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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 14233.1-2008

Replace GB/T 14233.1-1998

**Test Methods for Infusion, Transfusion, Injection
Equipments for Medical Use -**

Part 1: Chemical Analysis Methods

医用输液、输血、注射器具检验方法

第 1 部分：化学分析方法

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China**

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Foreword

"Test methods for infusion, transfusion, injection equipments for medical use" GB/T 14233 is divided into two parts:

- Part 1: Chemical analysis methods;
- Part 2: Biological test methods

This Part is Part 1 of GB/T 14233.

This Part replaces "Test methods for infusion, transfusion, injection equipments for medical use-Part 1: Chemical analysis methods" GB/T 14233.1 - 1998. Considering clauses of GB/T 14233.1 - 1998 have been extensively referred in a good many product standards, in order to avoid the confusion caused by changes of the standard clause numbers, clauses in this revision are mostly kept corresponding to the clauses numbers in the former standard. Therefore, the contents to be revised were revised in the former clauses, and new numbers and methods were added for the newly-added contents on the basis of the former numbers.

Compared with GB/T 14233.1 - 1998, this Part has the following major revisions:

- Solution preparation and expression methods were revised;
- Preparation methods for test solutions were added, such as irregular products with less service time (not greater than 24 hours) and larger volume, irregular products with longer service time (greater than 24 hours), and water absorbing materials;
- Turbidity and luster test methods were added;
- Test methods were revised for chloride, pH value, heavy metal, ammonium, zinc, ignition residue, ethylene oxide residue content;
- Atomic fluorescence spectroscopy test methods were added;
- Sulphate test methods were deleted.

This Part was proposed by the State Food and Drug Administration.

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

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The previous editions of the standard replaced by this Part are as:

--GB/T 14233.1-1993;

--GB/T 14233.1-1998.

Test Methods for Infusion, Transfusion, Injection Equipments for Medical Use - Part 1: Chemical Analysis Methods

1 Scope

This Part of GB/T 14233 specifies the chemical analysis methods for infusion, transfusion, injection equipments for medical use.

This Part is applicable to the chemical analysis for infusion, transfusion, injection and supporting equipments for medical use made of medical macromolecular materials; the chemical analysis for other medical macromolecular products may also be carried out by reference to this Part.

2 Normative references

The articles contained in the following documents have become this standard 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 601 Chemical reagent--Preparations of Standard volumetric solutions

GB/T 6682 Water for Analytical Laboratory Use-Specification and Test Methods (GB/T 6682-2008, ISO 3696: 1987, MOD)

Pharmacopoeia of People's Republic of China (2005 Edition) Volume II

3 General Rules

3.1 All analysis in this Part shall be carried out based on two parallel test groups; the test results shall be within the allowable relative deviation limits; arithmetic mean shall be adopted as the test result; in the case of one portion qualified and the other unqualified, the results shall not be averaged, and tests shall be carried out again instead.

3.2 Unless otherwise specified, all reagents used in this Part are analytically pure.

3.3 Unless otherwise specified, all test water in this Part shall meet the requirements of Class II water in GB/T 6682.

3.4 Term "room temperature" in this Part refers to 10 °C~ 30 °C.

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