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PHARMACEUTICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

ICS 11.040.20

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YY/T 0806-2010

Polycarbonate material for manufacture of infusion, transfusion and injection equipments for medical use and other medical devices

医用输液、输血、注射及其他医疗器械用聚碳酸酯专用料

Issued on: December 27, 2010 **Implemented on: June 01, 2012**

Issued by: China Food and Drug Administration

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Polycarbonate material for manufacture of infusion, transfusion and injection equipments for medical use and other medical devices

1 Scope

This Standard specifies the requirements for polycarbonate material for manufacture of infusion, transfusion and injection equipments for medical use and other medical devices

This Standard does not apply to polycarbonate copolymers.

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 1033.1-2008, Plastics - Methods for determining the density of non-cellular plastics - Part 1: Immersion method liquid pyknometer method and titration method (ISO 1183-1:2004, IDT)

GB/T 1843-2008, Plastics - Determination of izod impact strength

GB/T 2547-2008, Plastic resins - Sampling

GB/T 3682, Determination of the melt mass-flow rate (MFR) and the melt volume-flow rate (MVR) of thermoplastics

GB/T 9352-2008, Plastic - Compression moulding of test specimens of thermoplastic materials

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

GB/T 16886.1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

GB/T 2918-1998, Plastics - Standard atmospheres for conditioning and testing

Visual inspection.

4.4 Physical properties

4.4.1 Melt volume-flow rate

Take particle samples according to GB/T 3682.

4.4.2 Density

Take particle samples according to method B in GB/T 1033.1-2008.

4.4.3 Izod notched impact strength

Take samples prepared in 5.1 and carry out according to method A in GB/T 1843-2008.

4.4.4 Radiation-resistant materials

For radiation-resistant sterilization polycarbonate materials for medical use, take a 3 mm-thick test piece; after 30 kGy radiation, place it under natural light conditions for 15 days; test the yellow index before and after radiation according to HG/T 3862.

4.5 Chemical properties of dissolved substances

4.5.1 Preparation of test solution

Weigh particle samples and use the class-2 test water as specified in GB/T 6682-2008 to rinse them; add water in a ratio of 1:5 of mass (g) to water (mL); seal with a lid; place them in a pressure steam sterilizer, at 121 °C ± 1 °C of saturated steam, for 30 min; separate the sample from the solution; cool to room temperature. Take the same batch of water to prepare blank control solution by the same method.

4.5.2 Reducing substance

Take the test solution and control solution, which are prepared according to 4.5.1, and carry out according to 5.2.2 of GB/T 14233.1-2008.

4.5.3 pH value

Take the test solution and control solution, which are prepared according to 4.5.1, and carry out according to 5.4.1 of GB/T 14233.1-2008.

4.5.4 Evaporation residue

Take the test solution and control solution, which are prepared according to 4.5.1, and carry out according to 5.5 of GB/T 14233.1-2008.

4.5.5 Metal ion

Take the test solution that is prepared according to 4.5.1, and carry out according to 5.6.1 of GB/T 14233.1-2008 and/or the atomic absorption spectrophotometry (AAS) or equivalent method.

4.5.6 UV absorbance

Take the test solution that is prepared according to 4.5.1, and carry out in the wavelength range of 250 nm ~ 320 nm according to the provisions of 5.7 of GB/T 14233.1-2008.

5 Marking

The marking on the outer packaging bag of the medical polycarbonate material product shall include the following contents:

a) Product name;

b) Manufacturer's name or trademark;

c) Model;

d) Batch number;

e) Net weight.

6 Packaging and storage

6.1 Packaging

Polycarbonate materials for medical use shall be at least double-packed, and the packaging shall ensure that the product will not be contaminated during transportation and storage.

6.2 Storage

Polycarbonate materials for medical use shall be stored in a ventilated, dry and clean warehouse with well-maintained firefighting facilities. Store away from heat sources and avoid direct sunlight.

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Accountable person and shareholder: Wayne Zheng

About Us (Goodwill, Policies, Fair Trading…): https://www.chinesestandard.net/AboutUs.aspx

Contact: Wayne Zheng, Sales@ChineseStandard.net

Linkin: https://www.linkedin.com/in/waynezhengwenrui/

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