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Replacing GB 18671-2002

Intravenous needles for single use

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Issued by: General Administration of Quality Supervision, Inspection and Quarantine;

Standardization Administration Committee.

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Foreword

All technical content of this Standard is mandatory.

This Standard replaces GB 18671-2002 “Intravenous infusion needles for single use.” The main differences between this Standard and GB 18671-2002 are as follows:

- the applicable scope was expanded to infusion needles for: gravity feed-type infusion sets, infusion sets used with pressure infusion equipment, and transfusion sets; the corresponding requirements were added;
- added infusion needle with 0.36 mm needle tube specification and corresponding requirements;
- changed product mark to specification mark;
- made connection base requirements mandatory;
- re-categorized the requirement relating to inner diameter for quick evaluation of needle tube openness to flow; it is now a requirement in informational Annex form for further evaluation of needle tube and needle tip quality; eliminated the qualitative needle tip puncture force test methods;
- changed pH test to titrimetric method;
- eliminated the ethylene oxide residue quantity requirement for infusion needles sterilized with ethylene oxide; added a requirement that packaging make use of dialytic materials;
- revised mark and packaging requirements;
- eliminated the exit-factory inspection.

Annex A and Annex B of this Standard are normative. Annex C and Annex D are informative.

This Standard was proposed by China State Food and Drug Administration.

This Standard shall be under the jurisdiction of China National Technical Committee on Standardization of Medical Infusion Devices.

Drafting organizations of this Standard: Zhejiang Kangdelai Medical Apparatus Stock Co., Ltd., Jinan Quality Supervision and Inspection Centre for Medical Devices of China State Food and Drug Administration.

Introduction

There are two main forms in which intravenous infusion needles are supplied. One is supplied to hospitals together with infusion and transfusion sets.; the other is supplied to hospitals as independent commercial products. The first one accounts for the great majority of such needles in China. The sterility, packaging, and labelling requirements of this Standard do not apply to intravenous infusion needles supplied together with infusion and transfusion sets.

To meet different clinical needs, this Standard does not limit combinations of needle tube outer diameter and length. However, in view of the need to provide identification for product sales and clinical use, this Standard requires labelling of needle tube length, tube wall type, and needle tip type in addition to labelling of needle tube outer diameter.

As a transitional measure, GB 18671-2002 classified the G/T 1962 requirement on inner conical fittings as a suggested requirement. Seeing as many enterprises have gradually adopted semi-rigid 6% inner conical fittings, this version has reclassified the requirement as mandatory.

Intravenous needles for single use

1 Scope

This Standard specifies requirements for single-use intravenous infusion needles (hereinafter referred to as “infusion needles”) of which the nominal outer diameter is 0.36 mm ~ 1.2 mm to ensure adaptability to gravity feed-type infusion sets, infusion sets used with pressure infusion equipment, and transfusion sets.

This Standard provides a guide to the properties and quality norms for the materials used in infusion needles.

Clause 3 to 8.1, and 8.3 of Clause 8 of this Standard give quality norms for infusion needles supplied with infusion and transfusion sets.

2 Normative references

The following standards contain the provisions which, through reference in this Standard, constitute the provisions of this Standard. For dated references, subsequent amendments (excluding corrections) or revisions do not apply to this Standard. However, the parties who enter into agreement based on this Standard are encouraged to investigate whether the latest versions of these documents are applicable. For undated reference documents, the latest versions apply to this Standard.

GB/T 1962.1 *Conical fittings with a 6% (Luer) taper for syringes, needles and other medical equipment - Part 1: General requirements* (GB/T 1962.1-2001, idt ISO 594-1:1986)

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

GB/T 6682 *Water for analytical laboratory use-Specifications and test methods* (GB/T 6682-1992, idt ISO 3696:1987)

GB 8368-2005 *Infusion sets for single use - Gravity feed* (ISO 8536-4:2004 MOD)

GB/T 14233.1 *Infusion, transfusion, and injection equipment for medical use - Part 1: Chemical analysis methods*

7 - needle tube outer diameter specification [c];

[a] The flexible tube length is suggested.

