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**GB**

NATIONAL STANDARD OF THE  
PEOPLE'S REPUBLIC OF CHINA

ICS 11.040.20

CCS C 31

**GB/T 14233.1-2022**

Replacing GB/T 14233.1-2008

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**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

**Issued on: October 12, 2022**

**Implemented on: November 1, 2023**

**Issued by: State Administration for Market Regulation;**

**Standardization Administration of the People's Republic of China.**

## Table of Contents

Foreword.....	3
Introduction.....	5
1 Scope.....	6
2 Normative References.....	6
3 Terms and Definitions.....	6
4 General Rules.....	6
5 Analysis Methods of Extractable Matters of Test Solution.....	9
6 Analysis Method of Total Content of Heavy Metals in the Materials.....	19
7 Content Analysis Methods of Some Heavy Metal Elements in the Materials.....	20
8 Residue on Ignition.....	22
9 Determination of Ethylene Oxide Residue - Gas Chromatography.....	23
Bibliography.....	27

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

## 1 Scope

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 General Rules

### 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.

solution and dilute to the required concentration.

Silver nitrate test solution (17.5 g/L): weigh-take 1.75 g of silver nitrate, dissolve it in water, dilute to 100 mL and store it in a brown bottle.

Nitric acid solution: take 105 mL of nitric acid and use water to dilute to 1,000 mL.

### 5.3.3 Test procedures

Accurately measure-take 10 mL of the test solution, add it to a 50 mL Nessler colorimetric tube; add 10 mL of dilute nitric acid (if the solution is not clear, filter it and place the filtrate in a 50 mL Nessler colorimetric tube), add water to make it about 40 mL. Thus, the test solution is obtained.

Accurately measure-take 10 mL of the chlorine standard solution to another 50 mL Nessler colorimetric tube; add 10 mL of dilute nitric acid; add water to make it about 40 mL; shake it well. Thus, the standard control solution is obtained.

In the above-mentioned two test tubes, respectively add 1.0 mL of silver nitrate test solution, use water to dilute to 50 mL; place it in a dark place for 5 min; place it on a black background and observe from above the colorimetric tube. Compare the turbidity of the test solution with the standard control solution.

If the test solution is colored, unless it is otherwise specified, take two portions of the test solution and respectively place them in a 50 mL Nessler colorimetric tube. Add 1.0 mL of silver nitrate test solution to one portion, shake it well and let it stand for 10 min. If it becomes turbid, repeatedly filter it, until the filtrate is completely clear. Then, add the specified amount of chlorine standard solution and an appropriate amount of water to make it 50 mL; shake it well and place it in the dark for 5 min; use it as the control solution. Add 1.0 mL of silver nitrate test solution to another portion and an appropriate amount of water to make it 50 mL. Shake it well and place it in the dark for 5 min. In accordance with the above-mentioned method, compare it with the control solution. Thus, the solution is obtained.

## 5.4 pH

### 5.4.1 Method 1

Take the test solution and the blank control solution. In accordance with the 0631 pH value determination method of *Pharmacopoeia of the People's Republic of China* (Version 2020) Four Volumes, respectively determine the pH value and take the difference between them as the test result.

### 5.4.2 Method 2

#### 5.4.2.1 Solution preparation

Sodium hydroxide standard titration solution [ $c(\text{NaOH}) = 0.1 \text{ mol/L}$ ]: in accordance with the stipulations of GB/T 601, prepare and titrate it.

Sodium hydroxide standard titration solution [ $c(\text{NaOH}) = 0.01 \text{ mol/L}$ ]: before use, take the sodium hydroxide standard titration solution [ $c(\text{NaOH}) = 0.1 \text{ mol/L}$ ] and add water to dilute 10 times.

Hydrochloric acid standard titration solution [ $c(\text{HCl}) = 0.1 \text{ mol/L}$ ]: in accordance with the stipulations of GB/T 601, prepare and titrate it.

Hydrochloric acid standard titration solution [ $c(\text{HCl}) = 0.01 \text{ mol/L}$ ]: before use, take the hydrochloric acid standard titration solution [ $c(\text{HCl}) = 0.1 \text{ mol/L}$ ] and add water to dilute 10 times.

Tashiro indicator: dissolve 0.2 g of methyl red and 0.1 g of methylene blue in 100 mL of methanol (with a volume fraction of 95%).

