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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 14233.2-2025

Replacing GB/T 14233.2-2005

Test methods for infusion, transfusion, injection equipment for medical use - Part 2: Biological test methods

医用输液、输血、注射器具检验方法 第2部分：生物学试验方法

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1 Scope

GB/T 14233.2-2025 is the Chinese national standard on test methods for infusion, transfusion, injection equipment for medical use - part 2: biological test methods, in the field of health care technology. The /T suffix marks it as a recommended standard: it is not compulsory by itself, but it becomes binding as soon as a contract, a tender or a customer specification calls it up - which in practice is how most foreign buyers meet it. It was issued on 2 December 2025 by the State Administration for Market Regulation; Standardization Administration of China, and takes effect on 1 January 2027. Classification: ICS 11.040.20, CCS C31. This page is published from the official record of the standard held by the Chinese standards administration: the identification, the dates, the classification and the issuing body are taken from there. The clause text, the tables and the numeric limits are in the document itself, which is delivered complete in English translation.

This document describes the biological test methods for medical infusion, blood transfusion, and injection equipment. This document applies to medical infusion, blood transfusion, and injection equipment.

2 Normative References

The contents of the following documents constitute indispensable clauses of this document through the normative references in the text. In terms of references with a specified date, only versions with a specified date are applicable to this document. In terms of references without a specified date, the latest version (including all the modifications) is applicable to this document.

GB/T 16886.3 Biological Evaluation of Medical Devices - Part

3 Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity

GB/T 16886.4 Biological Evaluation of Medical Devices - Part

4 Preparation of Extracts

4.1 General Requirements The preparation of extracts shall conform to the provisions of GB/T 16886.12, simulating the clinical use environment of the sample as closely as possible (e.g., sample contact area, time and temperature, etc.). The simulated extraction time shall not be less than the normal use time of the sample; otherwise, its feasibility and rationality shall be demonstrated. When the sample use time is relatively long (e.g., exceeding 24 hours), it is advisable to prepare the extracts under more rigorous test conditions, but the feasibility and rationality shall be demonstrated. The test shall be conducted on the final products, representative samples taken from the final products, or materials prepared using the same process as the final products, or extracts prepared from the above samples or materials.

4.2 Main Equipment Clean bench or biosafety cabinet, electronic balance, constant-temperature oscillation incubator, constant-temperature water bath, pressure steam sterilizer, electric drying oven, etc.

4.3 Extraction Containers Unless otherwise specified, extraction shall be carried out in a clean, chemically inert, and sealed container. To ensure that the extraction containers do not interfere with the extract of the test material, the extraction containers shall be.

5 Pyrogen Test

5.1 Purpose This test involves injecting the sample extract into a rabbit's vein and observing whether the rabbit's body temperature rises within a specified time to determine if the sample has a potential pyrogenic effect.

5.2 Reagent 0.9% sodium chloride injection.

5.3 Main Equipment and Apparatus Electric drying oven, electric constant-temperature water bath, pressure steam sterilizer, pyrogen thermometer or rectal thermometer,

constant-temperature oscillation incubator, electronic balance, syringe, etc.

5.4 Pre-test Preparation

5.4.1 Pyrogen removal from apparatus All glassware in contact with the sample/extract shall be dry roasted in an electric drying oven at 250 C for at least 30 minutes. Other suitable methods may also be used for pyrogen removal.

5.4.2 Temperature measuring apparatus The rabbit body temperature test shall use a pyrogen thermometer or rectal thermometer with a precision of 0.1 C.

5.4.3 Laboratory environment 1 ~ 2 days prior to the test, the rabbits used for the test shall be kept in the same temperature environment. The temperature difference between the laboratory and the breeding room shall not exceed 3 C, and the laboratory temperature shall be between 17 C and 25 C. Throughout the test, the room temperature shall not fluctuate by more than 3 °C to prevent animal agitation and avoid noise interference.

5.4.4 Test rabbits Use test rabbits that conform to the Pharmacopoeia of the People's Republic of China (Volume IV, Pyrogen Test Method).

5.5 Test Method

5.5.1 Preparation of extracts In accordance with the provisions of Chapter 4, select appropriate extraction conditions.

5.5.2 Test procedures Proceed in accordance with the provisions in the Pharmacopoeia of the People's Republic of China (Volume IV, Pyrogen Test Method). The injection dose for rabbits is 10 mL/kg.

5.5.3 Result judgment In accordance with the provisions in the Pharmacopoeia of the People's Republic of China (Volume IV, Pyrogen Test Method), conduct the judgment.

5.6 Test Report The test report should provide the following information.

b) Production batch No.;

c) Preparation method of the extracts;

d) Injection dose;

e) Rabbit body temperature record;

f) Result judgment.

6 Acute Systemic Toxicity Test

6.1 Purpose This test involves injecting the sample extract into the veins and peritoneal cavity of mice. The mice are observed for toxic reactions and mortality within a specified time to determine whether the sample has potential acute systemic toxicity.

6.2 Extraction Media 0.9% sodium chloride injection, refined vegetable oil, etc.

6.3 Main Equipment and Apparatus Pressure steam sterilizer, constant-temperature oscillation incubator, electronic balance, syringe, etc.

6.4 Pre-test Preparation

6.4.1 Apparatus sterilization Place all apparatus in contact with the sample/extract in a pressure steam sterilizer at 121 C for 20 minutes, or other suitable sterilization modes may be used.

6.4.2 Preparation of test animals

6.4.2.1 Healthy, nascent adult mice of the same strain and origin are used for the test. Female mice are non-pregnant and had not given birth, weighing 17 g ~ 23 g. The weight difference between animals of the same sex shall not exceed 20% of the average value. Before the test, mice are acclimatized to the laboratory environment. Mice previously used in this test shall not be repeatedly used.

10 Tests for Irritation and Delayed-type Hypersensitivity

GB/T 16886.11 Biological Evaluation of Medical Devices - Part

11 Tests for Systemic Toxicity

GB/T 16886.12 Biological Evaluation of Medical Devices - Part

12 Sample Preparation and Reference Materials

GB/T 16886.23 Biological Evaluation of Medical Devices - Part

23.Tests for Irritation

YY/T 0870 (all parts) Test for Genotoxicity of Medical Devices

YY/T 0878.3 Test for Complement Activation of Medical Devices - Part