[b] The sheath is unnecessary when supplied assembled with another product.

[c] See GB 18457.

Note 1: The connecting base may have a protective device.

Note 2: Figure 1 shows the typical structure of an infusion needle. Another structure may be adopted so long as the same results are achieved.

Figure 1 Example of typical infusion needle

4 Examples of marking

4.1 Infusion needle specification mark is presented in terms of needle tube nominal diameter, nominal length, tube wall type, and angle (α) of first bevel of needle tip. The outer diameter and length are expressed in “mm”. The tube wall type is represented as RW (regular wall), TW (thin wall), or ETW (extra thin wall). The angle of the first angular plane of the needle tip is represented as LB (long bevel angle) or SB (short bevel angle).

4.2 For an infusion needle that is compliant with This Standard, that has a needle tube nominal outer diameter of 0.7 mm, a nominal length (L) of 30 mm, and a tube wall type of thin wall, and that has a needle tip first bevel angle that is a long bevel angle, the specification mark is:

0.7 X 30 TW LB

Note 1: The needle tube wall thickness and the needle tip first bevel angle can be selected according to need. See also Clause D.1.

Note 2: This Standard recommends use of thin-wall or extra-thin-wall needle tubes.

5 Materials

The needle tubing used to manufacture infusion needles shall comply with the requirements of GB 18457.

Infusion needle components (including lubricants) that come into contact with pharmaceutical liquids shall also comply with the requirements of Clause 7 and Clause 8.

6 Physical requirements

6.1 Color labelling

8.2 Sterility

Infusion needles in primary packaging shall undergo confirmed sterilization processes to make the product sterile.

Note 1: GB/T 14233.2-2005 prescribes a sterility test method, but this method cannot be used to verify the sterilization results of a sterilized lot.

Note 2: See GB 18279 or GB 18280 for suitable validation and routine control of the sterilization process.

8.3 Bacterial endotoxins

When testing according to GB/T 14233.2, draw 5 mL of extracting medium into a syringe and connect it to an infusion needle. After injecting until the inner cavity of the infusion needle is full, seal the head end of the needle. Place together in a 37 °C constant-temperature box, and extract for 1 h. Inject the extracting medium that is remaining in the syringe through the inner cavity of the infusion needle. Collect all of the extract fluid, and test it. The bacterial endotoxin limit shall be less than 0.5 EU/mL.

Note: YY/T 0618 presents a guide for bacterial endotoxin routine monitoring and alternating-lot inspections.

9 Marks

9.1 Primary package

The primary package shall have at least the following information:

a) product name and Clause 4-compliant specification mark;

b) the word (or words) “sterile,” “pyrogen free,” or “bacterial endotoxin free”;

c) lot number, beginning with the word “lot”;

d) expiration date;

e) the words “for single use” or equivalent words;

f) the letter “P” indicating “pressure”; it shall be higher than the surrounding words, if applicable;

g) a warning to examine the integrity of each primary package prior to use;

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

Note: One may use the graphic symbols presented in YY/T 0466 to meet the corresponding

requirements above.

9.2 Intermediate package

The intermediate package shall have at least the following information:

a) product name and Clause 4-compliant specification mark;

b) quantity;

c) the word (or words) “sterile,” “pyrogen free,” or “bacterial endotoxin free”;

d) lot number, beginning with the word “lot”;

e) expiration date;

f) the words “for single use” or equivalent words;

g) the letter “P” indicating “pressure”; it shall be higher than the surrounding words, if applicable;

h) moving, storage, and shipping requirements (when necessary);

i) name and address of manufacturer and/or distributor;

j) recommended storage conditions (if any).

