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NATIONAL STANDARD OF THE
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YBB 00042003-2015

Test for Acute Systemic Toxicity

Test for Acute Systemic Toxicity

This test is a method in which a certain dose of test sample is intravenously injected into the mouse, and the mouse is observed for toxic reaction and death within a prescribed period of time, so as to determine whether the test sample meets the requirements.

The test mice shall be healthy and qualified. They shall be kept under the same feeding condition (the temperature of laboratory and feeding room is controlled at 19~28 °C). The female mice shall have no pregnancy. The weight is 17~23 g. Mice which have been used in this test must not be reused. The mice are randomly divided into two groups -- test group and control group, with 5 in each group. For retest, 10 mice of 18~19 g are taken from each group.

[Preparation of the test solution] The preparation process shall be carried out according to the aseptic method.

RINSE test sample with purified water; after dried with filter paper, CUT into strips of about 0.5 cm X 3 cm; and then PLACE into an extraction container. Unless otherwise specified, in accordance with Table 1, ADD sodium chloride injection as the extract. The test sample is immersed in the extract. EXTRACT according to the conditions of Table 2; and OBTAIN the test solution. When necessary, before the preparation of test solution, the test sample is placed into a high-pressure steam sterilizer and is kept at 115 °C for 30 minutes.

[Blank control solution] Sodium chloride injection.

The blank control solution and the test solution shall be used within 24 hours after preparation.

Table 1 -- RATIO of the surface area or weight of test sample TO the volume of extract

Thickness of test sample (mm)	Ratio of surface area or weight to volume of extract
≤0.5	6 cm ² /ml
>0.5~1.0	3 cm ² /ml
>1.0	1.25 cm ² /ml
Irregular shape	0.2 g/ml

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