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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0862-2023

Replacing YY/T 0862-2011

Ophthalmic optics - Ocular endotamponades

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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" to be drafted: This document replaces YY/T 0862-2011 "Ophthalmic Implants Intraocular Fillers": Compared with YY/T 0862-2011, except for structural In addition to rectification and editorial changes, the main technical changes are as follows:

--- Changed the terms and definitions of "shear viscosity" (see 3:2, 3:2 of the:2011 edition);

--- Deleted the terms and definitions of "non-solid substances" (see 3:5 of the:2011 edition);

--- Added the term and definition of "intraocular filler" (see 3:5);

--- Changed the terms and definitions of "primary packaging" (see 3:6, 3:8 of the:2011 edition);

--- Added the terms and definitions of "secondary packaging" (see 3:9);

--- Added the term and definition of "surgical implant" (see 3:11);

--- Changed the terms and definitions of "vapor pressure" (see 3:12, 3:7 of the:2011 edition);

--- Added the terms and definitions of "minimum operating pressure" (see 3:13);

--- Changed the "expected performance" (see Chapter 4, Chapter 4 of the:2011 edition);

---Changed the "chemical description and impurities/pollutants" (see 5:2, 5:2, 5:3, 5:4 of the:2011 edition);

--- Changed the "kinematic viscosity" (see 5:6, 5:8 of the:2011 edition);

--- Added "shear viscosity" (see 5:7);

--- Changed "particles" (see 5:9, 5:10 of the:2011 edition);

1 Scope

YY/T 0862 covers ocular endotamponades, the gases and silicone oils injected into the vitreous cavity to hold a detached retina against the eye wall while it heals. It sets the requirements such materials have to meet and the test methods that verify them, covering purity and composition, viscosity and refractive index, the absence of toxic residues and low-molecular-weight components, sterility and the packaging and delivery system. The material sits inside the eye for weeks or months in contact with the retina, so an impurity that would be tolerable elsewhere causes irreversible visual loss here. Retinal detachment surgery is high-volume in China and the tamponade is what determines whether it succeeds. The 2023 edition replaces YY/T 0862-2011. This is the text a Chinese registration is assessed against.

This document specifies the expected performance, design attributes, design evaluation, sterilization, product stability, integrity of delivery system, etc: of intraocular fillers: General requirements such as integrity and performance, packaging, information provided by the manufacturer, etc: This document applies to intraocular fillers:

2 Normative references

The contents of the following documents constitute the essential provisions of this document through normative references in the text: Among them, dated references For documents, only the version corresponding to the date is applicable to this document; for undated reference documents, the latest version (including all amendments) is applicable to this document: GB/T 16886:

1 Biological evaluation of medical devices Part 1: Evaluation and testing in the risk management process (GB/T 16886: 1-2022, ISO 10993-1:2018, IDT) GB/T 16886:

2 Biological evaluation of medical devices Part 2: Animal welfare requirements (GB/T 16886:2-2011, ISO 10993-2:2006, IDT) GB/T 16886:

6 Biological evaluation of medical devices Part 6: Local reaction test after implantation (GB/T 16886:6- 2022, ISO 10993-6:2016, IDT) GB/T 19633:

1 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (GB/T 19633:1-2015,

ISO 11607-1:2006, IDT) Application of

GB/T 42062 Medical Device Risk Management to Medical Devices (GB/T 42062-2022, ISO 14971: 2019, IDT) YY/T 0466:

1 Symbols for Medical Device Labeling, Marking and Information Provision for Medical Devices Part 1: General Requirements (YY/T 0466:1-2016, ISO 15223-1:2012, IDT) YY/T 0567:

1 Aseptic processing of healthcare products Part 1: General requirements (YY/T 0567:1-2013, ISO 13408-1:2008, IDT)

YY/T 0640 General requirements for passive surgical implants (YY/T 0640-2016,

ISO 14630:2012, IDT) Pharmacopoeia of the People's Republic of China Volume Four

3 Terms and Definitions

The following terms and definitions apply to this document: 3:

1 Conveyor systemdeliverysystem Sealed container with product and add-on kit for infusing the product into the eye: 3:

2 Shear viscosity dynamicviscosity The quotient of shear stress and shear rate:

Note: Shear viscosity can be expressed in Pascal seconds (Pa·s):