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# PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

# YY/T 1863-2023

## Biological evaluation of nanomaterial medical devices - Testing and characterization methods for the release of nano-silver particles and silver ions from nano-silver dressings

纳米医疗器械生物学评价 含纳米银敷料中纳米银颗粒和银离子的释放与表征方法

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## 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 contents of this document may refer to patents. The issuing agency of this document assumes no responsibility for identifying patents. This document is proposed by the State Drug Administration. This document is sponsored by the National Medical Device Biological Evaluation Standardization Technical Committee Nano Medical Device Biological Evaluation Sub-Technical Committee (SAC/TC248/SC1) centralized. This document was drafted by: China National Institute for Food and Drug Control, National Center for Nanoscience and Technology. The main drafters of this document. Chen Liang, Liu Lin, Wu Meiyu, Liu Ying, Xu Liming, Xie Liming, Wang Xiaolei, Chen Chunying, Bai Ru.

Nanomaterials have unique characteristics such as small size and high specific surface area, and can be used in medicines, medical devices, pharmaceutical packaging materials, as well as food and cosmetics. product additives and other fields. Dressings containing nano-silver have been clinically applied in recent years. This type of product has antibacterial and bactericidal functions, adjustable Control the microbial environment of dressings and wounds, and create favorable conditions for wound healing. However, the potential toxicity risks that nanomaterials may pose require to be evaluated scientifically. The shedding amount of nano-silver particles in the dressing and the size of the shedding particles are used to evaluate the risk of silver particles being absorbed into the body. Important information. The short-term concentrated release of silver ions, the release rate over time and the sustained release period are also used to evaluate the local toxicity and systemic toxicity of silver ions. Important data on toxicity and antimicrobial efficacy. Therefore, the shedding/release characteristics of silver nanoparticles and silver ions, including shedding/release amount, release kinetics, etc. Mechanics is the basis for

evaluating the safety and effectiveness of nanosilver-containing dressings. However, there is currently a lack of standardized nanosilver particles in dressings containing nanosilver. Experimental method for grain and silver ion release. According to the publications and literature research in the pharmacopoeias of various countries, the release test methods of drug transdermal patches include shaking table method, flow cell method, paddle-disk method and Reciprocating support method. The release of nano-silver particles and silver ions in dressings containing nano-silver can refer to these methods. However, it is necessary to analyze its In order to evaluate the applicability of the release experiment of silver nanoparticles and silver ions in dressings containing nanosilver, it is necessary to establish the relationship between silver nanoparticles and silver ions in the release solution. Characterization and Measurement Methods. This document presents the experimental methods for evaluating the release of nano-silver particles and silver ions from dressings containing nano-silver in release media, including release methods. method, separation method of nano-silver particles and silver ions, measurement method of total silver content, silver ion content and silver particle content in release liquid, and release method Morphological characterization, chemical composition analysis and number concentration measurement method of silver particles in the tap. Biological evaluation of nanomedical devices in dressings containing nanosilver Release and characterization methods of silver nanoparticles and silver ions



## 1 Scope

YY/T 1863 specifies how to measure and characterise what a nano-silver wound dressing actually releases. Silver dressings work because silver leaves the dressing and reaches the wound, and the safety question is the same fact seen from the other side: how much crosses into the patient, and in what form. Particles and ions behave differently in the body and are measured differently, so a single figure for total silver tells you very little. This document fixes the extraction conditions, the separation of particulate from ionic silver, and the analytical characterisation, so that a release claim and a safety assessment rest on comparable numbers. Nano-silver dressings are sold in very large volume in China. For a manufacturer, this is the method a Chinese biological evaluation dossier is expected to use.

This document specifies the experimental method for evaluating the release of nano-silver particles and silver ions from dressings containing nano-silver in the release medium, as well as the release solution. Separation, determination and characterization methods of medium and nano silver particles and silver ions. This document is applicable to the evaluation of the release characteristics of nano-silver particles and silver ions of nano-silver dressings that are in contact with body surface wounds.

## 2 Normative references

The contents of the following documents constitute the essential provisions of this

document through normative references in the text. Among them, dated references For documents, only the version corresponding to the date is applicable to this document; for undated reference documents, the latest version (including all amendments) is applicable to this document.

GB/T 6682 Analytical laboratory water specifications and test methods

GB/T 36083 Guidelines for Characterization of Physicochemical Properties Related to Biological Effects of Nanotechnology Silver Nanomaterials

GB/T 38261-2019 Nanotechnology measurement of silver content in biological samples Inductively coupled plasma mass spectrometry (PTA) method] ISO /T S19590 Nanotechnology Measurement of Inorganic Nanoparticles in Aqueous Media by Single Particle Inductively Coupled Plasma Mass Spectrometry Pharmacopoeia of the People's Republic of China

## 3 Terms and Definitions

GB/T 36083, GB/T 38261-2019 and the following terms and definitions apply to this document.

3.1 Woven or non-woven fabric containing nano-silver particles, used for body surface covering and wound protection combination materials, through the nano-silver particles in the dressing Antibacterial and/or bactericidal properties can be used to control the microbial environment of dressings and/or wounds, and create favorable conditions for wound healing. NOTE. Dressings with predominantly metabolic, pharmacological or immunological effects are not included.

3.2 simulated body fluid simulated body fluid; SBF An inorganic solution similar in composition to human blood plasma without organic components.

## 4 Abbreviations

The following abbreviations apply to this document.