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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 0790-2024

Replacing YY 0790-2010

Hemoperfusion equipment

血液灌流设备

Issued on: September 29, 2024 **Implemented on: October 15, 2027**

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part

1.Structure and drafting rules for standardization documents" Drafting. This document replaces YY 0790-2010 "Hemoperfusion Equipment". Compared with YY 0790-2010, except for structural adjustments and editorial changes, In addition, the main technical changes are as follows:

--- Changed "Scope" (see Chapter 1, Chapter 1 of the.2010 edition);

--- Changed "Terms and Definitions" (see Chapter 3, Chapter 3 of the.2010 edition);

--- Changed "Normal working conditions of equipment" (see 4.1,

4.1 of the.2010 edition);

--- Changed the requirements and test methods for "blood flow error" (see

4.2.1 and 5.2.1,

5.2.1 of the.2010 edition);

--- Changed the requirements and test methods for "Control and protection of heparin pumps" (see

4.2.2 and 5.2.2,

5.2.2 of the.2010 edition) 5.2.2);

--- Changed the requirements and test methods for "temperature control" (see

5.3 of the.2010 edition);

1 Scope

YY 0790 is the mandatory standard for haemoperfusion equipment, the machine that pumps a patient's blood through an adsorbent cartridge to remove toxins, drugs or inflammatory mediators. It specifies the requirements for haemoperfusion equipment and the corresponding test methods. Haemoperfusion runs an extracorporeal circuit like dialysis but without a dialysate, so the safety case rests on blood pump control, pressure monitoring, air detection and the alarms that stop the circuit before air or a clot reaches the patient. The YY prefix without the /T suffix makes compliance compulsory in China. The 2024 edition takes effect on 15 October 2027, a three-year transition. For a manufacturer or an importer of haemoperfusion machines seeking Chinese registration, this is the governing document.

This document specifies the requirements for hemoperfusion equipment and describes the corresponding test methods. This document applies to the hemoperfusion equipment defined in 3.1 (hereinafter referred to as equipment). This document does not apply to.

---Peritoneal dialysis equipment;

---Centrifugal blood component separation equipment;

---Continuous blood purification equipment;

---Plasma exchange equipment;

---Plasma adsorption equipment;

---Hemodialysis equipment.

2 Normative references

The contents of the following documents constitute essential clauses of this document through normative references in this document. For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to This document.

GB 9706.1 Medical electrical equipment Part

3 Terms and definitions

The terms and definitions defined in GB 9706.216 and the following apply to this document.

3.1 It can draw the patient's blood out of the body to achieve blood perfusion, has the safety monitoring function required by this document, and can achieve blood transfusion equipment.

4 Requirements

4.1 Normal working conditions of equipment The normal operation of the equipment should meet the following conditions.

a) Ambient temperature. 10°C~40°C or as specified by the manufacturer;