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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/Z 12414-2021

Replacing GB/T 12414-1995

Pharmaceutical glass tube

药用玻璃管

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Table of Contents

1 Scope	
2 Normative references	
3 Terms and definitions	
4 Classification...	
5 Specifications and dimensions...	
6 Technical requirements...	
7 Test methods	
7.1 Specifications and dimensions	
7.1.1 Outer diameter USE a caliper with an accuracy of	
7.1.2 Inner diameter USE a caliper with an accuracy of	
7.1.3 Wall thickness USE a thickness gauge with an accuracy of	
8 Inspection rules...	
Appendix A	

1 Scope

This document specifies the classification, the specifications and dimensions, the technical requirements, the test methods, the inspection rules and the provisions on marking, packaging, transport and storage for pharmaceutical glass tubing. This document applies to glass tubing used in the manufacture of pharmaceutical packaging containers such as ampoules, injection vials, oral liquid bottles, oral medicine bottles, prefilled syringes and cartridges.

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.

7.1.1 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 °C 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). 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.