YY

PHARMACEUTICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

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YY 0762-2017

Replacing YY 0762-2009

Ophthalmic Optical - Capsular Tension Ring

眼科光学 囊袋张力环

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Ophthalmic Optical - Capsular Tension Ring

1 Scope

This Standard specifies requirements, test methods, label, instruction of usage, package, transport and storage of capsular tension ring.

This Standard is applicable to disposable capsular tension ring (hereinafter referred to as tension ring). Tension ring can be adopted to maintain capsular tension in aphakic eyes, prevent from posterior capsule wrinkles and fight against capsular contraction.

2 Normative References

The following documents are indispensable to the application of this Standard. In terms of references with a specified date, only versions with a specified date are applicable to this Standard. The latest version (including all the modifications) of references without a specified date is also applicable to this Standard.

GB/T 9969 General Principles for Preparation of Instructions for Use of Industrial Products

GB/T 14233.1 Test Methods for Infusion, Transfusion, Injection Equipment for Medical Use - Part 1: Chemical Analysis Methods

GB/T 16886.5 Biological Evaluation of Medical Devices - Part 5: Test for in Vitro Cytotoxicity

GB/T 16886.10 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Delayed-type Hypersensitivity

GB/T 16886.12 Biological Evaluation of Medical Devices - Part 12: Sample Preparation and Reference Materials

YY 0290.3-2008 Ophthalmic Implants - Intraocular Lenses - Part 3: Mechanical Properties and Test Methods

YY 0290.5-2008 Ophthalmic Implants - Intraocular Lenses - Part 5: Biocompatibility

YY 0290.6 Intraocular Lenses - Part 6: Shelf-life and Transport Stability

Pharmacopoeia of the People's Republic of China

Except from primary packaging, additional wrapping maintains sterility performance.

3.6 Storage Container

Storage container is a package that has protective effect during the storage and sales.

3.7 Prescription Diameter

Prescription diameter is anticipated implantation diameter issued by clinical practitioners that's suitable for patients.

4 Requirements

4.1 Mechanical Performance

4.1.1 Functional elasticity

4.1.1.1 Nominal value tolerance of functional elasticity

Manufacturers shall provide the nominal value of functional elasticity of tension ring. The functional elasticity shall be radial deformation force that's generated when symmetrical position of the tension ring reaches the prescribed diameter through radial deformation. The nominal value tolerance of functional elasticity shall be ± 10%.

4.1.1.2 Functional elasticity attenuation

Manufacturers shall provide yield characteristics when the tension ring reaches the prescribed diameter through radial deformation and maintains for 24 h under the state of clinical application. The yield characteristics can be represented by the proportion of functional elasticity attenuation or the proportion of deformation of the maximum peripheral diameter after compression and release.

4.1.2 Shape variable and stress

4.1.2.1 Elasticity limit

Materials of tension ring shall be uniform; the processing of tension ring shall be flawless. After tension ring experiences the following deformation tests, there are abnormal deformations triggered by the deficiency of concentrated stress. The following requirements shall be satisfied simultaneously under room temperature:

a) Impose radial force onto the tension ring in accordance with the symmetrical position. When compression reaches 50% shape variable, immediately release it. The variation of the maximum peripheral diameter shall be ≤ 1% of original value;

b) Impose force onto both sides of the tension ring along the peripheral axis

The surface of tension ring shall be smooth; the transition areas shall be successive; there shall be no defects that might cause human tissue damage.

4.4 Extraction

Conduct 0.9% NaCl inorganic solvent extraction test on the tension ring; the rate of extraction shall be < 0.5%.

4.5 Biocompatibility

4.5.1 General principles

Materials with verified conformity with biocompatibility shall be adopted to manufacture tension rings, otherwise, materials shall be verified through tests described in 4.5.2 ~ 4.5.5.

4.5.2 Cytotoxicity

No cytotoxicity shall be found in finished tension rings.

4.5.3 Eye irritation

No eye irritation shall be triggered by finished tension rings.

4.5.4 Delayed-type hypersensitivity

No delayed-type hypersensitivity shall be triggered by finished tension rings.

4.5.5 Intraocular implantation test

If manufacturers cannot provide documents to prove material safety of tension ring under intraocular environment, intraocular implantation test shall be conducted; compatibility between test materials and intraocular tissues shall be evaluated after the implantation.

4.6 Sterility

The sterility of tension rings shall be maintained before the expiration date indicated by the label.

4.7 Ethylene Oxide Residue

If ethylene oxide is adopted for sterilization, ethylene oxide residue shall be ≤ 10 mg/kg.

4.8 Validity Period

The performance of tension rings shall satisfy the requirements within the validity period.

5.1.3 Uniformity check

Instrument: projector.

Steps: take 10 tension rings; respectively select 5 points on each sample for measurement.

5.1.4 Dynamic fatigue durability test

Take 3 tension rings, conduct dynamic fatigue durability test in normal saline solution in accordance with the principle of equipment described in Appendix G in YY 0290.3-2008.

5.2 Dimension Measurement

Adopt measuring instrument for dimension measurement.

5.3 Surface Quality Check

Adopt optical microscope (above 10x) to check surface quality.

5.4 Extraction Test

Conduct extraction test in accordance with the method described in Appendix B in YY 0290.5-2008.

5.5 Biocompatibility Test

5.5.1 Cytotoxicity test

Test solution shall be prepared in accordance with the method described in GB/T 16886.12; conduct cytotoxicity test in accordance with the method stipulated in GB/T 16886.5.

5.5.2 Eye irritation test

Test solution shall be prepared in accordance with the method described in GB/T 16886.12; conduct eye irritation test in accordance with the method stipulated in GB/T 16886.10.

5.5.3 Delayed-type hypersensitivity test

Test solution shall be prepared in accordance with the method described in GB/T 16886.12; conduct delayed-type hypersensitivity test in accordance with the method stipulated in GB/T 16886.10.

5.5.4 Intraocular implantation test

Conduct applicability test in accordance with the method described in Appendix G in

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