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Pharmaceutical glass tube

药用玻璃管

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Table of Contents

Pharmaceutical glass tube

1 Scope

This document specifies the classification, specifications and dimensions, technical requirements, test methods, inspection rules and marking, packaging, transportation and storage of pharmaceutical glass tubes.

This document applies to the manufacture of glass tubes for pharmaceutical packaging containers such as ampoules, injection bottles, oral liquid bottles, medicine bottles, prefilled syringes and snap-on bottles.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

GB/T 191 Packaging - Pictorial marking for handling of goods

GB/T 2828.1 Sampling procedures for inspection by attributes - Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection

GB/T 12416.2 Glass - Hydrolytic resistance of glass grains at 121 °C - Test method and classification

GB/T 21170 Glass hollowware - Test method for lead and cadmium release

GB/T 35595 Glass containers - Testing methods for arsenic and antimony release

GB/T 35599 Laboratory glass and glassware outward defect terms

YBB 00392004 Test for straightness

3 Terms and definitions

For the purpose of this document, the following terms and definitions apply.

3.1

limit deviation

The difference between the actual measured value and the basic dimension of the glass tube.

7 Test methods

7.1 Specifications and dimensions

7.1.1 Outer diameter

USE a caliper with an accuracy of 0.01 mm or a measuring device with an equivalent accuracy to measure twice (rotate 90°) on the same measuring surface at a distance of 250 mm from both ends of the glass tube.

7.1.2 Inner diameter

USE a caliper with an accuracy of 0.01 mm or a measuring device with an equivalent accuracy to measure twice (rotate 90°) on the same measuring surface at an inner diameter of 250 mm from both ends of the glass tube.

7.1.3 Wall thickness

USE a thickness gauge with an accuracy of 0.01 mm or a measuring device with an equivalent accuracy to measure rotationally on the same measuring surface.

7.1.4 Length

MEASURE with a tape measure or ruler with an accuracy of 1 mm.

7.1.5 Straightness

It is determined according to the method specified in YBB 00392004.

7.2 Appearance

It is carried out according to the provisions of GB/T 35599, supplemented by a 10-fold reading magnifying glass or a caliper with an accuracy of 0.01 mm if necessary.

7.3 Hydrolytic resistance of glass grains at 121 ℃

It is determined according to the method specified in GB/T 12416.2.

7.4 Light transmittance

It is determined according to the method specified in Appendix A.

7.5 Arsenic, antimony, lead and cadmium release

Lead and cadmium release is determined according to the method specified in GB/T 21170.

Appendix A

(Normative)

Method for determination of light transmittance of colored glass

A.1 Definition

The light transmittance of colored glass refers to the percentage (T) of the intensity I of the light passing through TO the incident light intensity I_0, when the light beam emitted by the light source passes through the monochromator and becomes parallel light beams of different wavelengths, and is vertically irradiated on the sample to be tested. It is calculated according to formula (A.1).

$$T = \frac{I}{I_0} \times 100 \qquad \text{(A.1)}$$

where:

T - the light transmittance of colored glass, %;

I - the intensity of the light passing through colored glass;

I_0 - the intensity of incident light.

A.2 Instruments and equipment

A.2.1 UV-vis spectrophotometer

An instrument equipped with a photodiode detector or photomultiplier tube that can be coupled with an integrating sphere to detect light transmittance in the wavelength range of 250 nm ~ 800 nm.

A.2.2 Glass cutting machine

Equipment for cutting glass with a carbon-based or emery-based ring blade or saw blade of other materials.

A.3 Test procedure

A.3.1 Select glass pieces that can represent the wall thickness, and trim them to fit into the spectrophotometer. After cutting, wash and dry each sample, taking care to avoid scratching the surface. If the sample is too small to completely cover the opening in the sample holder, cover the uncovered portion of the opening with opaque paper or tape, provided the sample is longer than the narrow seam length.

