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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1920-2023

Blood compatibility tests of haemodialysers

透析器血液相容性试验

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Table of Contents

Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part

1.Structure and Drafting Rules of Standardization Documents" Drafting. Please note that some content in this document may be subject to patents. The publisher of this document assumes no responsibility for identifying patents. This document is proposed by the National Medical Products Administration. This document is under the jurisdiction of the National Medical Extracorporeal Circulation Equipment Standardization Technical Committee (SAC/TC158). This document was drafted by: China Institute of Food and Drug Control, Guangdong Medical Device Quality Supervision and Inspection Institute, Henan Pharmaceutical and Medical Device Mechanical Inspection Institute. The main drafters of this document. Xu Jianxia, Yang Wenrun, Yang Lifeng, Liu Kangbo, Mo Xiaoyan, Meng Xing, Luo Jiewei, Tian Liyan.

Dialyzers are suitable for patients with acute and chronic renal failure and are used to carry out routine hemodialysis, hemodiafiltration and other treatments in medical institutions. Treatment, repeated contact with circulating blood over a large area and for a long time, and is widely used in clinical applications. The evaluation of its blood compatibility is of great significance. GB/T 16886.4 gives the guiding principles for hemocompatibility testing. Based on this principle, this document gives specific test results for hemocompatibility of dialyzers. Physical testing methods. GB/T 16886.4 requires comprehensive testing of the hemocompatibility of dialyzers, including. coagulation, platelets, complement system, blood , thrombosis and hemolysis. The hemolysis test can reflect the potential damaging effect of the dialyzer on red blood cells, which is further clarified and optimized in this document. Hemolysis test method for dialyzers. This document includes three parts.

1.Coagulation, platelets, complement system, and hematology tests of dialyzer;

2.In vitro thrombosis test of dialyzer;

1 Scope

YY/T 1920 specifies the blood compatibility testing of haemodialysers. A dialyser exposes a patient's blood to several square metres of artificial membrane, three times a week for years, and the membrane's interaction with blood is what determines complement activation, platelet loss, leucopenia and the inflammatory burden the patient carries. This document sets out which compatibility endpoints are tested and how: the blood contact model, the markers measured, the controls and the interpretation, so that one membrane can be compared with another on evidence rather than on marketing. Dialysers are manufactured in China in very large volume and increasingly exported. For a manufacturer, this is the protocol a Chinese registration expects the haemocompatibility section of the dossier to follow.

This document specifies test methods for hemocompatibility of dialyzers. This document applies to the hemocompatibility of medical devices such as hemodialyzers, hemofilters, and hemoconcentrators that use hollow fiber membranes as the main body. sexual experimentation.

2 Normative reference documents

The contents of the following documents constitute essential provisions of this document through normative references in the text. Among them, the dated quotations For undated referenced documents, only the version corresponding to that date applies to this document; for undated referenced documents, the latest version (including all amendments) applies to this document.

GB/T 16886.1 Biological evaluation of medical devices Part

3 Terms and definitions

The terms and definitions defined in GB/T 16886.1, GB/T 16886.4 and GB/T 16886.12 apply to this document.

4 Coagulation, platelet, complement system, and hematology tests of dialyzer

4.1 Overview The main content of this chapter is the coagulation, platelet, complement system, and hematology test methods of the hollow fiber core component of the dialyzer. dialyzer For the test methods of other components, such as end caps, sealing glue, etc., each component can be taken in proportion and refer to the methods in this document. as needed, also Plasma can be used to test coagulation, and serum can be used to test

complement system activation. The hollow fiber flushing method in the following method is suitable for dialyzers without preservation fluid. For product comparison, select dialyzers without preservation fluid. Inside Dialyzers with a preservation solution can be pre-flushed and tested according to the clinical use method. There is no need to flush again. The product comparison should use a preservation solution that contains the solution. of dialyzer.

4.2 Test principle After the anticoagulated fresh blood is gently and dynamically contacted with the hollow fiber membrane in vitro for a certain period of time, coagulation, platelets, and complement are detected. Systemic and hematological changes.

4.3 Reagents and test control materials

4.3.1 Reagents 0.9% sodium chloride solution, 3.8% sodium citrate solution, snake venom factor, reagents for blood cell analyzer, prothrombin time