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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 14233.1-2022

Replacing GB/T 14233.1-2008

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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1 Scope

GB/T 14233.1-2022 is the Chinese national standard on test methods for infusion, transfusion, injection equipments for medical use - part 1: chemical analysis 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 14 October 2022 by the State Administration for Market Regulation; Standardization Administration of China, and has been in force since 1 November 2023. 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 specifies the chemical analysis methods for the infusion, transfusion and

injection equipment for medical use. This document is applicable to the chemical analysis of the infusion, transfusion, injection and supporting equipment for medical use and made of medical polymer materials. The chemical analysis of other medical polymer products can also take this document as a reference.

2 Normative References

The contents of the following documents constitute indispensable clauses of this document through the normative references in this 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 601 Chemical Reagent - Preparations of Standard Volumetric Solutions

GB/T 6682 Water for Analytical Laboratory Use - Specification and Test Methods
Pharmacopoeia of the People's Republic of China (Version 2020) Four Volumes

3 Terms and Definitions

This document does not have terms or definitions that need to be defined.

4.1 Overview

4.1.1 All analyses in this document are carried out in two parallel test groups; the results shall be within the allowable relative deviation limit; the arithmetic mean shall be taken as the determination result. If one is qualified and the other is disqualified, the average calculation shall not be performed and the determination shall be re-performed.

4.1.2 Unless it is otherwise specified, all reagents used in this document are analytically pure.

4.1.3 Unless it is otherwise specified, the test water in this document shall comply with the requirements of Grade-2 water in GB/T 6682.

4.1.4 The term "room temperature" used in this document refers to 10 C ~ 30 C.

4.1.5 The term "accurate weighing" used in this document refers to weighing accurate to

0.1 mg.

4.1.6 The term "accurate measuring" used in this document refers to measuring with a transfer pipette that complies with the accuracy requirements specified in the corresponding national standards.

4.1.7 Constant weight by gravimetric method means that the weight difference of the test sample after two consecutive ignitions or dryings shall not exceed

0.3 mg.

4.1.8 Unless it is otherwise specified, the glass containers used in this document are all borosilicate glass containers.

4.1.9 Most of the analysis methods provided in this document are non-specific analysis methods, and these methods can be used for the preliminary assessment of chemical hazards of medical devices. However, if there is a situation that does not comply with the preliminary expectations in a specific test, it does not suggest that the actual risk is unacceptable, and specific analysis methods need to be adopted to identify and evaluate the safety.

4.2 Preparation of Test Solution

4.2.1 The preparation of the test solution shall simulate the conditions (such as. the application area, time and temperature of the product, etc.) that the product goes through during the using process as much as possible. The simulated extraction time shall not be less than the normal use time of the product. When the product has been used for a long time (more than 24 h), consideration should be given to prepare the test solution under accelerated test conditions, but the feasibility and rationality need to be verified.

4.2.2 The methods used for the preparation of the test solution should try to extract all the tested surfaces of the sample.

4.2.3 It is recommended to select the test solution preparation method in Table 1, and.

---If the sample preparation conditions in the brackets are used, it shall be indicated in the product standard;

---The selection of temperature should take into account the highest temperature that the product may be subject to in clinical use. For polymers, the temperature shall be selected below the glass transition temperature.

5.1 Clarity and Color

5.1.1 Clarity Comply with 0902 clarity inspection method of the Pharmacopoeia of the People's Republic of China (Version 2020) Four Volumes.

5.1.2 Color Comply with 0901 solution color inspection method of the Pharmacopoeia of the People's Republic of China (Version 2020) Four Volumes.

5.2.1 Method 1.direct titration method

5.2.1.1 Principle Potassium permanganate us a strong oxidizing agent. In acidic medium, potassium permanganate reacts with reducing substances, and MnO4 is reduced to Mn2+.

5.2.1.2 Solution preparation Sulfuric acid solution. measure-take 128 mL of sulfuric acid

and slowly inject it into 500 mL of water; after cooling it down, dilute it to 1,000 mL. Sodium oxalate solution [c (1/2Na2C2O4) =

0.1 mol/L]. weigh-take

6.700 g of sodium oxalate dried at 105 C ~ 110 C to a constant mass; add water to dissolve and dilute it to 1,000 mL. Sodium oxalate solution [c (1/2Na2C2O4) =

0.01 mol/L]. before use, take the sodium oxalate solution [c (1/2Na2C2O4) =

0.1 mol/L] and add water to dilute 10 times. Potassium permanganate standard titration solution [c (1/5KMnO4) =

0.1 mol/L]. in accordance with the method in GB/T 601, prepare and calibrate it. Potassium permanganate standard titration solution [c (1/5KMnO4) =

0.01 mol/L]. before use, take the potassium permanganate standard titration solution [c (1/5KMnO4) =

0.1 mol/L] and add water to dilute 10 times. If necessary, boil it, let it cool down, filter it, then calibrate its concentration.

6 Analysis Method of Total Content of Heavy Metals in the

6.1 Principle In a weakly acidic solution, heavy metals, such as. lead, cadmium, copper and zinc, can react with thioacetamide to generate insoluble colored sulfides. By taking lead standard solution as the standard for colorimetric comparison, their total content can be determined.

6.2 Preparation of Reagents and Solutions Comply with 5.6.1.2.

6.3 Preparation of Test Solution Take an appropriate amount of sample and cut into pieces of 5 mm 5 mm; put it into a porcelain crucible; slowly blaze it, until it is completely charred, and let it cool. Then, add

0.5 mL ~ 1 mL of sulfuric acid to moisten it. At a low temperature, heat it, until the sulfuric acid vapor disappears. Then, add

0.5 mL of nitric acid and evaporate it to dryness; after the nitrogen oxide vapor is completely removed, let it cool. Then, at 500 C ~ 600 C, burn it to make it ash; after it cools down. Add 2 mL of hydrochloric acid, place it on a water bath and evaporate it to dryness, then add 15 mL of water. Add one drop of phenolphthalein test solution, then, dropwise add the ammonia test solution, until the above-mentioned solution turns reddish. Add 2 mL of acetate buffer solution (pH 3.5) and slightly heat to dissolve it (if there is any residue, it should be filtered with filter paper), then, transfer the solution to a 25 mL Nessler colorimetric tube; add water to make 25 mL of test solution. Place another porcelain crucible added with