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

YY/T 0573.2-2025

Replacing YY/T 0573.2-2018

**Sterile hypodermic syringes for single use - Part 2: Syringes for
use with power-driven syringe pumps**

一次性使用无菌注射器 第2部分：动力驱动注射泵用注射器

(English Translation)

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents".

Drafting.

This document is Part 2 of YY/T 0573 "Disposable Sterile Syringes". YY/T 0573 has already published the following parts.

---Part 2: Syringes for Powered Injection Pumps;

---Part 3: Self-Destructing Fixed-Dose Vaccine Injector;

---Part 4: Preventing the reuse of syringes.

This document replaces YY/T 0573.2-2018 "Disposable Sterile Syringes - Part 2: Power-Driven Injection Pumps" Compared with YY/T 0573.2-2018, the main technical changes in the "Equipment" standard, apart from structural adjustments and editorial modifications, are as follows.

---Add syringes with a nominal capacity of 1mL to 5mL to the scope of this document (see Chapter 1, Chapter 1 of the 2018 edition);

---The overall flow requirement in Chapter 14 has been removed because it is primarily affected by the inner diameter (ID) of the outer casing, which was addressed in Chapter 11;

---The test speed of the pump is adjusted for the nominal capacity of each syringe to better reflect the speed range set in a typical clinical setting.

This document is modified to adopt ISO 7886-2:2020 "Disposable sterile syringes - Part 2: Powered syringe pumps for use with sterile syringes".

The main technical differences between ISO 7886-2:2020 and ISO 7886-2:2020, and the reasons for these differences, are as follows.

---ISO 3696 (see A.3.2, B.2.2, C.2.2) has been replaced with the normatively referenced GB/T 6682 to adapt to my country's technical requirements.

Improve operability;

---ISO 7886-1:2017 has been replaced by the normatively referenced GB 15810-2019 (see Chapters 3, 4, 5, and 6).

Chapters 6, 7, 8, 9, 10, 11.1, 11.2, 12.2, 13.1, 13.2, 18, 19.1, 19.2, 19.3 19.4), to adapt to my country's technological conditions and increase operability;

---A section on "Test Methods for Dimension A" has been added to Chapter 10 to better suit my country's technological conditions and increase operability;

---The requirement for "easily oxidizable substances" has been added (see Chapter 14) to adapt to my country's technical conditions;

---The requirement for "ethylene oxide residue" has been added (see Chapter 15) to adapt to my country's technical conditions;

---The requirement of "sterility" has been added (see Chapter 16) to adapt to my country's technical conditions;

---The requirement for "bacterial endotoxins" has been added (see Chapter 17) to adapt to my country's technical conditions;

---The requirements for "syringe drive" (see A.3.1) have been amended to suit my country's technical conditions;

---The requirements for the "test apparatus" have been changed (see B.2.1) to suit my country's technical conditions.

Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents.

This document was proposed by the National Medical Products Administration.

This document is under the jurisdiction of the National Technical Committee on Standardization of Medical Syringes (Needles) (SAC/TC95).

Introduction

YY/T 0573 "Disposable Sterile Syringes" consists of three parts.

---Part 2: Syringes for Powered Injection Pumps. This section specifies the particular requirements for syringes used in powered injection pumps.

---Part 3: Self-destructing fixed-dose vaccine syringes. Designed for self-destructing fixed-dose syringes that are no longer intended for use after a predetermined dose has been administered.

Regulations were established for the quantity of vaccine syringes;

---Part 4: Prevention of Syringe Reuse. This aims to cover situations where syringes are not reused during, after, or after the intended dose has been administered.

The syringe used in the procedure.

0.1 General Provisions

Early in the preparation of this document, it was recognized that this could only be achieved by combining the power-driven injection pump and syringe into a complete system.

Absolutely standard performance. The dependence of one component of a system on the performance of another is a key factor. When considering design changes, for the manufacturer of one component needs to maintain contact with the manufacturer of the other component to ensure the system operates satisfactorily. This is especially true for syringes.

Manufacturers should provide information regarding the acceptable tolerances, expected variations, and performance characteristics of the syringe dimensional deviations specified in this document, such as the moving core.

The force.

The test speed selected through flow accuracy testing revealed that lower speeds resulted in worse conditions, leading to larger variations; regardless, by Due to limitations in the weight testing method (such as the difficulty in balancing and measuring trace amounts of liquid using a static balance), a weight lower than [a certain value] is selected.

A rate of 1 mL/h is considered inappropriate.

It should be recognized that start-up time and initial position may affect pump power; if necessary, these factors should be considered for elimination.

The characteristics of the syringe driver and measuring device can affect the error of the test method; therefore, it is recommended to include appropriate equipment accuracy and precision.

Density levels were determined, and methodological validation was performed.

0.2 Design Specifications

Originally designed and used in manually operated syringes placed in syringe pumps, modern syringes now take a larger size than manual ones.

Using more stringent requirements is advisable.

It is understood that all syringe manufacturers worldwide invest heavily in molding and manufacturing equipment, such as changing the diameter of the trigger or the inner diameter of the outer casing.

The process of transformation has largely exceeded the capabilities of the syringe industry.

Typically, the fixed height of a syringe is not considered a particularly critical dimension. Its acceptable level is relatively low.

The dimensional properties are not only a function of the total length of the piston rod and outer sleeve, but also a function of the piston assembly and the thickness of the outer sleeve's rolled edge. The piston assembly thickness is...

Due to their relatively simple manufacturing process, the differences are significant. Because all these components are made using multi-cavity molds from numerous molds around the world...

The previously insignificant dimensions, accumulated through limit tolerances from cavity to cavity, from mold to mold, and from position to position, make these...

The parts cannot be tightened immediately.

0.3 Syringe Recognition

Importantly, when the syringe is mounted on the syringe pump, proper programming, with respect to the specific syringe being installed, ensures optimal pump performance.

satisfy.

Given the consequences of the pump failing to correctly identify the syringe, the need for an automated system was recognized. Efforts have been made to reduce syringe identification errors.

The methods currently in use, such as mechanical sensing of the syringe's outer diameter, are considered impractical in the long run. This is because different manufacturers produce...

The range of syringe diameters overlaps. It is also recognized that standardizing the syringe sheath diameter across the entire industry is not a realistic approach.