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Pharmaceutical Industry Standard
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Ophthalmic optics

Capsular tension ring

眼科光学囊袋张力环

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Foreword

The performance requirements of this Standard are developed by basing on the product clinical requirements and referring to the YY 0290 series of standards.

Biocompatibility requirements of this Standard shall be determined by referring to GB/T16886.1 *Evaluation of Medical Devices Biology Part 1: Guide of Select Test.*

This Standard is approved by the State Food and Drug Administration.

This Standard is proposed and administered by National Medical Optical Instrument Standardization Technical Committee (SAC/TC 103/SC1).

This Standard is drafted by organizations: Hangzhou Medical Device Quality Supervision and Inspection Center of State Food and Drug Administration.

This Standard is mainly drafted by: Wen Yan, Jia Hang, and Feng Qin.

Ophthalmic optics -- Capsular tension ring

1 Scope

This Standard specifies the scope, requirements, test methods, marking and instructions, packaging, transportation and storage of capsular tension ring.

This Standard applies to one-time use of capsular tension ring (hereinafter referred to as “the tension ring”). Tension ring is for aphakia to maintain capsular tension, and prevents posterior capsular from wrinkle, and is also used against the capsular bag from contraction.

2 Normative references

The following normative documents contain provisions which, through reference in the text, constitute provisions of this Standard. For dated reference, subsequent amendments to, or revisions of, any of these publications (excluding contents of corrigenda) do not apply. However, parties who enter into agreements based on this Standard are encouraged to investigate the possibility of applying the most recent editions of the Standards indicated below. For undated references, the latest edition of the normative document referred to applies.

GB/T 191 Packaging-Pictorial marking for handling of goods

GB 9969.1 Instructions of industrial products – General Principles

GB/T 16886.1 Evaluation of Medical Devices Biology Part 1: Evaluation and Testing (ISO 10993.1:1997, IDT)

GB/T 16886.5 Evaluation of Medical Devices Biology Part 5: The Test of Vitro Cytotoxicity (ISO 10993.5:1999, IDT)

GB/T 16886.6 Evaluation of Medical Devices Biology Part 6: The Test of Local Reactions after Implanting (ISO 10993.6:1994, IDT)

GB/T 16886.7 Evaluation of Medical Devices Biology Part 6: The Amount of Ethylene Oxide Sterilization Residuals (ISO 10993.7:1995 IDT)

5 Testing Methods

5.1 Test of Mechanical Properties

5.1.1 Functional Stretch Test

5.1.1.1 Tolerance of Nominal Value of Functional Stretch

Instrument: Minimal reading of micro-force meter is: mN.

Steps: SAMPLE 3 tension rings. PLACE the samples on the fixture of the micro-force meter. The fixture may use the device of Appendix A of YY 0290.3. ADJUST the samples to make the outer force-point to be symmetric. Then IMMERSE the fixture in the 35ºC physiological salt solution. Under the state of the tension ring is not deformed, the meter's reading shall be reset to zero. ADJUST the shifter to make the tension ring meet the requirements of position-shift. READ the value on the meter. REPEAT the tests 3 times and GET the arithmetic mean.

5.1.1.2 Functional Stretch Attenuation

a) The ratio test of functional stretch attenuation shall be conducted and based on 5.1.1.1.1. CALCULATE the functional stretch attenuation and the ratio of functional stretch.

b) The ratio test of the deformation of the total diameter: SELECT 3 tension rings, MEASURE total diameter of the respective tension rings and RECORD the corresponding measuring points. PLACE the tension rings inside the device of Appendix F of YY 0290.3 and IMMERSE them in container with salt solution. Then IMMERSE the container into the 35ºC water bath and MAINTAIN for 24h. REMOVE them carefully and immediately MEASURE the total diameter of tension rings. CALCULATE the ratio of deformation and compression.

5.1.2 Deformation and Stress Measurement

Instrument: USE projector to measure

Environment: 23ºC to 5ºC.

Steps:

a) SAMPLE 3 tension rings, MEASURE and RECORD the total diameter. COMPRESS samples as required and MAINTAIN for 3 minutes. After Restoring for

5.5.3 Test of Delayed-type Hypersensitivity

CONDUCT the test according to the methods in GB/T 16886.10. The results shall be consistent with the regulations in 4.5.3.

5.5.4 Test of Ocular and Non-Ocular Implantation

CONDUCT the test according to the methods in GB/T 16886.6. The results shall be consistent with the regulations in 4.5.4.

5.6 Test of Sterilization

5.6.1 Test of sterilization shall be conducted according to the methods in GB/T 14233.2. The results shall be consistent with the regulations in 4.6.1.

5.6.2 The test of residual ethylene oxide shall be conducted according to the methods in GB/T 14233.1. The results shall be consistent with the regulations in 4.6.2.

5.7 Test of Packaging Integrity

Inspected with eyes and unpacking inspection - The results shall be consistent with the regulations in 4.7.

5.8 Test of Validity

CONDUCT the test according to the methods in YY 0290.6. TEST each testing point according to 4.2, 4.3, 4.6 and 4.7. The results shall be consistent with the requirements in 4.8.

6 Signs and Instructions for Use

6.1 The storage container of tension ring shall have the following contents:

a) Name of manufacturer, logo or trade name;

b) Manufacturer’s address;

c) Product name of tension ring (including possible product number);

d) Product lot number or production date;

e) Words of "Sterilization";

f) Expiration date – expressed in year and month (symbol expression may be used);

g) The appearance drawing of tension ring.

6.2 Instructions for use shall be consistent with the regulations in GB 9969.1-1998

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