YY

PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 0451-2023

Portable infusion devices for single use - Non electrically driven

一次性使用便携式输注泵 非电驱动

Issued on: September 5, 2023 **Implemented on: September 15, 2026**

Issued by: National Medical Products Administration

Table of Contents

Foreword

This document was drafted in accordance with the rules provided in GB/T 1.1-2020 Directives for Standardization - Part

1.Rules for the Structure and Drafting of Standardizing Documents. This document serves as a replacement of YY 0451-2010 Portable Infusion Devices for Single Use - Non Electrically Driven. In comparison with YY 0451-2010, apart from structural adjustments and editorial modifications, the main technical changes are as follows:

---The Scope is modified (see Chapter 1; Chapter 1 of Version 2010);

---The "composition" is modified (see 4.1;

4.1 of Version 2010);

---The "materials" is modified (see 4.2;

4.2 of Version 2010);

---The "general principle" in Design and Characteristics is modified (see 4.3.1;

4.3.1 of Version 2010);

---The "connectors" in Design and Characteristics is modified (see 4.3.2;

4.3.2 of Version 2010);

---The "filters" in Design and Characteristics is modified (see 4.3.3;

4.3.3 of Version 2010);

---The pressure resistance test is modified (see 6.3;

1 Scope

YY 0451 is the mandatory Chinese standard for single-use non-electric portable infusion pumps, the elastomeric balloon devices that deliver a drug at a fixed rate without a motor or a battery. They are used for postoperative analgesia, chemotherapy and antibiotic infusion at home, and their appeal is that nothing can be misprogrammed because nothing is programmed. What replaces the programming is the mechanical design, so the standard concentrates on flow rate accuracy and how it holds as the reservoir empties and as temperature changes, together with the filling, the filter, the tubing and the sterility of the assembly. A device running fast delivers an overdose with no alarm to say so. Being a YY standard without the /T suffix, compliance is compulsory. It takes effect in September 2026.

This document specifies the basic requirements and corresponding test methods for portable infusion devices for single use - non electrically driven (hereinafter referred to as the infusion devices).

2 Normative References

The contents of the following documents constitute indispensable clauses of this document through normative references in the text. In terms of references with a specified date, only versions with a specified date are applicable to this document. In terms of references without a specified date, the latest version (including all the modifications) is applicable to this document.

GB/T 6682 Water for Analytical Laboratory Use - Specification and Test Methods (GB/T 6682- 2008, ISO 3696.1987, MOD)

3 Terms and Definitions

The following terms and definitions are applicable to this document. The ratio of the nominal volume (3.10) to the actual time required to infuse the solution.

4 General Requirements

The materials used in parts that come into contact with medicinal liquids shall undergo biological evaluation in accordance with the relevant parts of GB/T 16886.1. When cutting a sample from the liquid storage bag and testing in accordance with Chapter 9 in GB/T 14233.1-2022, the residue of ethylene oxide shall not exceed 10 g/g.

5 Operating Requirements

When tested in accordance with 6.7, the bolus volume shall not exceed 115% of the nominal bolus volume.

6 Test Methods

In accordance with the instructions for use and the accompany documents, prepare the infusion device [see 8c)], so that it can infuse solution.

7 Information That Shall Be on the Packaging and / or Product

The infusion device, sterile barrier system and / or protective packing shall be labeled with the information provided in Table 1.

8 Accompanying Documents

The accompanying documents shall contain at least the following information.

Appendix A

(informative) Technical Differences between This Document and ISO 28620.2020, and Causes for the Differences