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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 1001-2024

Glass syringes

全玻璃注射器

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Foreword

This document was drafted in accordance with the provisions of GB/T 1.1-2020 "Directives for standardization - Part

1.Rules for the structure and drafting of standardizing documents". This document replaces YY 1001.1-2004 "Glass syringes - Part

1 Scope

YY 1001 is the mandatory Chinese standard for all-glass syringes, the reusable barrel-and-plunger syringes still used in dispensing, laboratory work and some clinical procedures. Being a YY standard without the /T suffix, compliance is compulsory in China rather than advisory. It sets the requirements a glass syringe has to meet and the test methods that verify them, covering the dimensional and functional characteristics that decide whether the plunger seals, whether the graduation reads true and whether the assembly withstands repeated sterilization. The 2024 edition is the current text and takes effect in 2026, giving manufacturers a transition period they have to plan against. For anyone supplying glass syringes into China, or buying them from a Chinese maker, this is the document conformity is asserted against.

This document specifies the structural type, materials, requirements, marking, packaging, transportation and storage of glass syringes and blue syringes with all-glass (hereinafter referred to as "syringes"), and describes the corresponding test methods. This document applies to glass syringes and blue syringes with all-glass. After the product is equipped with an injection needle, it is used for subcutaneous, intramuscular, and intravenous injection of

liquid and extraction of liquid.

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 1962.1 Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Part

3 Terms and definitions

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

3.1 glass syringes Medical syringes of which the barrel, plunger and hub are all made of borosilicate aluminum glass material and can be reused after sterilization.

3.2 blue syringes with all-glass Syringes of which the barrel, plunger and hub are all made of borosilicate aluminum glass material (the plunger is blue solid) and can be reused after sterilization.

3.3 nominal capacity Syringe capacity marked by the manufacturer.

4 Structural form

The structural form of syringes is shown in Figure 1.

5 Materials

The syringes shall be made of borosilicate aluminum glass.

6 Requirements and test methods

6.1 Dimensions Measured with general or special measuring tools, the maximum length (L) and hub aperture (H) of the syringes shall comply with the provisions of Table 1.

6.3 Conical fitting The conical fitting dimensions of the syringes shall meet the requirements of GB/T 1962.1.

6.4 Capacity tolerance Test in accordance with A.1 in Annex A, the capacity tolerance of the syringes shall meet the requirements of Table 3.

6.5 Position of graduation lines and metering numbers After testing in accordance with A.2, the graduation lines and metering numbers of the syringes shall be complete, uniform in thickness, and durable, the lines shall be straight and equally divided, and the graduation lines shall be perpendicular to the axis of the

6.6 Metering numbers After testing in accordance with A.2, the position of metering numbers of the syringes is shown in Figure

1.The writing direction is parallel to the axis of the syringe body. The arrangement of metering numbers starts from the zero line, and the word "0" can be omitted. The metering numbers of syringes of various specifications shall meet the requirements of Table 4.

6.10 Hub tightness The syringe hub shall fit tightly with the injection needle. Suck 1/4 of the capacity of water into the syringe, then clean and dry the syringe hub and the standard fitting cone hole that meets the requirements of GB/T 1962.1 and tighten them, put the syringe flat on the tightness tester, and pass the specified water pressure value from the barrel fitting. When subjected to a water pressure of 300 kPa, no water shall drip within 30 s.

6.13 Residual liquid volume in syringe Suck water into the dry syringe to the nominal capacity, then remove the air, push the plunger to the bottom of the barrel and pull it out, so that the water on the plunger and the barrel wall can fully circulate and concentrate at the bottom of the barrel; use a syringe of appropriate specifications (

0.25 mL, 1 mL, 2 mL) with a long injection needle, completely absorb the water remaining in the barrel (including the hub hole), and then read the value as the residual liquid volume. The residual liquid volume of the syringe shall not exceed the requirements of Table 6.

6.15 Welding firmness The syringe barrel and hub shall be welded firmly and straight, so that the syringe is in a horizontal position. The force specified in Table 7 is evenly applied to the middle of the frosted surface of the hub, then the force is removed, and the hub is rotated 180° along the axis. Repeat the force again, the two shall not separate.

6.17 Cut edge of barrel The opening at the end face of the barrel shall have a cut edge to ensure that the syringe shall not rotate 180° when placed on a surface with an angle of 10° to the horizontal, and there shall be no shaking of itself and no sharp edges.

7 Marking

7.1 Unit packaging The unit packaging shall have at least the following information.

7.2 Shelf or multi-unit packaging Shelf packaging or multi-unit packaging (if used) shall be marked with at least the following information.

8 Packaging

8.1 The packaged syringes shall be clean and dry, and soft padding shall be placed in the barrel. The packaging box shall have cushion to prevent the syringe from loosening or hitting to prevent damage to the syringe.

9 Transportation and storage

9.1 The syringes shall be protected from heavy pressure, direct sunlight, rain and snow during transportation.