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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

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Biological evaluation of nanomaterial medical devices - Test for antimicrobial performance

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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 involve patents. The issuing organization of this document assumes no responsibility for identifying patents. This document was proposed by the National Medical Products Administration. This document was prepared by the Subcommittee on Biological Evaluation of Nanomedical Devices of the National Technical Committee for Standardization of Biological Evaluation of Medical Devices. (SAC/TC248/SC1) is under its jurisdiction. This document was drafted by: China National Institutes for Food and Drug Control, Shandong Provincial Institute for Medical Device and Pharmaceutical Packaging Inspection and Testing, and Guangdong Provincial Science and Technology Commission. Institute of Microbiology, Chinese Academy of Sciences (Guangdong Provincial Center for Microbiology Analysis and Testing), Zhongguancun Huizhi Antimicrobial New Materials Industry Technology Innovation Alliance, Anxin Nanobio Biotechnology (Zhuhai) Co., Ltd., Smith & Nephew Medical Products International Trading (Shanghai) Co., Ltd., China Textile Standard (Zhejiang) Testing Co., Ltd., Zhangjia Hongnaier Nanotechnology Co., Ltd. The main drafters of this document are. Duan Xiaojie, Luan Tongqing, Peng Ruqun, Zhang Yingzeng, Fang Liangyan, Xie Xiaobao, Zhou Jiafa, Pan Li, Si Yanzhou, and Ruan Guanqiang. Zhang Feng.

With the rapid development of my country's nanotechnology industry, some nanomaterials are being applied in the research and development and application of medical device products, such as those containing... Nanomaterial dressings, nanomaterial-coated catheters, etc. The small size effect and high specific surface activity of nanomaterials make them easily permeable to bacteria. The cell membrane acts directly on the cell, even intracellular nucleic acids, thereby exerting antibacterial and bacteriostatic effects. For example, nano-silver has broad-spectrum antibacterial properties. Possible mechanisms of

action include. disrupting and penetrating the bacterial cell membrane, altering its structure and permeability; entering the cell interior, and altering cellular structures. Microorganisms are killed through DNA structure manipulation and interference with protein synthesis. In addition, nano-silver may release silver ions, whose charge also... It can influence the interactions of cellular components, alter metabolic pathways, and even genetic material, thereby exerting antibacterial effects. Different nanomaterials exhibit different functions. The mechanisms of antibacterial action may differ, and their antibacterial effects may also vary. Therefore, antibacterial performance is an important indicator of the safety and effectiveness of this type of medical device. One of the main aspects of the evaluation is also the entry threshold for clinical research and market registration. The evaluation of the antibacterial properties of inorganic nanomaterials can refer to GB/T 21510.However, there is currently a lack of evaluation methods for the medical applications of nanomaterials. Standardized methods for evaluating the antibacterial properties of medical devices. Current conventional methods for evaluating antibacterial properties do not take into account the characteristics of nanomaterials and have certain limitations. The limited applicability of nano-silver dressings makes it difficult to effectively evaluate their antibacterial properties. For example, when using the conventional inhibition zone method to test nano-silver dressings, the antibacterial properties of nano-silver are not readily apparent. Due to different adhesion methods, the antibacterial zone of some products is not obvious, making it impossible to objectively evaluate their antibacterial ability. This document establishes a standardized test method suitable for evaluating the antibacterial performance of medical devices using nanomaterials, based on the characteristics of their antibacterial activity. This method provides technical support for the rational testing and evaluation of the antibacterial properties of such products. Biological evaluation of antibacterial properties of nanomedical devices

1 Scope

YY/T 1953 is the antimicrobial test method for devices that use nanomaterials to kill bacteria. It specifies the test methods for the antibacterial properties of medical devices employing nanomaterials, naming three: the agar diffusion method, the absorption method and the oscillation method. Nano-silver and similar coatings are claimed on a growing range of devices, from dressings to catheters to implant surfaces, and the claim only means something if the measurement is defined; the choice among the three methods depends on the device form rather than on the manufacturer's preference. It belongs to the Chinese series on biological evaluation of nanomaterial medical devices. For a manufacturer making an antibacterial claim for a nano-enabled device in China, this is the method behind the claim, and the one a reviewer will expect the test report to name.

This document describes the testing methods for the antibacterial properties of medical devices using nanomaterials, including the agar plate diffusion method, absorption method, and vibration method. Swaying method. This document applies to the evaluation of the

antibacterial properties of medical devices that utilize nanomaterials. Note

1.Currently, this mainly includes medical devices containing nanomaterials that come into contact with wounds on the body surface. Note

2.Currently, this document mainly provides test methods for antibacterial performance. Test methods for bactericidal performance will be considered for inclusion in this document once the technology matures.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included. For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies. This document.

YY/T 1477.1 Standard test models for evaluating the performance of contact wound dressings - Part

1.Evaluation of antimicrobial activity in vitro for wounds Model Pharmacopoeia of the People's Republic of China (2020 Edition) Disinfection Technical Specifications (2002 Edition)

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 nanomaterials Materials whose external dimension, internal or surface structure is in the size range of 1nm to 100nm. [Source: GB/T 30544.4-2019, 2.3, with modifications]

3.2 antimicrobial The process of killing bacteria and fungi or inhibiting their growth, reproduction and activity using chemical or physical methods. [Source: Disinfection Technical Specifications (2002 Edition), 1.3.30, with modifications]

3.3 Colony forming unit (CFU) In live bacteria culture counting, colonies are formed by the growth and reproduction of single bacteria or multiple bacteria aggregated together on a solid culture medium.

Note. It is used to express the number of live bacteria.

3.4 test sample The samples prepared from medical device products using nanomaterials contain a corresponding proportion of nanomaterial components.

3.5 control sample Except for the absence of nanomaterial components, it is consistent with the test sample (3.4).