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PHARMACEUTICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

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YY/T 0328-2015

Replacing YY/T 0328-2002

A.V. fistula needle sets for single use

一次性使用动静脉穿刺器

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Foreword

This standard was drafted in accordance with the rules given in GB/T 1.1-2009.

Please note that some of the contents of this document may involve patents. The publication institute of this document does not assume responsibility for identifying these patents.

This standard replaces YY/T 0328-2002 “Single use blood-taking set for blood processing equipment”. As compared with YY/T 0328-2002, the main technical changes of this standard are as follows:

- MODIFY the Chinese and English names of this standard;
- ADD a description of the two-way type;
- CANCEL the description of the product mark;
- MODIFY the requirements for particulate pollution;
- MODIFY the sealing requirements;
- MODIFY the flow rate requirements;
- MODIFY the requirements for puncture needles;
- MODIFY the appearance of the needle handle;
- MODIFY the recommended requirements of needle handle color scales;
- ADD the recommended requirements for stop-flow clip color scales;
- ADD recommended requirements for protection against needle puncture;
- MODIFY the requirements of the pH and test methods;
- MODIFY the requirements for total amount of evaporation residues;
- ADD the requirements that the non-single set package shall be marked of the quantity and recommended maximum positive and negative pressure.

This standard shall be under the jurisdiction of the National Standardization Technical Committee for Medical Infusion Devices (SAC/TC 106).

Main drafting organizations of this standard: Shandong Provincial Medical Device Product Quality Inspection Center.

A.V. fistula needle sets for single use

1 Scope

This standard specifies the requirements for the A.V. fistula needle sets for single use (hereinafter referred to as puncture devices), to ensure that they are compatible with the blood flow and blood processing systems that they support.

2 Normative references

The following documents are essential to the application of this document. For the dated documents, only the versions with the dates indicated are applicable to this document; for the undated documents, only the latest version (including all the amendments) are applicable to this standard.

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

GB/T 14233.2 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 18457 Stainless steel needle tubing for the manufacture of medical devices

GB 18671-2009 Intravenous needles for single use

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

ISO 11607-1:2006 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems [1)]

[1] The Chinese standard GB/T 19633.1 equivalent to ISO 11607-1:2006 is currently in the approval stage.

GB 18671-2009 gives the evaluation method of needle tip puncture performance.

5.6.3 Lubricants

If the needle is coated with a lubricant and observed with the normal or corrected vision, there shall be no visible accumulation of lubricant on the outside surface of the needle.

Note: The suitable lubricant is undiluted polydimethylsiloxane in accordance with national pharmacopoeia. The amount of lubricant per square centimeter of the surface of the needle shall not exceed 0.25 mg.

5.6.4 Needle handle

5.6.4.1 Appearance

The appearance shall meet the following requirements:

a) The edge of the needle handle shall be complete without burrs;

b) In the appropriate position of the needle handle, it shall have the nominal outer diameter marking of the needle, the marking shall be clear.

Note: There shall be embossed buckles on the needle edge to facilitate the fingers to control the angle of the puncture needle.

5.6.4.2 Color scales

The needle handle color should be used to indicate the outer diameter of the puncture needle. It is recommended to use the color specified in Table 1.

5.6.4.3 Needle handle direction

The needle handle shall be in the same direction as the needle bevel (as shown in Figure 1).

Note: Movable needles that can rotate axially around the needle handle are not subject to this requirement, but additional indications of the direction of the bevel of the needle tip must be provided on the needle handle.

5.7 Flow-stop clip

5.7.1 The flow-stop clip on the puncture device should be a locking pin. The flow-stop clip shall be able to effectively open and close the hose. When closed, it shall be able to block the gas that is 50 kPa above atmospheric pressure for 1 min without leakage.

chromium, copper, lead, and tin in the puncture test solution shall not exceed 1 μg/mL. The content of cadmium shall not exceed 0.1 μg/mL.

6.3.2 When tested in accordance with the method of 5.6.1 of GB/T 14233.1-2008, the color of the puncture device test solution shall not exceed the standard control solution which has a mass concentration $\rho(Pb^{2+})$ = 1 μg/mL.

6.4 pH

When tested in accordance with the method of 5.4.2 of GB/T 14233.1-2008, any standard solution required for graying the indicator shall not exceed 1 mL.

6.5 Evaporation residue

When tested in accordance with them method of 5.5 in GB/T 14233.1-2008, the total amount of evaporation residues shall not exceed 5 mg.

6.6 UV absorbance

When tested in accordance with the method of 5.7 in GB/T 14233.1-2008, the absorbance of the puncture test solution in the range of 250 nm ~ 320 nm shall not exceed 0.1.

6.7 Ethylene oxide residues

When tested in accordance with the methods of clause 9 or clause 10 of GB/T 14233.1-2008, the residual ethylene oxide of each puncture device shall not exceed 0.5 mg.

7 Biological requirements

7.1 Biocompatibility

The puncture device shall be evaluated biologically in accordance with the requirements of GB/T 16886.1.

7.2 Asepsis

The puncture device shall undergo a confirmed sterilization process to make the product sterile.

Note 1: Refer to the reference for suitable sterilization methods.

Note 2: GB/T 14233.2 specifies a sterile test method, but this method should not be used for exit-factory inspection.

expressed in kPa.

Note: The graphic symbols given in YY/T 0466.1 may be used to satisfy the above requirements.

9.2 Middle packaging

The middle packaging shall have at least the following clearly identified information:

a) Product name, needle size and length;

b) Quantity;

c) “Sterile”;

d) Lot number;

e) Year and month of failure;

f) Words or equivalent text of “single-use”;

g) Requirements for handling, storage and transportation (if required);

h) The name and address of the manufacturer and/or distributor.

Note: The graphic symbols given in YY/T 0466.1 can be used to satisfy the above requirements.

9.3 Transport packaging

There must be at least the following clearly identifiable signs on the transport packaging:

a) Product name, needle size and length;

b) Quantity;

c) Words of “sterile”;

d) Lot number;

e) Year and month of failure;

f) Words or equivalent text of “single-use”;

g) Requirements for handling, storage and transportation;

h) The name and address of the manufacturer and/or distributor.

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