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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0907-2023

Replacing YY/T 0907-2013

Requirements and test methods for medical needle-free syringes

医用无针注射器 要求及试验方法

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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 replaces YY/T 0907-2013 "Requirements and Test Methods for Medical Needleless Syringes". Compared with YY/T 0907-2013, In addition to editorial changes, the main technical changes are as follows:

a) Added requirements for adaptability of needleless syringe components (see 5.5.4);

b) Added chemical requirements for needleless syringes (see 5.5.5);

c) Added biological requirements (see 5.5.6);

d) Added test procedures (see 6.2);

e) Added instructions for use of needleless syringes and unit packaging labeling requirements (see 7.3);

f) Added extraction solution preparation and test methods (see Appendix C). This document is modified to adopt ISO 21649.2006 "Requirements and Test Methods for Medical Needleless Syringes" The technical differences and reasons between this document and ISO 21649.2006 are as follows:

---Replaced IEC 60068-2-30.2005 (see 6.3) with the normatively cited GB/T 2423.4 to adapt to my country's technical conditions, Improve operability;

---Replaced IEC 60068-2-27.1987 (see 6.2.7) with the normatively quoted GB/T 2423.5 to adapt to my country's technical conditions parts to improve operability;

---Replaced IEC 60068-2-64.1993 (see 6.2.7) with the normatively cited GB/T 2423.56 to adapt to my country's technical requirements parts to improve operability;

---Replaced ISO 3746.1995 (see 6.2.9) with normatively cited GB/T 3768 to adapt to my country's technical conditions and improve Operability;

---Replaced ISO 10993 (all parts) with normatively cited GB/T 16886 to adapt to my country's technical conditions and improve reliability operability;

---Replaced ISO 11201.1995 (see 6.2.9) with normatively cited GB/T 17248.2 to adapt to my country's technical conditions, Improve operability;

1 Scope

YY/T 0907 covers the medical needle-free injector, the device that drives a drug through the skin as a high-velocity jet instead of through a needle. It specifies the requirements such an injector has to meet and the test methods that verify them, covering the pressure and velocity of the jet, the dose actually delivered, the depth and consistency of penetration, and the safety features that prevent cross-contamination between patients. Needle-free injection is used for insulin, vaccines and local anaesthesia, and its appeal is the removal of needlestick injury and sharps waste, but the delivery has to be shown to be equivalent to a needle before that trade is acceptable. The 2023 edition replaces YY/T 0907-2013. This is the document a Chinese registration dossier for such a device is assessed against.

This document specifies medical needleless syringes for single or multiple use for use in clinical and related medical settings or for personal use. (hereinafter referred to as "needleless syringe") requirements and test methods. This document applies to single- or multiple-use needleless syringes for use in clinical and allied health care settings or for personal use.

Note. The medication chamber of a needleless syringe is usually disposable and must be

replaced after a single use or a limited number of uses. Sometimes it is separated from the injection mechanism Isolated, and often referred to as "cartridge", "ampule", "syringe", "capsule" or "disc". On the contrary, the medicine chamber can also be a permanent inner chamber, and its usability Can remain valid within the validity period. This document does not apply to the following administration methods using needleless syringes.

---Puncture a part of the needleless injection device itself into or penetrate the skin or mucous membrane (such as needle, tip, microneedle, implantable slow drug release device);

---Produces aerosols, droplets, powders or other forms for inhalation, insufflation, nasal or oral deposition (such as sprays, inhalers, atomization device);

---The deposited liquid, powder or other substances on the surface of the skin or mucous membranes are passively diffused or ingested by the body (such as transdermal absorption patches, liquid drop);

---Applied to acoustic energy or electromagnetic energy (such as ultrasound or ion introduction device);

---Infusion system, which uses artificial pipes, catheters and/or needles inserted into the human body to add or measure drugs.

2 Normative reference documents

The contents of the following documents constitute essential provisions of this document through normative references in the documents. Among them, dated references For documents, only the version corresponding to the date applies to this document; for undated referenced documents, the latest version (including all modification orders) applies in this document.

GB/T 2423.4 Environmental testing of electrical and electronic products Part

2.Test methods Test Db. Alternating damp heat (12h 12h cycle Ring) (GB/T 2423.4-2008,

IEC 60068-2-30.2005, IDT)

GB/T 2423.5 Environmental testing Part

2.Test method Test Ea and guidance. Impact (GB/T 2423.5-2019, IEC 60068-2-27.2008,IDT)

GB/T 2423.7-2018 Environmental testing Part

2.Test methods Test Ec. Impact caused by rough operation (mainly used for Equipment type sample)(IEC 60068-2-32.2008,IDT)

GB/T 2423.56 Environmental testing Part

2.Test method test Fh; Broadband random vibration and guidelines (GB/T 2423.56- 2018, IEC 60068-2-64.2008,IDT)

GB/T 3768-2017 Acoustic sound pressure method determines the sound power level and sound energy level of noise sources using the envelope measurement surface above the reflective surface Simple method (ISO 3746.2010, IDT)

GB/T 3785.1-2010 Electroacoustic sound level meter Part

7 Portable and non-stationary use (IEC 60721-3-7. 2002,MOD)

Note. There is no technical difference between the quoted content of

GB/T 4798.7-2007 and the quoted content of IEC 60721-3-7.2002.

GB 9706.1 Medical electrical equipment Part

1.General requirements for basic safety and basic performance (GB 9706.1-2020, IEC 60601-1.2012, MOD)