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PHARMACEUTICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

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YY/T 1758-2020

Cardiovascular implants - Pulmonary valve conduit

心血管植入物 肺动脉带瓣管道

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Cardiovascular implants - Pulmonary valve conduit

1 Scope

This Standard specifies the basic requirements for pulmonary valve conduit.

This Standard applies to the pulmonary valve conduit which corrects or reconstructs the ventriculus dexter outflow tract.

This Standard does not apply to prostheses which are derived from allogeneic and autologous tissues (autologous transplantation).

2 Normative references

The following documents are indispensable for the application of this document. For dated references, only the dated version applies to this document. For undated references, the latest edition (including all amendments) applies to this document.

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

GB/T 9969, General principles for preparation of instructions for use of industrial products

GB 12279, Cardiovascular implants - Cardiac valve prostheses

GB/T 14233.1-2008, Test methods for infusion, transfusion, injection equipment for medical use - Part 1: Chemical analysis methods

GB/T 14233.2-2005, Test methods for infusion, transfusion, injection equipment for medical use - Part 2: Biological test methods

GB/T 16886.1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

GB/T 16886.12, Biological evaluation of medical devices - Part 12: Sample preparation and reference materials

YY/T 0313, Medical polymer products - Requirement for package and information supplied by manufacturer

YY/T 0466.1, Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

YY 0500-2004, Cardiovascular implants - Tubular vascular prostheses

5 Requirements

5.1 Physical properties

5.1.1 Appearance

The pulmonary valve conduit shall be well-defined and complete; the surface shall be clean and free of flaws, spots, and other defects that affect its use.

5.1.2 Specifications

The inner diameter and length of the pulmonary valve conduit shall meet the manufacturer's specifications.

5.1.3 External durability

Perform the in vitro accelerated fatigue test for 2.0×10^{8} cycles to evaluate the performance of pulsating flow in vitro; the results shall meet the manufacturer's specifications. The valve leaflet shall be undamaged.

5.1.4 Fluid dynamics

5.1.4.1 Steady-state forward flow test

The results of the steady-state forward flow test of the pulmonary valve conduit shall meet the manufacturer's specifications.

5.1.4.2 Steady-state leakage test

The steady-state leakage test results of the pulmonary valve conduit shall meet the manufacturer's specifications.

5.1.4.3 Pulsating flow test

The pulsating flow test results of the pulmonary valve conduit shall meet the manufacturer's specifications.

5.1.5 Valve opening and closing state

The valve leaflets of the pulmonary valve conduit shall be opened and closed completely.

5.1.6 Expanded inner diameter

Under the pressure of 8 kPa (60 mmHg), the expanded inner diameter of the valve of the pulmonary valve conduit shall meet the manufacturer's specifications.

5.2.1 pH value

Compare the test solution with the blank solution of the same batch; the difference in pH value shall not exceed 1.5.

5.2.2 Heavy metal

The total content of heavy metals in the test solution shall not exceed 1 μg/mL.

5.2.3 Residues

The manufacturer shall clarify chemical treatment and modification methods, and give acceptance criteria for residual substances.

5.2.4 Other chemical properties

If the product contains non-biological components, its chemical properties shall be evaluated.

5.3 Biological properties

5.3.1 Sterility

The pulmonary valve conduit shall be sterile.

5.3.2 Bacterial endotoxin

The bacterial endotoxin of the pulmonary valve conduit shall be less than 2.15 EU/piece.

5.3.3 Pyrogen

Pulmonary valve conduit shall not cause pyrogen reactions.

5.3.4 Calcification

Implant the pulmonary valve conduit subcutaneously for 8 weeks, and the calcium content shall not be higher than the reference substance.

5.3.5 Biocompatibility

Pulmonary valve conduit shall be biologically evaluated in accordance with GB/T 16886.1.

6 Test method

6.1 Physical test

6.1.1 Appearance

Perform the test in accordance with the method that is specified in 8.3.1 of YY 0500-2004; the result shall meet the requirements of 5.1.7.1.

6.1.7.2 Axial tensile strength

Perform the test in accordance with the method that is specified in 8.3.2 of YY 0500-2004; the result shall meet the requirements of 5.1.7.2.

6.1.8 Conduit bursting strength

Perform the test in accordance with the method that is specified in 8.3.3 of YY 0500-2004; the result shall meet the requirements of 5.1.8.

6.1.9 Conduit pulling strength

Perform the test in accordance with the method that is specified in 8.8 of YY 0500-2004; the results shall meet the requirements of 5.1.9.

6.1.10 Conduit water permeability

Perform the test in accordance with the method that is specified in 8.2 of YY 0500-2004; the result shall meet the requirements of 5.1.10.

6.1.11 Wall thickness

Perform the test in accordance with the method that is specified in 8.7 of YY 0500-2004; the result shall meet the requirements of 5.1.11.

6.1.12 Kinking diameter

Perform the test in accordance with the method that is specified in 8.9 of YY 0500-2004; the result shall meet the requirements of 5.1.12.

6.1.13 Compliance

Perform the test in accordance with the method that is specified in 8.10 of YY 0500-2004; the result shall meet the requirements of 5.1.13.

Note: If the length of the bio-derived product does not meet the requirement of 10 times the diameter, record the test length in the result.

6.1.14 Connection strength

Perform the test in accordance with the method that is specified by the manufacturer; the result shall meet the requirements of 5.1.14.

6.2 Chemical test

6.2.1 Preparation of test solution

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