ICS 11.040.70
CCS C40

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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 0861-2024

Replacing YY 0861-2011

Ophthalmic optics - Ophthalmic viscosurgical devices

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Issued on: July 8, 2024 **Implemented on: July 20, 2027**

Issued by: National Medical Products Administration

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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 0861-2011 "Ophthalmic Optical Viscoelastics". Compared with YY 0861-2011, in addition to structural adjustments and compilation In addition to logical changes, the main technical changes are as follows:

--- Deleted the definition of "lost to follow-up cases" (see

3.5 of the.2011 edition);

--- Changed the definition of "primary packaging" (see 3.6,

3.7 of the.2011 edition);

--- Added the definition of "surgical implant" (see 3.11);

--- Changed "Expected Performance" (see Chapter 4, Chapter 4 of the.2011 edition);

--- Changed the "General requirements" of design attributes (see 5.1,

5.1 of the.2011 edition);

--- Changed "Ingredient Characteristics" (see 5.2,

5.2 of the.2011 edition);

--- Changed "Chemical and biological pollutants" (see 5.3.3,

5.3.3 of the.2011 edition);

1 Scope

YY 0861 is the mandatory standard for the ophthalmic viscosurgical device, the viscoelastic gel injected into the eye during cataract and other anterior segment surgery to maintain space, protect the corneal endothelium and manipulate tissue. It is usually hyaluronate-based, and its rheology is the product: the balance of cohesion and dispersion decides whether it stays where it is put, whether it coats and protects, and how completely it can be removed at the end of the case, since retained viscoelastic raises intraocular pressure. The YY prefix without the /T suffix makes compliance compulsory in China. For a manufacturer or an importer of OVDs seeking Chinese registration, this is the governing product standard.

This document specifies the expected performance, design attributes, design evaluation, sterilization, product stability, and delivery system integrity of ophthalmic viscoelastics. and performance, packaging and information provided by the manufacturer. This document applies to viscoelastics for ophthalmic use (hereinafter referred to as "viscoelastics").

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/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 16886.6 Biological evaluation of medical devices Part

6.Local reaction test after implantation (GB/T 16886.6-2022, ISO 10993-6.2016, IDT)

GB/T 16886.7 Biological evaluation of medical devices Part

7.Ethylene oxide sterilization residues (GB/T 16886.7-2015, ISO 10993-7.2008, IDT)

GB/T 16886.9 Biological evaluation of medical devices Part

9.Qualitative and quantitative framework for potential degradation products (GB/T 16886.9-2022, ISO 10993-9.2019,IDT)

GB/T 16886.16 Biological evaluation of medical devices Part

16.Toxicokinetic study design of degradation products and leachables (GB/T 16886.16-2021, ISO 10993-16.2017,IDT)

GB 18278.1 Sterilization of health care products by moist heat Part

1.Development, validation and routine control of sterilization processes for medical devices Request (GB 18278.1-2015, ISO 17665-1.2006, IDT)

GB 18279 Sterilization of healthcare products - Development, validation and routine control requirements for ethylene oxide sterilization processes for medical devices (GB 18279-2023, ISO 11135.2014, MOD)

3 Guide to dose measurement (GB/T 18280.3-2015, ISO 11137-3.2006, IDT)

GB/T 19633.1 Terminally sterilized medical device packaging Part

1.Requirements for materials, sterile barrier systems and packaging systems (GB/T 19633.1-2015, ISO 11607-1.2006,IDT)

GB/T 42062 Application of medical device risk management to medical devices (GB/T 42062-2022, ISO 14971.2019, IDT)

YY/T 0567.1 Aseptic processing of health care products Part