Appendix B

(Normative)

Methods for determination of arsenic and antimony release of pharmaceutical glass tubes

B.1 Determination of arsenic and antimony release of pharmaceutical glass tubes by atomic fluorescence spectrometry

B.1.1 Principle

Atomic fluorescence spectrometry is to use an excitation light source to irradiate the atomic vapor containing a certain concentration of the element to be tested, so that the atoms of ground state transition to the excited state; and then they are de-excited back to a lower energy state or ground state, and emit atomic fluorescence. Determine the intensity of atomic fluorescence so that the content of this element in the sample to be tested can be obtained. Arsenic (or antimony) in the leaching solution, under acidic conditions, in which pentavalent arsenic (or antimony) is reduced to trivalent arsenic (or antimony) by adding thiourea and ascorbic acid. Trivalent arsenic (or antimony) and reducing agent (usually potassium borohydride or sodium) reacts in the hydride generation system to generate gaseous hydride, which is brought into the atomizer by the carrier gas (argon) for atomization. Under the irradiation of the excitation light source (usually a hollow cathode lamp) of the element to be tested, the atoms of ground state are excited to a high energy state. When they are de-excited back to the ground state, they emit fluorescence with a characteristic wavelength. The fluorescence intensity is proportional to the content of the element to be tested, and is quantitatively compared with the standard series.

B.1.2 Reagents

Glacial acetic acid; high-grade pure hydrochloric acid; analytically pure ascorbic acid; analytically pure thiourea; analytically pure sodium hydroxide; analytically pure sodium borohydride; arsenic element standard solution; antimony element standard solution.

B.1.3 Test procedure

B.1.3.1 TAKE a glass tube with a total surface area (including inner and outer surfaces) of about 500 cm^2; finely GRIND the cross-sections at both ends. It is taken as the sample to be tested for later use.

B.1.3.2 CLEAN the pharmaceutical glass tube sample after fine grinding; PUT it in a glass container containing 1000 mL of 4 % acetic acid solution (the glass container shall

not contain arsenic, antimony, lead, and cadmium elements); COOK at 98 °C for 2 h; TAKE OUT the sample after cooling. The solution is the sample solution to be tested.

B.1.3.3 PREPARE a series of arsenic and antimony standard solutions with mass concentrations of 1 μg/mL, 2 μg/mL, 3 μg/mL, 4 μg/mL, and 5 μg/mL, respectively. USE inductively coupled plasma emission spectrometer to determine the sample solution to be tested and the blank solution; CALCULATE the arsenic and antimony release according to the test data.

B.2 Determination of arsenic and antimony release of pharmaceutical glass tubes by hydride generation atomic absorption method

B.2.1 Principle

Arsenic (or antimony) in the leaching solution, under acidic conditions, in which pentavalent arsenic (or antimony) is reduced to trivalent arsenic (or antimony) by adding thiourea and ascorbic acid. Trivalent arsenic (or antimony) and reducing agent (usually potassium borohydride or sodium) reacts in the hydride generation system to generate gaseous hydride, which is brought into the atomizer by the carrier gas (argon) for atomization, and then it transitions from the ground state to the excited state. The absorption is proportional to the arsenic content, which can be compared with the standard series for quantitative analysis.

B.2.2 Reagents

Glacial acetic acid; high-grade pure hydrochloric acid; analytically pure ascorbic acid; analytically pure thiourea; analytically pure sodium hydroxide; analytically pure sodium borohydride; arsenic element standard solution; antimony element standard solution.

B.2.3 Test procedure

B.2.3.1 TAKE a glass tube with a total surface area (including inner and outer surfaces) of about 500 cm^2; finely GRIND the cross-sections at both ends. It is taken as the sample to be tested for later use.

B.2.3.2 CLEAN the pharmaceutical glass tube sample after fine grinding; PUT it in a glass container containing 1000 mL of 4 % acetic acid solution (the glass container shall not contain arsenic, antimony, lead, and cadmium elements); COOK at 98 °C for 2 h; TAKE OUT the sample after cooling. The solution is the sample solution to be tested.

B.2.3.3 PREPARE a series of arsenic and antimony standard solutions with mass concentrations of 1 μg/mL, 2 μg/mL, 3 μg/mL, 4 μg/mL, and 5 μg/mL, respectively. USE inductively coupled plasma emission spectrometer to determine the sample solution to be tested and the blank solution; CALCULATE the arsenic and antimony release according to the test data.

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