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

YY/T 0109-2024

Replacing YY/T 0109-2013

Medical ultrasonic nebulizer

医用超声雾化器

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part

1. Structure and drafting rules for standardization documents" Drafting. This document replaces YY/T 0109-2013 "Medical Ultrasonic Atomizer". Compared with YY/T 0109-2013, except for structural adjustment and editing In addition to the changes in performance, the main technical changes are as follows:

- Added the term and definition of "total amount of atomization" (see 3.2);
- Changed the term and definition of "atomization rate" (see 3.3, 3.2 of the.2013 edition);
- Deleted the term and definition of "equivalent volume particle size" (see 3.3 of the.2013 edition);
- Changed the term and definition of "volume median particle size" (see 3.4, 3.4 of the.2013 edition);
- Added the term and definition of "aerodynamic mass median particle size" (see 3.5);
- Added the requirements and test methods for "total amount of ultrasonic atomization" (see
- Changed the requirements and test methods for "atomized particle distribution characteristics" (see 5.5 of the.2013 edition);
- Deleted the requirements and test methods for "continuous working time" (see

1 Scope

YY/T 0109 is the product standard for the medical ultrasonic nebuliser, the device that uses a vibrating element to turn a drug solution into an inhalable aerosol. It specifies the

requirements for medical ultrasonic nebulisers and the corresponding test methods, and it applies to nebulisers working on the ultrasonic principle. What decides whether a nebuliser is effective is the particle size distribution it produces, because that determines how far into the airway the drug reaches, together with the output rate and the residual volume left behind. Ultrasonic devices also heat the solution, which matters for drugs that do not tolerate it. For a manufacturer or an importer of ultrasonic nebulisers seeking Chinese registration, this is the standard the type testing follows.

YY/T 1420 Environmental requirements and test methods for medical ultrasonic equipment

YY 9706.102 Medical electrical equipment Part 1-

2.General requirements for basic safety and essential performance Collateral standard.
Electromagnetic compatibility Requirements and tests

2 Normative references

The contents of the following documents constitute essential clauses of this document through normative references in this document. For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to This document.

GB 9706.1 Medical electrical equipment Part

GB/T 14710 Environmental requirements and test methods for medical electrical appliances

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 The electrical frequency that excites the ultrasonic oscillation of the nebulizer.

Note. The unit of ultrasonic oscillation frequency is megahertz (MHz).

3.2 Nebulization quantity For a given filling volume, the total volume or total mass of liquid that the nebulizer can atomize.

Note. The unit of total atomization volume is milliliters (mL) or grams (g).

3.3 Nebulization rate The volume or mass of liquid atomized by the atomizer per unit time.

Note. The unit of atomization rate is milliliters per minute (mL/min) or grams per minute (g/min).

3.4 When the particles are sorted by size, the volume of particles larger than it and smaller than it each accounts for 50% of the total volume of the particles. Particle size.

Note. The unit of volume median particle size is micrometer (μm).

3.5 When the particles are sorted by aerodynamic size, the mass of particles larger and smaller than it each accounts for a portion of the total mass of the particles.

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