#### **5.4.2.2 Test procedures**

Accurately measure-take 20 mL of the test solution and place it in a 100 mL ground-mouth bottle; add 0.1 mL of Tashiro indicator. If the color of the solution turns purple, then, use the sodium hydroxide standard titration solution [ $c(\text{NaOH}) = 0.01 \text{ mol/L}$ ] to titrate it; if it turns green, use the hydrochloric acid standard titration solution [ $c(\text{HCl}) = 0.01 \text{ mol/L}$ ] to titrate it, until it turns gray. Take the volume (in mL) of the consumed sodium hydroxide standard titration solution [ $c(\text{NaOH}) = 0.01 \text{ mol/L}$ ] or hydrochloric acid standard titration solution [ $c(\text{HCl}) = 0.01 \text{ mol/L}$ ] as the test result.

### **5.4.3 Method 3**

#### **5.4.3.1 Solution preparation**

Sodium hydroxide standard titration solution [ $c(\text{NaOH}) = 0.1 \text{ mol/L}$ ]: same as 5.4.2.1.

Sodium hydroxide standard titration solution [ $c(\text{NaOH}) = 0.01 \text{ mol/L}$ ]: same as 5.4.2.1.

Hydrochloric acid standard titration solution [ $c(\text{HCl}) = 0.1 \text{ mol/L}$ ]: same as 5.4.2.1.

Hydrochloric acid standard titration solution [ $c(\text{HCl}) = 0.01 \text{ mol/L}$ ]: same as 5.4.2.1.

Phenolphthalein indicating solution (10 g/L): weigh-take 1 g of phenolphthalein, dissolve it in ethanol (with a volume fraction of 95%) and dilute to 100 mL.

Methyl red indicating solution (1 g/L): weigh-take 0.1 g of methyl red, dissolve it in ethanol (with a volume fraction of 95%) and dilute to 100 mL.

#### **5.4.3.2 Test procedures**

Add 2 drops of the phenolphthalein indicating solution to 10 mL of test solution, and the solution shall not turn red. Add 0.4 mL of the sodium hydroxide standard titration solution [ $c(\text{NaOH}) = 0.01 \text{ mol/L}$ ], and the solution shall turn red. Add 0.8 mL of the hydrochloric acid standard titration solution [ $c(\text{HCl}) = 0.01 \text{ mol/L}$ ], and the red color shall disappear. Add 5 drops

store it in the refrigerator. Before use, take 5 mL of the mixed solution [composed of 15 mL of sodium hydroxide (1 mol/L), 5 mL of water and 20 mL of glycerin], add 1 mL of the above-mentioned thioacetamide solution; place it on a water bath to heat for 20 s, cool it down and immediately use it.

Lead standard stock solution (0.1 mg/mL): weigh-take 0.160 g of lead nitrate, use 10 mL of nitric acid solution (1 + 9) to dissolve it, then, transfer it into a 1,000 mL volumetric flask and use water to dilute to the scale.

Lead standard solution: before use, accurately measure-take the lead standard stock solution and dilute it to the required concentration.

### **5.6.1.3 Test procedures**

Accurately measure-take 25 mL of the test solution in a 25 mL Nessler colorimetric tube; take another 25 mL Nessler colorimetric tube and add 25 mL of the lead standard solution. Respectively add 2 mL of acetate buffer solution (pH 3.5) to the above-mentioned two colorimetric tubes, then, respectively add 2 mL of thioacetamide test solution, let it stand for 2 min. Place it on a white background and observe from above; compare the color shades.

If the test solution develops color, a small amount of dilute caramel solution or other non-interfering colored solutions can be added to the standard control solution, so as to make it consistent with the color of the test solution. Then, respectively add 2 mL of thioacetamide test solution to the test solution and the standard control solution; shake it well and let it stand for 2 min. Place it on a white background and observe from above; compare the color shades.

Alternatively, take 10 mL of the test solution, then, the amount of lead standard solution added is 10 mL.

## **5.6.2 Method 2**

### **5.6.2.1 Principle**

In an alkaline solution, heavy metals, such as: lead, chromium, copper and zinc, can react with sodium sulfide to generate insoluble colored sulfides. Take lead as a representative to prepare a standard solution for colorimetric comparison and determine the total content of the heavy metals.

### **5.6.2.2 Solution preparation**

Sodium hydroxide test solution (43 g/L): take 4.3 g of sodium hydroxide and add water to dissolve it to 100 mL. Thus, the solution is obtained.

Sodium sulfide test solution (100 g/L): before use, weigh 1 g of sodium sulfide and add water to dissolve it to 10 mL. Thus, the solution is obtained.

Lead standard stock solution (0.1 mg/mL): same as 5.6.1.2.

Lead standard solution: same as 5.6.1.2.

