

ICS 11.040.30
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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 1272-2016

**Dialysis fluid filter
(English Translation)**

Issued on: March 23, 2016

Implemented on: January 1, 2018

Issued by: State Food and Drug Administration

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Foreword

All technical contents of this standard are mandatory:

This standard is drafted in accordance with the rules given in GB/T 1.1-2009:

Please note that some contents of this document may refer to patents: The issuing agency of this document assumes no responsibility for identifying these patents:

This standard was proposed by China Food and Drug Administration:

This standard is under the jurisdiction of the National Standardization Technical Committee of Medical Extracorporeal Circulation Equipment (SAC/TC158):

This standard was drafted: State Food and Drug Administration Guangzhou Medical Device Quality Supervision and Inspection Center, Jinbao Kidney Care Products (Part 1) Sea) Co., Ltd., Braun Elton (Shanghai) Trading Co., Ltd., Fresenius Medical Supplies (Shanghai) Co., Ltd:

1 Scope

This standard specifies the requirements, test methods, inspection rules, packaging marks and accompanying documents, packaging, transportation and storage of dialysate filters:

This standard applies to the dialysate filter, which is used in conjunction with hemodialysis equipment, and its working principle is to use the hollow fiber membrane as the Used to remove endotoxins, microorganisms and insoluble particles in the dialysate:

2 Normative references

The following documents are indispensable for the application of this document: For dated references, only the dated version applies to this document pieces: For undated references, the latest version (including all amendments) applies to this document:

GB/T 14233.1-2008 Test methods for medical infusion, blood transfusion and injection equipment Part 1: Chemical analysis methods GB/T 14233.2-2005 Test methods for

medical infusion, blood transfusion and injection equipment Part 2: Biological test methods
GB/T 16886.5 Biological evaluation of medical devices - Part 5: Cytotoxicity test in vitro
GB/T 16886.10 Biological evaluation of medical devices - Part 10: Irritation and delayed hypersensitivity
GB/T 16886.11 Biological evaluation of medical devices - Part 11: Systemic toxicity test
YY 0465-2009 Disposable hollow fiber plasma separator
Pharmacopoeia of the People's Republic of China (Part Two):2010 Edition

3 Requirements

3.1

Appearance

The shell of the dialysate filter should have smooth surface, uniform plasticization, no burrs and peaks, and there should be no impurities visible to the naked eye in the liquid channel:

3.2

Chemical properties of the dialysate filter

3.2.1

Reducing substances (easy to oxidize) the difference in the volume of potassium permanganate solution [$c(\text{KMnO}_4)=0.002\text{mol/L}$] consumed by the 20mL test solution and the same batch of blank solution should not exceed 2.0mL:

3.2.2

Metal ions

3.2.2.1

When the atomic absorption spectrophotometer (AAS) or equivalent method is used for determination, the total content of barium, chromium, copper, lead and tin in the test solution shall be not more than 1 $\mu\text{g/mL}$: The content of cadmium should not exceed 0.1 $\mu\text{g/mL}$:

3.2.2.2

Colorimetric analysis method

The color of the test solution should not exceed the mass concentration $\rho(\text{Pb}^{2+})=1\mu\text{g/mL}$ standard control solution:

3.2.3 pH

The pH difference between the test solution and the same batch of blank solution should not exceed 1.5:

3.2.4

Evaporation residue the total amount of evaporation residue in 50mL test solution should not exceed 2mg:

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