YY

PHARMACEUTICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

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YY/T 1704.1-2020

Cervical dilator for single use - Part 1: Gradual dilator

一次性使用宫颈扩张器 第 1 部分:渐进式

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Cervical dilator for single use - Part 1: Gradual dilator

1 Scope

This Part of YY/T 1704 specifies the classification, requirements, test methods, marks, packaging and instruction manual, transport, storage and sterilization period for gradual cervical dilator for single use (hereinafter referred to as the dilator).

This Part is applicable to cervical dilator for single use. This product is used for dilatation of the cervix in obstetrics and gynecology and family planning departments.

This Part is not applicable to the cervical dilator made of metal.

2 Normative references

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

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

GB/T 16886.1, *Biological evaluation of medical devices - Part 1: Evaluation and testing*

YY/T 0171, *Surgical instruments - Packaging, Marking and Instructions*

Pharmacopoeia of the People's Republic of China (2015 Edition) Part IV

3 Classification

3.1 Type

3.1.1 The dilator is the expansion section within 60mm of the ring line from the head end. It is usually composed of 3 gradual units. Each unit is about 20mm long.

4 Requirements

4.1 Appearance

4.1.1 The head of the dilator shall be round and smooth, and no fibers shall be pulled out.

4.1.2 The marks of the dilator shall be clear and obvious.

4.1.3 The overall dilator shall be smooth and uniform in color, and there shall be no cracks, burrs, plastic flow, or defects.

4.2 Dimensions

The gradual diameter range d_1 and d_2 of the dilator, the tilt angle θ of the tip shall meet the requirements of Table 1.

4.3 Physical properties

4.3.1 The dilator shall be able to withstand 50N axial tension without breaking.

4.3.2 Apply a force of 15N to the head of the dilator, and there shall be no obvious deformation or fracture.

NOTE: Obvious deformation can be understood as the tip tilt angle θ≤0° after applying force.

4.4 Chemical properties

4.4.1 Heavy metals

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

4.4.2 PH

Compare the dilator test solution with the blank solution. The difference in pH shall not exceed 1.5.

4.4.3 UV absorbance

The absorbance of the dilator test solution in the wavelength range of 250nm~320nm shall not exceed 0.1.

4.5 Sterilization

The dilator shall be sterilized by a confirmed sterilization process, and the sterilized dilator shall be sterile.

NOTE: N is the loading force.

Figure 2 -- Schematic diagram of bending performance test of the dilator

5.4 Chemical properties

5.4.1 Test solution preparation

Take sample. Add water at a ratio: 0.2g of sample to 1mL of water. Keep constant temperature at (37±1)°C for 8h. Separate the sample from water. Cool to room temperature as the test solution. Take the same volume of water and place it in a glass container. Prepare blank control solution in the same way.

5.4.2 Heavy metals

Test according to the method specified in 5.6.1 of GB/T 14233.1-2008, in accordance with the requirements of 4.4.1.

5.4.3 PH

Test according to the method specified in 5.4.1 of GB/T 14233.1-2008, in accordance with the requirements of 4.4.2.

5.4.4 UV absorbance

Test according to the method specified in 5.7 of GB/T 14233.1-2008, in accordance with the requirements of 4.4.3.

5.5 Sterilization

The inspection is carried out in accordance with the method stipulated in the fourth part 1101 sterile inspection method of the "Pharmacopoeia of the People's Republic of China" (Edition 2015), in accordance with the requirements of 4.5.

NOTE: Each sterilization batch undergoes an effective monitoring process to make the product sterile.

5.6 Residual ethylene oxide

Test according to the method in Clause 9 of GB/T 14233.1-2008, in accordance with the requirements of 4.6.

5.7 Biological evaluation

Evaluate according to the corresponding method of biological evaluation, in accordance with the requirements of 4.7.

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