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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 14233.3-2024

Test methods for infusion, transfusion, injection equipments for medical use - Part 3: Microbiological test methods

医用输液、输血、注射器具检验方法 第3部分：微生物学试验方法

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1 Scope

GB/T 14233.3-2024 is the Chinese national standard on test methods for infusion, transfusion, injection equipments for medical use - part 3: microbiological 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 26 October 2024 by the State Administration for Market Regulation; Standardization Administration of China, and takes effect on 1 November 2026. 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 test methods of test for sterility, bacterial endotoxin test, test of bioburden and test of sterility for infusion, transfusion, injection equipment for medical use. This document applies to infusion, transfusion, injection equipment for medical use.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

GB/T 19973.1, Sterilization of health care products - Microbiological methods - Part

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1 test for sterility A technical procedure performed on products that have undergone aseptic processing or sterilization to check for sterility.

3.2 direct inoculation method A method of test for sterility/test of sterility that involves directly immersing the product in a liquid culture medium for incubation.

3.3 membrane filtration method recovery efficiency A measure of the ability of a specific technique to transfer, collect and/or cultivate microorganisms from a product. [Source: ISO 11139.2018, 3.228]

3.11 bioburden correction factor A value used to compensate for values that cannot be completely collected from the product and/or microbial cultures when counting viable microorganisms. [Source: ISO 11139.2018, 3.24]

3.12 bioburden estimate A value determined by applying the bioburden correction factor to the bioburden count. [Source: ISO 11139.2018, 3.25]

3.13 test of sterility A technical operation required during development, validation or requalification to determine whether a product or its fraction contains viable microorganisms. [Source: ISO 11139.2018, 3.299]

4.1 Materials and instruments

4.1.1 Culture media The culture media for the test for sterility are usually Fluid

Thioglycollate Medium (FTM) and Tryptic Soy Broth (TSB). The preparation, sterilization, storage and quality control of culture media should comply with the requirements of Chapter 1101 Test for Sterility and Chapter 9203 Guidance for Quality Management in Pharmaceutical Microbiology Laboratories, Part IV of the 2020 edition of the Pharmacopoeia of the People's Republic of China.

4.1.2 Strains The strains used for the test for sterility are mainly used for suitability test of culture media, method suitability test and positive control test. The species, source, revival, storage, subculture and use of strains should comply with the requirements of Chapter 1101 Test for Sterility and Chapter 9203 Guidance for Quality Management in Pharmaceutical Microbiology Laboratories, Part IV of the 2020 edition of the Pharmacopoeia of the People's Republic of China.

Note. The method recovery efficiency validation test generally uses spores of Bacillus.

4.1.3 Dilution and rinsing solutions Dilution and rinsing solutions for the test for sterility are usually 0.1% sterile peptone water solution, pH

7.0 sterile sodium chloride-peptone buffer solution, etc. Their preparation should comply with the requirements of Chapter 1101 Test for Sterility of the 2020 edition of the Pharmacopoeia of the People's Republic of China.

4.1.4 Culture vessels Membrane filtration apparatus, test tubes, conical flasks, etc.

4.1.5 Instruments Balance, pressure steam sterilizer, clean bench, biosafety cabinet, membrane filtration device, incubator, etc.

4.2 Test environment Sample handling and inoculation of culture media should be performed in a clean bench or biosafety cabinet within a clean laboratory of not less than Grade 10 000, or in an isolator system within a clean laboratory of not less than Grade 100 000.Operations involving biosafety shall be carried out in a biosafety cabinet within a biosafety laboratory.

4.3.1 Method design

4.3.1.1 Test quantity Generally, the whole test item shall be selected for testing with each type of culture medium. If the properties of the test item do not allow, representative portions may be selected, including. -- portions representing each material of the test item in proportion; or -- the most difficult-to-sterilize portion of the whole test item; or -- the portion of the test item that comes into contact with patients.

4.3.1.2 Test item handling and inoculation into culture media Depending on the characteristics of the test item, one or more of the following methods shall be used for test item handling and inoculation into culture media. Direct inoculation method. cut or disassemble the test item and immerse it in the culture medium. Adequate contact between culture medium and test item should be ensured; the volume and height of culture medium

in the culture vessel should be specified. Medium elution method. use culture medium to thoroughly rinse the test item internally and/or externally, and incubate the elution culture medium. The volume of culture medium and rinsing time should be specified. Medium filling method. fill culture medium into the internal cavity of the test item, seal, and directly incubate. The volume of culture medium should be specified. Membrane filtration method. use rinsing solution to thoroughly rinse the test item internally and/or externally; combine the rinsing solutions to obtain the test solution. Subject the test solution to membrane filtration, and incubate the membrane. The type of rinsing solution, volume of rinsing solution and rinsing time should be specified. Considering microbial recovery efficiency, where applicable, the direct inoculation method or medium filling method should be preferably used for test item handling and inoculation into culture media. For test items claimed to be sterile only internally, the direct inoculation method is not applicable. For test items with complex structures, they may be disassembled and then subjected separately to test item handling and inoculation into culture media. For container-type test items containing liquid, after sufficient contact with the container, the internal liquid may be tested using the membrane filtration method.

4.3.1.3 Incubation and observation Incubation and observation should be carried out with reference to Chapter 1101 Test for Sterility of the 2020 edition of the Pharmacopoeia of the People's Republic of China.

4.3.1.4 Positive control test Positive control test should be carried out with reference to Chapter 1101 Test for Sterility of the 2020 edition of the Pharmacopoeia of the People's Republic of China.

4.3.1.5 Negative control test Negative control test should be carried out with reference to Chapter 1101 Test for Sterility of the 2020 edition of the Pharmacopoeia of the People's Republic of China.

4.3.1.6 Result interpretation Results should comply with the requirements of Chapter 1101 Test for Sterility of the 2020 edition of the Pharmacopoeia of the People's Republic of China.

4.3.2 Method validation

4.3.2.1 Method suitability test When performing the test for sterility on test items, a method suitability test should be carried out with reference to Chapter 1101 Test for Sterility of the 2020 edition of the Pharmacopoeia of the People's Republic of China to validate that the method is suitable for the test for sterility of the test item. If changes in the test method or test item may affect the test results, the method suitability test shall be repeated.

4.3.2.2 Method recovery efficiency validation test When the medium elution method and membrane filtration method are used, in addition to the method suitability test, a method recovery efficiency validation test should be carried out with reference to GB/T 19973.1,