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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

中华人民共和国国家标准

GB/T 14233.2–2005

Replace GB/T 14233.2–1993

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：生物学实验方法

Issued on November 17, 2005 **Implemented on May 01, 2006**

Issued by General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China

Standardization Administration of the People's Republic of China

Contents

Foreword

GB/T 14233 *Test methods for infusion, transfusion, injection equipment for medical use* consist of following two parts:

— Part 1: Chemical analysis methods;

— Part 2: Biological test methods.

This is part 2 of GB/T 14233. This part will replace GB/T 14233.2-1993 *Infusion, transfusion, injection equipment for medical use—Part 2: Biological test methods*. This revision for three testing such as sterile, pyrogen and bacterial endotoxin and direct reference to application articles in *Chinese Pharmacopoeia II*, so as to keep pace with latest revision version of Chinese Pharmacopoeia; refer to GB/T 16886 Biological evaluation of medical devices, revised the test methods of cytotoxicity; sensitization, intradermal reaction and implantation test direct refer to GB/T 16886 Biological evaluation of medical devices; added interactional test methods for subacute (subchronic) general toxicity sanguis (apparatus), canceled product index of pass.

Annex A, B and C of this part are informative annex.

This part is proposed by State Food and Drug Administration (NADFC).

This part is under the jurisdiction of National Technical Committee on Medical Syringes of Standardization Administration of China

The responsible drafting organizations are Jinan MDSIN Quality Inspection Center of NADFC and Tianjin Medical Biomaterials Testing and Research Center.

The chief drafting staff of this standard includes Shao Hua, Zhu Xuetao, Liu Xin, Huang Jingchun, Wang Xin, Zhu Junmei, Wang Kelei and Hao Shubin.

This part was issued for the first time on March, 1993.

Introduction

Biological test methods given in this part are based on basic principles of GB/T 16886.1 *Biological Evaluation of Medical Equipment Part 1: Evaluation and Test*, and established especially for needs of biological evaluation of infusion, transfusion and injection equipment for medical use. Based on proper test methodology principles and test procedures specified in GB/T 16886 *Biological Evaluation of Medical Equipment* and *Chinese Pharmacopoeia* (second edition), this revision is made according to the characteristics of infusion, transfusion, and injection equipment for medical use, therefore, this part is equal with methods of GB/T 16886 and *China Pharmacopoeia* in methodology and applies to the method standards measuring biological performance of infusion, transfusion, and injection equipment for medical use..

This revision makes direct reference to applicable parts in *China Pharmacopoeia* for sterility, pyrogen and bacterial endotoxin tests without indications of the year numbers of the pharmacopoeia in order to keep pace with the latest revision of *China Pharmacopoeia*, details the test projects that have no specific steps provided in GB/T 16886, such as cell toxicity, acute general toxicity, sub-acute (sub-chronic) general toxicity and blood (equipment) reciprocity reaction tests and directly refers to applicable parts in GB/T 16886 for stimulation, sensitization and implantation tests that give detailed test steps in GB/T 16886.

As a method standard for tests, this revision has canceled the index of qualified products in the text, but a current general index for identification is provided in the note for reference. Appropriate qualification indices should be provided in accordance with the characteristics of products when this part is quoted by related product standards.

Test Methods for Infusion, Transfusion, Injection Equipment for Medical Use

Part 2：Biological Test Methods

1 Scope

This part of GB/T 14233 specifies test methods of infusion, transfusion, injection equipment for medical use.

This part applies to infusion, transfusion, injection equipment for medical use.

2 Normative reference

The articles contained in the following documents have become this part of GB/T 14233 when they are quoted herein. For the dated documents so quoted, all the modifications (excluding corrections) or revisions made thereafter shall not be applicable to this Standard. For the undated documents so quoted, the latest editions shall be applicable to this Standard.

GB/T 16886.1 *Biological Evaluation of Medical Equipment Part 1: Evaluation and Test* (GB/T 16886.1-2001, idt ISO 10993-1:1997)

GB/T 16886.4 *Biological Evaluation of Medical Equipment Part 4: Blood Reciprocity Reaction Test Selection* (GB/T 16886.4-2003, ISO 10993-4:2000, IDT)

GB/T 16886.5 *Biological Evaluation of Medical Equipment Part 5*: *In Vitro Cell Toxicity Test* (GB/T 16886.5-2003, ISO 10993-5:1999, IDT)

GB/T 16886.6 *Biological Evaluation of Medical Equipment Part 6*: *Post-Implantation Local Response Test* (GB/T 16886.6-1997, idt ISO 10993-6:1996)

GB/T 16886.10 *Biological Evaluation of Medical Equipment Part 10*: *Stimulation and Delayed Type Hypersensitivity Test* (GB/T 16886.10-2005, ISO 10993-10:2002, IDT)

GB/T 16886.11 *Biological Evaluation of Medical Equipment Part 11*: *Acute General Toxicity Test* (GB/T 16886.11-1997, idt ISO 10993-11: 1993)

GB/T 16886.12 *Biological Evaluation of Medical Equipment Part 12*: *Sample Preparation and Reference* (GB/T 16886.12-2005, ISO 10993-12: 2002, IDT)

China Pharmacopeia Second edition

3 Sterility test

3.1 Objective

This test is to inoculate medical equipment or its extract into the culture medium with an intention to test whether the samples would be contaminated by bacteria and funguses.

3.2 Reagent

Sterile sodium chloride solution with mass concentration of 9 g/L and other dilution and washing liquid that meet the requirements of *China Pharmacopoeia*.

3.3 Main equipment

Clean bench, optical microscopy, constant temperature incubator, thermostat water bath box, pressure steam sterilizer and electrically heated drying cabinet.

3.4 Preparations before test

3.4.1 Equipment sterilization

All equipment in contact with the test solution should be sterilized reliably in a 12l℃ pressure steam sterilizer for 30 minutes or in a 160℃ electrically heated drying cabinet for 2 hours.

3.4.2 Requirements for sterile rooms

3.4.2.1 Bench boards or clean benches in sterile rooms shall locally meet the requirements of Class 100 cleanliness with unidirectional air flow part. After the sterile room is disinfected, the number of bacteria colonies shall be checked by the way as follows: take a petri dish with a diameter about 90 mm and inject it with about 20mL of melted nutrient agar with aseptic technique. If it proves sterile after cultivation for 48 hours at 30℃～35℃, place another 3 dishes on the bench board or clean bench at the average position and open their covers, then cover the dishes and cultivate them in the environment of 30℃～35℃ for 48 hours after exposure 30min and take them out to check. The number of bacterial colonies growing in each of 3 dishes shall not be more than 1 on average.

3.4.2.2 In sterility test, colony forming units in the air shall be checked by the way as above. Cultivation as above with opening dish covers at the beginning and covering at the end of the test shall comply with the said requirements.

3.5 Culture medium

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