### 5.6.2.3 Test procedures

Accurately measure-take 25 mL of the test solution in a 25 mL Nessler colorimetric tube; take another 25 mL Nessler colorimetric tube and add 25 mL of the lead standard solution. Respectively add 5 mL of the sodium hydroxide test solution to the above-mentioned two colorimetric tubes, then, respectively add 5 drops of the sodium sulfide test solution and shake it well. Place it on a white background and observe from above; compare the color shades.

## 5.7 UV Absorbance

Take the test solution, if necessary, use a 0.45  $\mu\text{m}$  microporous filter membrane to filter it. Within 5 h, use a 1 cm cuvette with the blank control solution as a reference. Within the specified wavelength range, determine the absorbance.

## 5.8 Ammonium

### 5.8.1 Principle

Ammonium ions can react with Nessler reagent in alkaline solution to generate a yellow substance. Through colorimetric comparison with the standard control solution, determine its ammonium content.

### 5.8.2 Solution preparation

Sodium hydroxide solution (40 g/L): weigh-take 4.0 g of sodium hydroxide, use water to dissolve and dilute it to 100 mL.

Nessler reagent (alkaline potassium mercuric iodide test solution): take 10 g of potassium iodide, add 10 mL of water to dissolve it, then, slowly add a saturated aqueous solution of mercuric dichloride, stir as it is added, until the generated red precipitate is no longer dissolved. Add 30 g of potassium hydroxide and dissolve it, then, add 1 mL or above of a saturated aqueous solution of mercuric dichloride, and use an appropriate amount of water to dilute it to 200 mL; let it stand and precipitate. Thus, the solution is obtained. During use, pour off the supernatant. Inspection: take 2 mL of this solution, add it to 50 mL of water containing 0.05 mg of ammonia, and it shall immediately appear yellowish brown.

Ammonium standard stock solution (0.1 mg/mL): weigh-take 0.297 g of ammonium chloride dried to a constant mass at 105 °C ~ 110 °C; use water to dissolve and dilute it to 1,000 mL.

Ammonium standard solution: before use, accurately measure-take the ammonium standard stock solution and dilute to the required concentration.

### 5.8.3 Test procedures

Accurately measure-take 10 mL of the test solution in a 25 mL Nessler colorimetric tube; take another 25 mL Nessler colorimetric tube and add 10 mL of the ammonium standard solution.



### 5.9.3 Atomic fluorescence spectrometry

#### 5.9.3.1 Instrument

Atomic fluorescence spectrophotometer. During use, operate it in accordance with the instruction manual.

#### 5.9.3.2 Analysis method (standard curve method)

Within the concentration range recommended by the atomic fluorescence spectrophotometer, at least 5 standard solutions (excluding the zero point) containing the elements to be determined and with increasing concentrations in sequence shall be prepared. The concentration range of the standard solutions should consider the concentration of the element to be determined. Then, take the solvent used to prepare the standard solutions as a blank and successively determine the fluorescence intensity of each standard solution; draw a standard curve relative to the concentration.

Determine the test solution and the blank control solution. In accordance with the absorbance, find out the corresponding concentration on the standard curve; calculate the content of the element.

## 6 Analysis Method of Total Content of Heavy Metals in the Materials

### 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 0.5 mL ~ 1 mL of sulfuric acid, 0.5 mL of nitric acid and 2 mL of hydrochloric acid on a water bath to evaporate it to dryness. Add 2 mL of acetate buffer solution (pH 3.5) and 15 mL of water, slightly heat to dissolve it, then, transfer the solution to a 25 mL Nessler colorimetric tube. Add a certain amount of lead standard solution, then, use water to dilute it to 25 mL; take it as the standard control solution.

#### **6.4 Test Procedures**

Respectively add 2 mL of thioacetamide test solution to the test solution and the standard control solution; shake it well and let it stand for 2 min. On a white background, observe it from above and compare the color shades.

If the test solution develops color, a small amount of dilute caramel solution or other non-interfering colored solutions can be added to the standard control solution to make it consistent with the color of the sample solution.

## **7 Content Analysis Methods of Some Heavy Metal Elements in the Materials**

### **7.1 Atomic Absorption Spectrophotometry**

#### **7.1.1 Sample digestion**

**7.1.1.1** Wet digestion: take 1 g ~ 2 g of sample, accurately weigh it and cut it into pieces of about 5 mm × 5 mm; place it in a 100 mL conical flask, add 30 mL of nitric acid and 1.25 mL of sulfuric acid, shake it well and place it overnight; heat it on a hot plate for digestion. If there are still undecomposed substances or the color becomes darker when the digestion solution reaches about 10 mL, remove it and let it come down. Add 5 mL ~ 10 mL of nitric acid, then, digest it to about 10 mL for observation. Repeat this two or three times, and pay attention to avoid charring. Cool it down, add 25 mL of water, then evaporate it, until white fumes of sulfuric acid are emitted. Cool it down, then, use water to transfer the content to a 50 mL volumetric flask; add water to obtain 50 mL of test solution. Use the same method to prepare the blank control solution.

