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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

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YY 1290-2016

Single-use bilirubin plasma haemoperfusion device

一次性使用胆红素血浆吸附器

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Foreword

All technical content of this Standard is compulsory. This Standard was drafted in accordance with the rules given in GB/T 1.1-2009. Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. The issuer of this document shall not be held responsible for identifying any or all such patent rights. This Standard was proposed by China Food and Drug Administration. This Standard shall be under the jurisdiction of Technical Committee 158 on Medical Extracorporeal Circulation Equipment of Standardization Administration of China (SAC/TC 158). The drafting organizations of this Standard. China Food and Drug Administration Guangdong Medical Devices Quality Surveillance and Test Centre, Jafron Biomedical Co., Ltd., Tianjin Zibo High Technology Co., Ltd., Langfang Aier Hemopurification Equipment Factory, Asahi Kasei Medical (HangZhou) Co., Ltd. The main drafters of this Standard. Wu Jingbiao, He Xiaofan, Wang Peilian, Zhang Guanghai, Li Tao, Guo Jianqin, Tianning. Single use bilirubin plasma hemoperfutor

1 Scope

YY 1290 is the mandatory Chinese standard for single-use bilirubin plasma adsorbers, the cartridges that remove bilirubin from separated plasma in the treatment of liver failure and severe jaundice. It sets the requirements such a device has to meet and the test methods that verify them, covering the adsorption capacity and selectivity, the biocompatibility of the sorbent in contact with plasma, the particle shedding that would send sorbent material into the patient, the pressure drop and mechanical integrity of the housing, and the sterility and packaging. Artificial liver support is used in China for hepatitis-related liver failure at a scale

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seen in few other countries. Being a YY standard without the /T suffix, compliance is compulsory in China.

This Standard specifies the terms and definitions, classification, requirements, test methods, inspection rules, marking and operation instructions, packaging, transportation and storage for single use bilirubin hemoperfutor (hereinafter referred to as hemoperfutor). This Standard applies to single use bilirubin hemoperfutor. The hemoperfutor uses plasma separator and hemopurification system to take the blood of hyperbilirubinemia patients out of their body; the plasma is separated through the plasma separator; and then plasma absorption is conducted to lower the level of bilirubin in plasma.

2 Normative References

The following referenced documents are indispensable for the application of this document. For dated references, only the edition dated applies to this document. For undated references, the latest edition of the referenced documents (including all amendments) applies to This Standard.

GB/T 191, Packaging - Pictorial marking for handling of goods

GB/T 13074, Terms of blood purification

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

GB/T 14233.2-2005, 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

GB/T 16886.4, Biological evaluation of medical devices - Part 4. Selection of tests for interactions with blood

GB/T 16886.5, Biological evaluation of medical devices - Part 5. Test for in vitro cytotoxicity

GB/T 16886.10, Biological evaluation of medical devices - Part 10. Tests for irritation and delayed-type hypersensitivity Carry out test as specified in 6.7. The absorption capacity of hemoperfutor for bilirubin shall be within the range specified by the manufacturer and shall not be lower than 0.8 μmol/mL resin.

5.10 Total protein absorption rate The total protein absorption rate of hemoperfutor's absorbent shall be as specified by the manufacturer. The absorption rate shall be < 15%.

5.11 Temperature resistance Hemoperfutor shall have no deformation or cracking within the range 0°C ~ 50°C.

6 Test methods

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6.1 Appearance Use normal or corrected visual acuity to observe and observe under average illumination of 300 lx ~ 750 lx without amplification. It shall be as specified in 5.1.

6.2 Capacity of blood chamber Use water to fill the blood chamber in laboratory, avoiding air bubble entrainment; place aside for 60 min; use pressurized air (about 50 kPa) to drain the water in the blood chamber; and use a general measuring tool to measure. It shall be as specified in 5.2.

6.3 Particle shedding Carry out test as specified in Annex A to YY 0464-2009. It shall be as specified in 5.3.

6.4 Chemical property

6.4.1 Test solution preparation Take one sterilized hemoperfutor and one glass flask to form a closed cycle system; use 500 mL of normal saline to lavage and soak the hemoperfutor from bottom to top; add up to 250 mL of normal saline in the glass flask after bubble disappears; maintain temperature at 37°C ± 1°C; use a peristaltic pump to act on a section of silicone tube as short as possible to make the circulating solution to circulate for 2 h at the flow rate of 1 L/h; take 50 mL of circulating solution; and use normal saline to dilute to 1 000 mL as standby. Take the same volume of normal saline and use the same method to make blank control solution without loading sample.

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6.4.2 Reducing substance (readily oxidizable substance)

6.5.5.2 Complement activation test Carry out test as specified in GB/T 16886.4. There shall be no significant difference in statistics between the result and the negative control.

6.6 Sterility Carry out sterility test using the test method specified in GB/T 14233.2-2005. The result shall be as specified in 5.6.

6.7 No heat source Carry out heat source test using the test method specified in GB/T 14233.2-2005. The result shall be as specified in 5.7.

6.8 Sealability Use pressurized air (about 50 kPa) to empty hemoperfutor; seal one end of hemoperfutor; apply air pressure 100 kPa at the other end; soak into water at 23°C ± 2°C; and observe for 10 min. There shall be no air bubble generated. A proved equivalent method can also be used to test sealability.

6.9 Absorption property of hemoperfutor for bilirubin Registered diagnostic kits and relevant methods can be used to test absorption property. Carry out test using the method specified in Annex A. The result shall be as specified in 5.9.

6.10 Total protein absorption rate Registered diagnostic kits and relevant methods can be used to test absorption property. Carry out test using the method specified in Annex A. The result shall be as specified in 5.10.

6.11 Temperature resistance Place hemoperfutor in a refrigerator for 30 min at 0°C; then

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place in an incubator for 3 h at 50°C; take out to recover to room temperature before observing; and carry out test as specified in 6.6. It shall be as specified in 5.11.

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