Japan Food Research Laboratories

Japan Food Research Laboratories
Authorized by the Japanese Government
52-1 Motoyoyogi-cho, Shibuya-ku, Tokyo 151-0062, Japan
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May 24, 2012

REPORT

Client: BAN-YU CO., LTD.
2-4-10 Kawara-machi, Chuo-ku, Osaka-shi, Osaka 541-0048, Japan

Test sample(s): BY-50

Title: Acute Oral Toxicity Test in Mice

Received date of test sample(s): April 25, 2012

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Y. Kawamoto

Yasuharu Kawamoto
Study Director
Section of Biological Safety Research

May 31, 2012
Date

JAPAN FOOD RESEARCH LABORATORIES

Acute Oral Toxicity Test in Mice

Abstract

The test sample, BY-50, was tested for acute oral toxicity in male and female mice. To the experimental animals, the test sample was administered orally at a dose of 2000 mg/kg b.w. (body weight) in a single dose, and the experimental period was 14 days. The control animals were administered water for injection as vehicle control. As a result, the test sample caused no death in any of the mice during the observation period. Consequently, the LD50 value (single dose, oral administration) of BY-50 is considered to be more than 2000 mg/kg b.w. in male and female mice.

Client

BAN-YU CO., LTD.

Test sample

BY-50

Testing period

From April 25 to May 24, 2012

Test facility

Tama Laboratory, Japan Food Research Laboratories
6-11-10 Nagayama, Tama-shi, Tokyo 206-0025, Japan

Study director

Yasuharu Kawamoto
Section of Biological Safety Research
Department of Biological Safety Research
Tama Laboratory, Japan Food Research Laboratories

1. Purpose

The acute oral toxicity in male and female mice of BY-50 is evaluated.

2. Test sample

BY-50

Character: colorless transparent liquid

3. Preparation of test dilution

The test sample was diluted in water for injection to make a 100 mg/mL test dilution.

4. Experimental animals

Male and female mice of ICR strain, at an age of 5 weeks, were purchased from Japan SLC, Inc. Before test, they were acclimated to laboratory conditions for about 1 week to verify that no abnormalities were shown in general conditions. And then, they were housed in plastic cages (five animals per cage) under standard laboratory conditions (Temperature: 23 °C ± 2 °C, Light-dark cycle: 12/12 hours). Feed (Labo MR Stock diet, Nihon Nosankogyo K.K.) and tap water were provided *ad libitum* throughout the experiment.

5. Procedures

Male and 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 administered orally the test dilution at a dose of 20 mL/kg b.w. (at a dosage of 2000 mg/kg b.w. test sample) in a single dose using a stomach tube. The animals in the control group were administered water for injection, as vehicle control, at a dose of 20 mL/kg b.w. in the same manner.

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, and the mean body weight values of the experimental and control groups were statistically analyzed by t-test ($\alpha = 0.05$).

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

6. Results

1) Death of animals

Neither male nor female mice died during the experimental period.

2) Clinical observations

No abnormalities were observed in either male or female mice during the experimental period.

3) Body-weight changes (Tables 1 and 2)

In male mice, no significant differences in body weight were detected between the experimental and control groups after 7 and 14 days of the administration.

In female mice, no significant difference in body weight of the mice was detected between the experimental and control groups after 7 days of the administration. However, the body weight of the experimental group after 14 days was significantly lower ($p<0.05$) than that of the control group.

4) Necropsy

No remarkable changes were found in any male or female mice.

7. Conclusion

The acute oral toxicity of BY-50 was determined in male and female mice.

Oral administration of 2000 mg/kg b.w. of the 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 2000 mg/kg b.w. in male and female mice.

8. Reference

• OECD Guidelines for the Testing of Chemicals 420 (2001).

Table 1. Body-weight changes (male)

Group	Body weight (g)		
	Pre-administration	7 days	14 days
Experimental group	33.3 ± 1.4 (5)	38.0 ± 1.5 (5)	41.0 ± 1.9 (5)
Control group	33.6 ± 1.7 (5)	38.1 ± 2.8 (5)	41.1 ± 2.9 (5)

Values represent mean ± SD.
Values in the parentheses show the number of animals.

Table 2. Body-weight changes (female)

Group	Body weight (g)		
	Pre-administration	7 days	14 days
Experimental group	26.0 ± 0.8 (5)	29.6 ± 1.1 (5)	30.4 ± 1.5* (5)
Control group	26.3 ± 0.9 (5)	29.4 ± 1.0 (5)	32.2 ± 0.9 (5)

Values represent mean ± SD.
Values in the parentheses show the number of animals.
* A significant difference is detected between the experimental and control groups ($p<0.05$).

End of Report