

**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 0497-2025

**Sterile insulin syringe for single use
(English Translation)**

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1 Scope

This document specifies the requirements for sterile insulin syringe for single use (hereinafter referred to as syringe) and describes the corresponding test methods. This syringe is for single use only and is intended for immediate injection into the human body after drawing up insulin.

This document applies to syringes used for injecting 40 units per milliliter (U-40) and 100 units per milliliter (U-100) of insulin.

This document does not apply to syringes used for long-term storage of insulin.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including

any amendments) applies.

GB/T 6682, Water for analytical laboratory use - Specification and test methods (GB/T 6682-2008, ISO3696.1987, MOD);

GB/T 14233.1-2022, Test methods for infusion, transfusion, injection equipment for medical use - Part 1.Chemical analysis methods;

GB/T 14233.2, Test methods for infusion, transfusion, injection equipment for medical use - Part 2.Biological test methods;

GB 15810-2019, Sterile syringes for single use (ISO 7886-1.2017, MOD);

GB 15811, Sterile hypodermic needles for single use (GB 15811-2016, ISO 7864.1993, NEQ);

GB/T 16886.1, Biological evaluation of medical devices - Part 1.Evaluation and testing within a risk management process (GB/T 16886.1-2022, ISO 10993-1.2018, IDT);

GB 18278.1, Sterilization of health care products - Moist heat - Part 1.

Requirements for the development, validation and routine control of a sterilization process for medical devices (GB 18278.1-2015, ISO 17665-1.2006, IDT);

GB 18279.1, Sterilization of health care products - Ethylene oxide - Part 1.

Requirements for development, validation and routine control of a sterilization process for medical devices (GB 18279.1-2015, ISO 11135-1.2007, IDT);

GB 18280.1, Sterilization of health care products - Radiation - Part 1.

Requirements for the development, validation and routine control of a sterilization process for medical devices (GB 18280.1-2015, ISO 11137-1.2006, IDT);

GB/T 18457, Stainless steel needle tubing for the manufacture of medical devices

- Requirements and test methods (GB/T 18457-2015, ISO 9626.1991.2001, MOD);

YY/T 0466.1, Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1.General requirements (YY/T 0466.1-2023,

ISO 15223-1.2021, MOD);

ISO 80369-7, Small-bore connectors for liquids and gases in healthcare applications - Part

7.Connectors for intravascular or hypodermic applications

3 Terms and definitions

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

3.1

needle cap

A cap used to protect the needle tube from physical damage before use and to keep the needle tube sterile for the syringe with fixed needle tube (type 8).

3.2

plunger stopper

The sealing assembly between the barrel and the plunger delivery.

3.3

plunger cap

A cap used to keep the inside of the syringe sterile and to seal the plunger delivery and the protruding part of the push-button.

3.4

fiducial line

Available length of a needle tube.

Note: The needle length is shown in Figure 1.

3.12

nozzle cap

A protective component for the nozzle before use.

3.13

plunger delivery

A device for pushing the plunger stopper (3.2) to deliver liquid medicine.

Figure 1 - Schematic diagram of needle length

4 Product classification

4.1

The names of the syringe structure and its components are shown in Figure 2.

Type 3.Male Luer connector, with a removed or removable needle, packaged in a unit

packaging.

Type 4. Male Luer connector, with a removable needle and a protective end cap.

Type 5. Non-male Luer connector, with a non-removable needle, packaged in a unit packaging.

Type 6. Non-male Luer connector, with a non-removable needle and a protective end cap.

Type 7. With a fixed needle tube, packaged in a unit packaging.

Type 8. With a fixed needle tube and a protective end cap.

5 Materials

Materials used in the manufacture of syringe and its components shall comply with the requirements of Chapter 6. Components that come into contact with the liquid medicine shall also comply with the requirements of Chapters 7 and 8.

6.1 Appearance

When viewed with normal or corrected vision without magnification, the surfaces of syringes and needles that come into contact with insulin shall be clean and free of foreign matter.

6.2 Lubricant

If lubricant is used on the inner surface of the syringe (including the plunger stopper) and the outer surface of the needle tube, when viewed with normal or corrected vision without magnification, there shall be no visible accumulation of lubricant on the inner surface of the syringe, the outer surface of the needle tube, and the needle hole.

6.3 Range of sizes

The range of sizes and scales of the syringe shall comply with the requirements of Table

1.

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