Note: One may use the graphic symbols presented in YY/T 0466 to meet the corresponding requirements above.

9.3 Shipping package

The shipping package shall have at least the following labels:

a) product name and Clause 4-compliant specification mark;

b) quantity;

c) the word (or words) “sterile,” “pyrogen free,” or “bacterial endotoxin free”;

d) lot number, beginning with the word “lot”;

f) expiration date;

g) the words “for single use” or equivalent words;

h) moving, storage, and shipping requirements (when necessary);

i) name and address of manufacturer and/or distributor.

Annex B

(Normative)

Methods of chemically analyzing dissolved matter

B.1 Preparation of test liquid

Take 25 infusion needles. Remove the sheaths, and snip the flexible tube so that it is only 1 cm long. Place them into glass container together with the needle tubes. Add 250 mL of GB/T 6682-compliant secondary water and maintain at a constant temperature of 37°C ±1°C for 2 h. Collect all liquid, and cool to room temperature. This is the test liquid.

Put an equal volume of water in a glass container. Without loading a sample, employ the same method to prepare the control liquid.

B.2 Reducing substance (easily oxidized substance) test

Carry out in accordance with the second method in 5.2.2 in GB/T 14233.1-2008.

B.3 Metal ion tests

B.3.1 Atomic absorption: Carry out in accordance with 5.9.1 in GB/T 14233.1-2008.

B.3.2 Color comparison: Carry out in accordance with the first method in 5.6.1 in GB/T 14233.1-2008.

B.4 pH test

Carry out in accordance with 5.4.2 in GB/T 14233.1-2008.

B.5 Evaporation residue test

Carry out in accordance with 5.5 in GB/T 14233.1-2008.

B.6 Ultraviolet light absorption test

Carry out within the 250 nm ~ 320 nm wavelength range in accordance with 5.7 in GB/T 14233.1-2008.

Annex C

(Informative)

Type inspection

C.1 The type inspection is a full-performance inspection. In which, the biocompatibility evaluation is carried out in accordance with the requirements of GB/T 16886.1.

C.2 During the type inspection, randomly sample-inspection 5 needles for each-item's requirement in Clause 6, Clause 9.1 and Clause 10.

C.3 If they pass all test items, then they pass the type inspection. If it fails to pass the type inspection, then batch production must not be proceeded.

D.3.1 Tester for evaluating puncture force

Figure D.2 is a structural diagram of a typical device used to measure and record puncture force. One may also use another device having the same performance and precision. The instrument shall provide:

a) speed V = 50 ~ 250 mm/min, mean drive precision ≤ set drive speed ±5%;

b) 0 ~ 50 N sensor, mean precision is ±5% of full measurement range;

c) after polymeric membrane is fastened, puncture area diameter is equal to 10 mm.

D.3.2 Polymeric membrane material

A polymeric membrane suitable for a puncture test will be a polyurethane membrane that is elastic, 0.35 mm ±0.05 mm thick, with Shore A hardness of 85 ±10.

D.3.3 Puncture force evaluation test procedure

D.3.3.1 Leave the polymeric membrane at 22°C ±2°C for at least 24 h, and conduct the test at the same temperature.

D.3.3.2 Vertically clamp a part of a continuous length polymeric membrane “c” in clamp “d”; protect the polymeric membrane from tensile force. If the polymeric membrane has a finished face, orient this face towards the needle tip.

D.3.3.3 Load the test needle in the securing device, with its axis perpendicular to the polymeric membrane surface and the needle tip pointing at the center of the round area provided for puncture.

D.3.3.4 Set the travel speed at 100 mm/min.

D.3.3.5 Activate the tester.

D.3.3.6 Record the force-shift curve upon puncture of the polymeric membrane.

D.3.3.7 Measure the corresponding peak values F_0, F_1, F_2, and F_4.

D.3.3.8 Select a previously unused and un-punctured area of the polymeric membrane for each new puncture.

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