**7.1.1.2** Dry-ashing: take 1 g ~ 2 g of sample, accurately weigh it and place it in a crucible. Add 10 mL of magnesium nitrate solution with a mass concentration of 150 g/L and mix it well. At low heat, evaporate it to dryness. Carefully cover 1 g of magnesium oxide on the dry residue, char it, until there is no black smoke, then, at 550 °C, ash it for 4 h. Take it out and let it cool; carefully add 10 mL of hydrochloric acid (1 + 1) to neutralize the magnesium oxide and dissolve the ash (if there is any residue, it should be filtered with filter paper). Transfer it to a 50 mL volumetric flask, and add water to make 50 mL of test solution. Use the same method to prepare the blank control solution.

## **9 Determination of Ethylene Oxide Residue - Gas Chromatography**

### **9.1 Instrument**

Gas chromatograph. During use, operate it in accordance with the instruction manual.

### **9.2 Analysis Method**

Any gas chromatography can be used as long as the analysis is proven to be reliable. “Analytical reliability” means that when determining a device with a specified residual amount of ethylene oxide (EO), the selected analysis method has sufficient accuracy, precision, selectivity, linearity and sensitivity, and suitable for the device to be analyzed.

For different products, necessary methodological evaluation is required to determine the reliability of the selected method.

Other validated analysis methods may also be adopted, for example, mass spectrometry.

### **9.3 Sample Extraction Methods**

#### **9.3.1 General rule**

There are three basic sample extraction methods for the determination of ethylene oxide residue on medical devices sterilized with ethylene oxide: simulated use extraction method, stringent extraction method and extreme extraction method.

The simulated use extraction method refers to the method that makes the extraction simulate the use of the product as much as possible. This simulation process allows the measured residual ethylene oxide to correspond to the actual ethylene oxide intake of the patient using the device.

The stringent extraction method is an extraction that is expected to result in the release of greater or a larger amount of chemical constituents than under clinical use conditions.

The extreme extraction method means that the amount of ethylene oxide determined in the second extraction is less than 10% of the value determined in the first extraction, or the cumulative residual amount determined by extraction has no obvious increase.

The extract should be prepared after sampling, otherwise, the test sample shall be sealed in a metal container sealed with polytetrafluoroethylene for preservation.

When citing the method of this document, if no extraction method is specified, then, it shall be carried out in accordance with the extreme extraction method or the stringent extraction method.

#### **9.3.2 Simulated use extraction method**

#### 9.4.3 Draw a standard curve

Use the stock solution to prepare standard solutions with at least 5 series of concentrations ranging from 1  $\mu\text{g/mL}$  ~ 20  $\mu\text{g/mL}$ . Accurately measure-take 5 mL and place it in a 20 mL extraction vessel, seal it; at a constant temperature ( $60\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ ), balance it for 40 min.

Use a sample injector to successively and quickly take the upper part of gas from the balanced standard sample, inject it into the sample injection chamber and record the peak height (or area) of ethylene oxide. Draw a standard curve ( $X$ : mass concentration of ethylene oxide,  $\mu\text{g/mL}$ ;  $Y$ : peak height or area).

#### 9.4.4 Measurement of test sample

Use the sample injector to quickly take the upper part of gas from the balanced specimen extraction vessel, inject it into the sample injection chamber and record the peak height (or area) of ethylene oxide.

In accordance with the standard curve, calculate the corresponding concentration of the sample.

If the result of the measured sample is beyond the range of the standard curve, the concentration of the standard solution shall be changed to re-draw the standard curve.

#### 9.4.5 Recommended chromatographic conditions

Chromatographic column: the stationary phase is generally 6% cyanopropyl benzene and 94% dimethyl siloxane.

Injection port temperature: 200  $^{\circ}\text{C}$ .

Column flow rate: 1.5 mL/min.

Detector: FID.

Split ratio: 20 : 1.

Column oven temperature: maintain at 50  $^{\circ}\text{C}$  for 8 min.

Detector temperature: 250  $^{\circ}\text{C}$ .

Other validated chromatographic conditions may also be adopted.

### 9.5 Result Calculation

The residual amount of ethylene oxide is expressed by the absolute content or relative content.

**9.5.1** In accordance with Formula (5), calculate the absolute content of ethylene oxide per unit of product:

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