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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1913-2023

Determination of residual 2,2-bis(4-hydroxyphenyl)propane (bisphenol A) in medical polycarbonate materials

医用聚碳酸酯材料中2,2-二（4-羟基苯基）丙烷（双酚A）残留量测定方法

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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 Standardization Technical Committee for Biological Evaluation of Medical Devices (SAC/TC248). This document was drafted by: Shandong Medical Device and Drug Packaging Inspection Institute, Shandong Zhongbaokang Medical Device Co., Ltd., Liaoning Province Medical Device Inspection and Testing Institute, Lifetech Technology (Shenzhen) Co., Ltd. The main drafters of this document. Guo Lijuan, Qu Ruilian, Yu Yang, He Fa, Li Feifei, Gong Bengang, Wang Shiqi, Ruan Chengxiang, Li Qiuying, Liu Chunyue, Zhang Liying.

This document provides guidance methods for the determination of 2,2-bis(4-hydroxyphenyl)propane (bisphenol A) residues in medical polycarbonate materials. Medical polycarbonate material is a high molecular polymer containing carbonate groups in the molecular chain. According to the structure of the ester group, it is divided into aliphatic, aromatic, and fatty. Aliphatic-aromatic and other types. Aromatic polycarbonate has better mechanical properties than other types of polycarbonate materials and is widely used in medical field. Bisphenol A is one of the synthetic monomers of aromatic polycarbonate materials. Bisphenol A may remain in the polycarbonate production process. Pro When the bed is used, residual bisphenol A in polycarbonate medical devices has the risk of migrating into the patient's body. When bisphenol A is introduced into the human body, it may Causes diseases such as diabetes, cardiovascular and cerebrovascular and reproductive systems, thus affecting the normal functions of the body. Therefore, it is necessary to monitor the double content of medical polycarbonate materials. The residual amount of phenol A is very necessary. 2,2-bis(4-hydroxyphenyl) in medical polycarbonate materials Method for determination of propane (bisphenol A) residue

1 Scope

YY/T 1913 specifies how residual bisphenol A is measured in medical polycarbonate. Polycarbonate is used throughout medical devices for its clarity and toughness, in connectors, housings, oxygenators and dialyser casings, and it is made from bisphenol A: unreacted monomer and hydrolysis products can migrate out into blood or infusate. BPA is an endocrine disruptor and is regulated tightly in food contact materials, so a device in prolonged blood contact attracts the same question. This document fixes the extraction, the analytical method and the calculation, so that a residual figure can be compared and enforced. For a manufacturer of polycarbonate devices or a purchaser of medical-grade resin, this is the method a Chinese specification and a release test refer to.

This document describes a method for the determination of 2,2-bis(4-hydroxyphenyl)propane (bisphenol A) residues in medical polycarbonate materials. This document is applicable to the determination of 2,2-bis(4-hydroxyphenyl)propane (bisphenol A) residue in medical polycarbonate materials.

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 6682 Specifications and test methods for water used in analytical laboratories

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 extreme extractionexhaustiveextraction Perform multi-step leaching until the leached substance is measured gravimetrically (or achieved by other methods) in subsequent leaching steps. The amount is less than 10% of the amount measured in the first extraction. [Source: ISO 10993-18.2020,3.15]

3.2 Leaching that is expected to result in the release of greater or greater amounts of chemical constituents than would be expected under clinical use conditions. NOTE. It is important to ensure that intensive leaching does not result in chemical changes in the material or substance being leached. [Source: ISO 10993-18.2020,3.14]

3.3 simulated extraction Extraction using a method that simulates clinical use. NOTE. The purpose of conducting simulated leaching is to estimate the type and amount of substances expected to be released from the medical device during clinical use. Simulated leaching

aims to generate a Leachables spectrum, which represents the worst-case leachables spectrum, i.e., all leachables are also leachables, and the levels of all individual leachables At least equal to the level of all individual leachables. [Source: ISO 10993-18.2020, 3.35, with modifications]

4 General requirements

4.1 The room temperature in this document, unless otherwise specified, should be 10°C~30°C.

4.2 The test water used in this document should comply with the requirements for secondary water in GB/T 6682.