ICS 11.040.01
CCS C30

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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1939-2024

Test for bacterial endotoxins of medical devices - Recombinant factor C method

医疗器械细菌内毒素试验方法 重组C因子法

Issued on: July 8, 2024 **Implemented on: July 20, 2025**

Issued by: National Medical Products Administration

Table of Contents

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. Please note that some of the contents of this document may involve patents. The issuing organization of this document does not assume the responsibility for identifying patents. This document is proposed by the State Food and Drug Administration. This document is under the jurisdiction of the National Technical Committee for Biological Evaluation of Medical Devices (SAC/TC248). This document was drafted by: Shandong Medical Device and Drug Packaging Inspection Institute, China Food and Drug Inspection Institute, Liaoning Medical Medical Equipment Inspection and Testing Institute. The main drafters of this document. Sun Lingxiao, Shao Anliang, Yu Yang, Qin Yue, Wang Xiaolei and Wang Shiqi.

Bacterial endotoxin is an important component of the cell wall of Gram-negative bacteria, usually composed of polysaccharide O-type antigen, core oligosaccharide and lipid A. From a clinical perspective, endotoxin-induced sepsis, septic shock, and multiple organ damage are In nature, Gram-negative bacteria are widely distributed in water (rivers and oceans), air, soil, In the human body, high-pressure steam sterilization, irradiation and gas sterilization during the manufacturing process of medical devices can kill bacteria but cannot inactivate endotoxins. Since bacterial endotoxins are widely present in nature, are stable in nature and can penetrate conventional sterilization filters, it is difficult to prevent bacterial endotoxins. Element pollution. At present, the gel method and photometry are the most important test methods for bacterial endotoxin testing of medical devices. The sensitivity, specificity, accuracy and economy of this method are high, but the method requires a large amount of horseshoe crab blood to produce horseshoe crab reagents, and the Oriental horseshoe crab has become a The second-class protected animal, therefore, the continued promotion of the use of gel method and photometric method is not conducive to the protection and development of horseshoe crab resources. A supplementary method

for bacterial endotoxin testing. The promotion and use of this method can protect the ecological environment and slow down the depletion of horseshoe crab resources. There is no G factor bypass interference and it has high specificity. Bacterial endotoxin test method for medical devices Recombinant Factor C Method

1 Scope

YY/T 1939 brings the recombinant factor C endotoxin test into Chinese medical device testing. Bacterial endotoxin testing has for decades relied on lysate from horseshoe crab blood; the recombinant factor C method reproduces the first step of that cascade with an engineered enzyme instead, giving equivalent detection without the animal-derived reagent and without the interference that the rest of the natural cascade can introduce. The standard describes how the method is applied to medical devices, which differ from injectables in that the endotoxin has to be extracted from a surface before it can be measured. For a manufacturer of implants, infusion devices or any product carrying an endotoxin limit for the Chinese market, this is the standard that makes the recombinant method usable in a registration test report.

This document describes a test method for the detection of bacterial endotoxins in medical devices using the recombinant Factor C assay. This document applies to the testing of bacterial endotoxins in medical devices.

2 Normative references

This document has no normative references.

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 C factor A protein in horseshoe crab reagent that is sensitive to bacterial endotoxins and can selectively recognize endotoxins.

3.2 recombinant factor C Factor C (3.1) in horseshoe crab reagent is a recombinant protein expressed in eukaryotic cells through genetic recombination technology.

4 Test Principle

The recombinant factor C method uses the change in the fluorescence signal during the reaction between the recombinant factor C reagent and endotoxin to determine the endotoxin content. Method. Recombinant factor C is activated after binding to bacterial endotoxin, and is converted from an inactive protease to a biologically active protease. The recombinant factor C test The fluorescence values before and after incubation of the reagent and the test sample solution were measured and corrected, and the content of

bacterial endotoxin in the test sample was calculated using the standard curve.

5 Main Equipment

Fluorescence microplate reader or multifunctional microplate reader, electric drying oven, vortex mixer, etc.

6 Reagents and Materials

Bacterial endotoxin national standard or bacterial endotoxin working standard (hereinafter referred to as "endotoxin standard"), recombinant factor C reagent Box, water for bacterial endotoxin test, pipette, tip, microplate. Note

1.The recombinant Factor C kit generally includes recombinant Factor C enzyme solution, fluorescent substrate, buffer and other reagents. Note

2.The heat-resistant instruments used in the test are usually sterilized by dry heat, using an electric drying oven (250°C, at least 30 min) to remove possible exogenous endotoxins; plastic Instruments such as microtiter plates and pipette tips should be marked as pyrogen-free or with an endotoxin content of < 0.005EU/mL.