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GB/T 18457-2015

Replacing GB/T 18457-2001

Stainless-steel needle tubing for the manufacture of medical devices

制造医疗器械用不锈钢针管

(ISO 9626:1991, MOD)

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Issued by: General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China;

Standardization Administration of the PRC.

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Foreword

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

This standard replaces GB 18457-2001 “Stainless-steel needle tubing for the manufacture of medical devices”.

Compared with GB 18457-2001, the technical change mainly includes:

- ADD the technical requirements for three needle tubing sizes of 0.2 (33G), 0.23 (32G), 0.25 (31G);

- MDOFIY the distance between the fixed support point and the load acting point for the ductile test of the needle tubing having the specifications of 1.4 mm ~ 3.4 mm in Table 3.

This standard, through the redrafting method, adopts ISO 9626:1991 “Stainless-steel needle tubing for the manufacture of medical devices” AND its Amendment 1:2002.

The technical differences between this standard and ISO 9626:1991 & its Amendment 1:2002 AND the causes are as follows:

- On the normative references, adjustment on technical differences is made in this standard to adapt to the technical conditions of China, AND the detailed adjustments are provided in Chapter 2 “Normative references”, as below:

  • USE GB/T 6682 which adopts international standard through modification to replace ISO 3696;

  • ADD reference to GB/T 14233.1.

- ADD the designations of austenitic stainless-steel in Chapter 3 AND in the Appendix A, PROVIDE the equivalent austenitic stainless-steel designations and chemical composition;

- ADD Appendix C (Normative): Needle tubing pH test method;

This standard has made the following editorial changes:

- ADD Appendix A (Informative) Stainless-steel designations;

- DELETE the Appendix A “Needle tubing pH judgment method” of ISO 9626:1991;

Stainless-steel needle tubing for the manufacture of medical devices

1 Scope

This standard specifies the size, surface and mechanical properties of the tube having normal wall and thin wall of nominal specification 0.2 mm ~ 3.4 mm AND the ultra-thin wall of specification 0.6 mm ~ 2.1 mm.

This standard applies to the rigid straight stainless-steel needle tubing used for human body skin, subcutaneous, muscle and vein injection (hereinafter referred to as the needle tubing).

This standard does not apply to easy-to-bend stainless-steel needle tubing, because its mechanical properties are different from the rigid stainless-steel needle tube as specified in this standard; however, it is recommended for the manufacturer and purchaser of the easy-to-bend stainless-steel needle tubing to select the sizes as specified in this standard.

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 6682 Water for analytical laboratory use - Specification and test methods (GB/T 6682-2008, ISO 3696:1987: MOD)

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

ISO/TS 15510:2003 Stainless-steels - Chemical composition

3 Materials

The needle tubing shall be made by such austenitic stainless-steel as X2CrNi18-9, X5CrNi18-9, X6CrNiNb18-10, X5CrNiMo17-12-2, X6CrNiMoTi17-12-2, X6CrNiMoNb17-12-2 which comply with ISO/TS 15510:2003, OR other austenitic stainless-steels equivalent to the aforementioned steels. In Appendix

Appendix B

(Normative)

Test solution preparation method

B.1 Principle

The needle is immersed in water to precipitate a soluble substance.

B.2 Instruments and reagents

B.2.1 Test water is the grade III water newly prepared in accordance with GB/T 6682.

B.2.2 Borosilicate glassware for laboratory use.

B.3 Test solution preparation procedure

B.3.1 WEIGH 3.0 g of needle tubing; CUT it into appropriate lengths; ADD 250 mL of water (B.2.1) into the glassware (B.2.2) of appropriate volume; IMMERSE the needle tubing into it; MAINTAIN the water and the needle tubing at 37 °C ± 3 °C for 1h; TAKE the needle tubing out; ENSURE that all the water at the inner and outer surface of the needle tubing are back to the glassware.

B.3.2 FOLLOW the procedures as described in B.3.1 without placing the needle tubing into the glassware, in order to prepare the blank control solution.

a) MAKE the span equal to the values corresponding to the tested needle tubing specifications in Table 2;

b) MAKE the end surface of the push rod at the center of the span;

c) MAKE the needle tubing be perpendicular to the two needle tubing supports and push rod, and meanwhile MAKE the needle tubing centerline coincide with the needle tubing support centerline.

D.3.2 Based on the force corresponding to the nominal specifications of this needle tubing in Table 2, APPLY downwards the bending force through the push rod to the needle tubing at the rate of 1 mm/min.

D.3.3 MEASURE and RECORD the needle tubing deflection at the force application point D.2.2), accurate to 0.01 mm.

D.4 Test report

The test report contains at least the following information:

a) Specifications and description of the needle tubing;

b) Wall type of needle tubing: normal wall, thin wall, ultra-thin wall;

c) Measured deflection (unit in mm, accurate to 0.01 mm) and judgment results;

d) Test date.

Appendix F

(Normative)

Test method for corrosion resistance of needle tubing

F.1 Principle

SOAK a portion of the needle tubing into the sodium chloride solution for a predetermined period of time; COMPARE the soaked portion and the non-soaked portion; and visually OBSERVE the corrosion trace.

F.2 Instruments and reagents

F.2.1 Sodium chloride solution: Distilled or deionized water in accordance with the level 3 water requirements in GB/T 6682. PREPARE solution of c (NaCl) = 0.5 mol/L (analytical pure reagent).

F.2.2 Borosilicate glassware for laboratory use.

F.3 Test procedure

PLACE a needle tubing into the glassware (F.2.2) containing sodium chloride solution (F.2.1) at 23 °C ± 2 °C, so that half of the length of the needle tubing is immersed in the solution. MAINTAIN the solution and the needle tubing at 23 °C ± 2 °C for 7 h ± 5 min. TAKE the needle tubing out and USE the distilled water or deionized water to rinse and dry it; USE normal vision or corrected visual acuity to observe and compare the socked portion and the non-soaked portion, so as to see whether there is corrosion trace due to immersion.

F.4 Test report

The test report contains at least the following information:

a) Specifications and description of the needle tubing;

b) Wall type of needle tubing: normal wall, thin wall, ultra-thin wall;

c) Corrosion of soaked portion of the needle;

d) Test date.

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