

8. Procedures

Female mice were allocated into experimental and control groups each consisting of five mice.

The mice were not fed for about 4 hours before administration. After measurement of body weight, the animals in the experimental group were orally administered with the test dilution at a single dose of 20 mL/kg b.w. (at a dosage of 5000 mg/kg b.w. test sample) using a stomach tube. The animals in the control group were administered with water for injection, as vehicle control, at the same dose.

The clinical observation was carried out frequently on the day of the administration and once a day for the following 13 days. The body weight was measured after 7 and 14 days of the administration. The mean body weight values of the experimental group and the control group were assessed for homogeneity of variance by Levene's test. Since the Levene's test was not significant, Student's t-test was applied for the comparison of two groups ($\alpha = 0.05$).

At the completion of the test, all of the mice were sacrificed for necropsy.

9. Results

1) Death of animals

None of the mice died during the experimental period.

2) Clinical observations

No abnormalities were observed in any of the mice during the experimental period.

3) Body-weight changes (Table 1)

After 14 days of administration, one mouse in the experimental group exhibited a weight loss.

After 7 days of administration, no significant difference in body weight was detected between the experimental group and the control group. After 14 days, however, the body weight of the animals in the experimental group was significantly lower ($p < 0.05$) than that in the control group.

4) Necropsy

No remarkable changes were found in any of the mice.

10. Conclusion

The acute oral toxicity in female mice of the test sample was determined.

Oral administration of 5000 mg/kg b.w. test sample caused no death in any of the mice during the observation period.

Consequently, the LD50 value (single dose, oral administration) of the test sample is considered to be more than 5000 mg/kg b.w. in female mice.

Table 1. Body-weight changes

Group	Body weight (Units: g)		
	Pre-administration	7 days	14 days
Experimental group	28.4 ± 1.1 (5)	30.3 ± 1.8 (5)	31.0 ± 1.7* (5)
Control group	28.5 ± 1.2 (5)	31.7 ± 1.2 (5)	34.0 ± 0.7 (5)

The values are mean ± SD.

The values in parentheses represent the number of animals.

* A significant difference is detected between the experimental and control groups ($p < 0.05$).

End of Report