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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 14233.1-2008

Replacing GB/T 14233.1-1998

Test Methods for Infusion, Transfusion, Injection Equipment 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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Foreword

GB/T 14233 Test Methods for Infusion, Transfusion, and Injection Equipmenst for Medical Use consists of two parts: - Part 1: Chemical Analysis Methods; and - Part 2: Biochemical Test Methods. This standard is Part 1 of GB/T 14233. The Standard replaces GB/T 14233.1 – 1998 Test Methods for Infusion, Transfusion, and Injection Equipmenst for Medical Use Part 1: Chemical Analysis Methods. Given that GB/T 14233.1 – 1998 has been widely quoted in many product standards, the clause numbers in this Standard are kept as closely as possible to the original standard to avoid confusions caused by the change of clause No. in standard revision. The original clauses are altered wherever the alteration is necessary, and new amendments, followed by new methods, are numbered on the basis of the original serial number. The Standards, as compared with GB/T 14233.1 – 1998, is mainly changed as follows: - Solution Preparation methods and their description are revised; - Two test solution preparation methods are added: one for irregular shaped and bulky products with short using time (less than 24 hours), another for irregular shaped products with long using time (more than 24 hours) and water-absorbing materials; - Test methods for turbidity, color and luster are added; - Test methods for the determination of chloride, pH value, heavy metal, ammonium, zinc, burning residue and residual ethylene oxide are revised; - Test methods for atomic fluorescence spectrophotometry is added; and - Test methods for sulfate are deleted. The Standard is brought up by the State Food and Drug Administration. The Standard resides with the National Standardization Technical Committee for Transfusion Equipments. The Standard was mainly drafted by: Jinan Medical Device Testing Center, State Food and Drug Administration Primary drafters of the Standard: Luo Hongyu, Pan Huaxian, Shi Yanping, Sun Guangyu, Li Kefang, Qin Dongli, Liu Bin, Liu Lili, and Guo Lun. Replaced previous editions by the Standard are: - GB/T 14233. 1 – 1993; and - GB/T 14233. 1 – 1998.

1 Scope

Test methods for chemical analysis of infusion, transfusion, injection equipments for medical use are specified in this part of Standard GB/T 14233. This part of Standard applies to chemical analysis of infusion, transfusion, injection and attached equipments for medical use that are made of medical polymer materials. Chemical analysis of other medical polymer products can also refer to this Standard.

2 Referenced Standards

This part of Standard GB/T 14233 incorporates clauses of the following documents if they

are quoted. If the references are dated, all the following lists of modifications (errata excluded) or revised editions thereof shall not be applicable to the Standards. However, parties concerned that have reached an agreement based on the Standards are encouraged to hold discussions on whether the latest editions of the said references can be adopted. Where the references are undated, the updated editions thereof shall apply to the Standards. GB/T 601 Chemical Reagents - Preparation of Standard Titrating Solution GB/T 6682 Specifications on Water for Analytical Laboratory and Test Methods (GB/T 6682 – 2008, ISO 3696: 1987, MOD) Pharmacopoeia II of the People's Republic of China (2005 edition)

3 General Principles

3.1 All the analysis in the Standard is performed by two parallel test groups and the results should be within permissible relative deviation limits. The arithmetic average is used as experimental result. If only one test is qualified and the other one is not qualified, the arithmetic average calculation can't be calculated and the test should be performed again. 3.2 All the reagents in the Standard, unless specified otherwise, are all analytically pure. 3.3 Water for test use in the Standard, unless specified otherwise, should meet requirements for level II water in GB/T 6682.

3.4 The glossary 'room temperature' in the Standard refers to 10 – 30°C. 3.5 The glossary 'precisely weigh' in the Standard indicates weighing in precision 0.1mg. 3.6 The glossary 'precisely measure' in the Standard indicates measuring with transfer pipettes that meet the accuracy requirements specified in relevant national standards. 3.7 Weight law of permanence indicates weight difference of the test product after two times burning or drying is no more than 0.3mg. 3.8 All the glass containers in the Standard, unless specified otherwise, are all silicon borate glass containers.

4 Preparation of Test Solution

4.1 When preparing test solution, it's required to simulate as much as possible the conditions products undergo in use (such as application area, time, temperature, etc.). If using time of the product is a little long (more than 24h), it's recommended to prepare the test solution under accelerated test condition, but feasibility and reasonability of the methods should be verified. 4.2 The method of preparing test solution should be those that try every means to make all measurable surfaces of the samples extracted. 4.3 It's recommended to choose preparation methods of test solution from Table 1. 1 3 sets of samples are chosen and they're connected to be a circular system with a glass flask. 250mL water is added and kept at temperature of 37°C±1°C. Through a wiggly pump operating on a silicon rubber tube for medical use, which is as short as possible, water is circulated at 1L/h for 2h. All liquid is collected and cooled to room temperature, which is to

be used as test solution. Water of the same volume is placed into glass flask. Blank control solution is prepared according to the same method. glass container. Add water and make sure that the ratio of entire surface area of inside and outside sample (cm2) and In vivo catheters with short using time (no more water (ml) is 2:1. With container cover, it is stored at 37°C±1°C for 24h. Separate the sample from the solution and cool the solution to room temperature which is to be used as test solution. Water of the same volume is placed into glass container. Blank control is prepared according to the same method. into fragments of 1cm2. Wash them with water and dry them. Then, put them into a glass container. Add water and make sure that the ratio of entire surface area of inside and outside sample (cm2) and water (ml) is 5:1(or 6:1). With container cover, it is placed into Pressure Steam Sterilizer. Heat it with temperature of 121°C±1°C for 30min. After heating, separate the sample from the solution and cool the solution to room temperature which is to be used as test solution. Water of the same volume is placed into glass container.

5 Analytical Methods for Test Solution Extraction

5.1 Turbidity, color and luster 5.1.1

5.1.1.1 Preparation of solution

Hydrazine sulfate solution: take 1.00g hydrazine sulfate dried to constant weight at temperature of 105°C into glass flask, add water to be dissolved and then diluted to scale, shake up, and stand for 4h to 6h. Methenamine solution: dissolve 2.5g methenamine with 25mL water in 100mL glass flask with plug. Primary lactescent suspension: add 25mL hydrazine sulfate solution into methenamine solution; mix them and stand for 24h.

5.1.1.2 Test process

5.1.1.2.1 Method I

Use bottom-flatted neutral glass test tube that is colorless and transparent, with 15mm – 25mm inner diameter to compare the test solution with the control suspension. The liquid in the test tube shall be 40mm in layer depth. Stand the prepared control suspension for 5min, and then observe the solution vertically to a black background in diffused sunlight.

5.1.1.2.1 Method II

Under room temperature condition, place the test solution and equivalent control suspension respectively into a bottom-flatted neutral glass test tube that is colorless and transparent, with 15mm – 25mm inner diameter. Stand the prepared control suspension for 5min, and then observe and compare horizontally the solution, which is placed together with the test solution right below the umbrella lamp, with intensity of illumination being 1000 lx. It shall be performed according to Annex IX A Inspection Techniques of Solution Color in