : +
 2 : ++
 3 : +++
 4 : ++++

(g/dL)
 0.1
 0.25
 0.5
 1<=

Ketone body 0 : -
 1 : ±
 2 : +
 3 : ++
 4 : +++

(mg/dL)
 5
 15
 40
 80

Bilirubin 0 : -
 1 : +
 2 : ++
 3 : +++

Occult blood 0 : -
 1 : ±
 2 : +
 3 : ++
 4 : +++

Urobilinogen 0 : ±
 1 : +
 2 : ++
 3 : +++
 4 : ++++

(Ehrlich unit/dL)
 0.1
 1
 2
 4
 8<=