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PHARMACEUTICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

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YY 0285.4-2017

Replacing YY 0285.4-1999

Intravascular catheters - Sterile and single-use catheters - Part 4: Balloon dilatation catheters

血管内导管 一次性使用无菌导管 第 4 部分：球囊扩张导管

(ISO 10555-4:2013, MOD)

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Table of Contents

Foreword

YY 0285 "Intravascular catheters - Sterile and single-use catheters" consists of four parts:

- Part 1: General requirements;
- Part 3: Central venous catheters;
- Part 4: Balloon dilatation catheters;
- Part 5: Over-needle peripheral catheters.

This Part is Part 4 of YY 0285.

This Part is drafted in accordance with the rules given in GB/T 1.1-2009.

This Part replaces YY 0285.4-1999 "Sterile, single-use intravascular catheters - Part 4: Balloon dilatation catheters". Compared with YY 0285.4-1999, the main technical changes are as follows:

- UPDATE normative references;
- ADD the requirements and test methods for balloon rated burst pressure, balloon deflation time, and relationship between balloon diameter and inflation pressure.

This Part uses the redraft law to modify and adopt ISO 10555-4:2013 "Intravascular catheters - Sterile and single-use catheters - Part 4: Balloon dilatation catheters".

The technical differences between this Part and ISO 10555-1:2013 and their reasons are as follows: (Translator note: should be "ISO 10555-4:2013".)

- As for the normative references, this Standard has made adjustments with technical differences, to adapt to the technical conditions of China. The adjustments are mainly reflected in Clause 2 “Normative references”. The specific adjustments are as follows:
  - Replace ISO 594-1 with GB/T 1962.1, which is identical to the international standard;
  - Replace ISO 594-2 with GB/T 1962.2, which is identical to the international standard;
  - Replace ISO 10555-1 with YY 0285.1, which is identical to the

Intravascular catheters - Sterile and single-use catheters - Part 4: Balloon dilatation catheters

1 Scope

This Part of YY 0285 specifies requirements for balloon dilatation catheters supplied in the sterile condition, and intended for single use.

2 Normative references

The following documents are indispensable for the application of this document. For the dated references, only the editions with the dates indicated are applicable to this document. For the undated references, the latest edition (including all the amendments) are applicable to this document.

GB/T 1962.1 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirement (GB/T 1962.1-2015, ISO 594-1:1986, IDT)

GB/T 1962.2 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings (GB/T 1962.2-2001, ISO 594-2:1998, IDT)

YY 0285.1 Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements (YY 0285.1-2017, ISO 10555-1:2013, MOD)

3 Definitions

For the purposes of this document, the terms and definitions given in YY 0285.1 and the following apply.

3.1

Balloon dilatation catheter

Intravascular catheter fitted with a balloon near the distal end, which is introduced into an artery or vein to dilate a part or parts of the vascular system.

Annex B

(Normative)

Balloon fatigue test for freedom from leakage and damage on inflation

B.1 Principle

The catheter is inflated and deflated a number of times to simulate use *in vivo*. The catheter in an inflated condition is examined for leakage, rupture or herniation.

B.2 Apparatus

B.2.1 Recommended guidewire or equivalent.

B.2.2 Water bath, controlled at (37 ± 2) °C.

B.2.3 Leak detection mechanism, e.g. dye in test fluid, pressure drop monitor, flow rate monitor.

B.2.4 Timing mechanism, with specified accuracy for test.

B.2.5 Inflation syringe or equivalent device, fitted with a means of measuring pressure with an accuracy of ± 5 % of the reported value and maintaining the inflation pressure and fitted with a male 6 % (Luer) taper, complying with GB/T 1962.1 or GB/T 1962.2 as applicable, for connection to the catheter under test.

B.2.6 Compliant tube (if applicable, with a clinically relevant compliance and rationale for use, e.g. when measuring within a stent) of a diameter that represents the recommended vessel diameter for the catheter under test in order to keep the device from moving excessively during inflation cycles.

B.3 Test procedure

B.3.1 Fill the inflation device (B.2.5) with water or other clinically relevant media (selection of media to be justified).

B.3.2 If the instructions for use specify that a guidewire should be used during balloon inflation, insert the appropriate guidewire (B.2.1) in the device.

B.3.3 Connect the inflation device to the catheter under test and immerse at least the whole of the balloon portion(s) in the water bath (B.2.2) at (37 ± 2) °C. If a compliant tube is being used, insert device into the compliant tube.

Annex C

(Normative)

Test for balloon deflation time

C.1 Principle

The purpose of this test is to determine the time required to deflate the balloon from the rate burst pressure (RBP) level. This test provides information that might be clinically useful for treatment planning (e.g. potential occlusion time).

C.2 Apparatus

C.2.1 Recommended guidewire or equivalent.

C.2.2 Water bath, controlled at (37 ± 2) °C.

C.2.3 Inflation medium, which is clinically relevant or in accordance with the instructions for use (IFU).

C.2.4 Timing mechanism, with a specified accuracy for test.

C.2.5 Inflation syringe or equivalent device, fitted with a means of measuring pressure with an accuracy of ± 5 % of the reported value and maintaining the inflation pressure and fitted with a male 6 % (Luer) taper, complying with GB/T 1962.1 or GB/T 1962.2 as applicable, for connection to the catheter under test.

C.2.6 Rigid tube if appropriate, of a diameter that represents the largest recommended vessel diameter for the compliant balloon under test.

C.3 Test procedure

C.3.1 Fill the inflation device (C.2.5) with the medium in accordance with the IFU.

C.3.2 Insert the appropriate guidewire (C.2.1) in the catheter under test.

C.3.3 Connect the inflation device to the catheter under test and immerse at least the whole of the balloon portion(s) in the water bath (C.2.2) at (37 ± 2) °C. Insert the device into the rigid tube (C.2.6), if appropriate.

C.3.4 Allow the catheter to equilibrate for a minimum of 2 min.

C.3.5 Inflate the balloon to the RBP in accordance with the IFU, simulating

Annex D

(Normative)

Test for balloon diameter to inflation pressure

D.1 Principle

The purpose of this test is to determine the relationship between the balloon diameter and the inflation pressure.

D.2 Apparatus

D.2.1 Recommended guidewire or equivalent.

D.2.2 Water bath, controlled at (37 ± 2) °C.

D.2.3 Fluid for inflation, e.g. room temperature water.

D.2.4 Inflation syringe or equivalent device, fitted with a means of measuring pressure with an accuracy of ± 5 % of the reported value and maintaining the inflation pressure and fitted with a male 6 % (Luer) taper, complying with GB/T 1962.1 or GB/T 1962.2 as applicable, for connection to the catheter.

D.2.5 Equipment for measuring balloon diameter with an appropriate accuracy (e.g. micrometer, optical profile projector, laser-micrometer), capable of measuring to 10 % of the specified tolerance or 1 % of the measured value. If a tolerance is specified, the lesser value of the respective percentages shall be used.

D.3 Test procedure

D.3.1 Fill the inflation device (D.2.4) with the fluid for inflation (D.2.3).

D.3.2 Insert the appropriate guidewire (D.2.1) in the device.

D.3.3 Connect the inflation device to the catheter under test and immerse at least the whole of the balloon portion(s) in the water bath (D.2.2) at (37 ± 2) °C.

D.3.4 Allow the catheter to equilibrate for a minimum of 2 min.

D.3.5 Inflate the balloon incrementally, allowing the system to stabilize between intervals; pressures should be chosen to determine the balloon diameter at appropriate intervals (e.g. 100 kPa) over the indicated range of diameters.

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