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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

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Tissue engineered medical devices - Collagen

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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 Medical Device Products Subcommittee of the National Technical Committee for Standardization of Surgical Implants and Orthopedic Devices. (SAC/TC110/SC3) is under its jurisdiction. This document was drafted by: China National Institutes for Food and Drug Control, Institute of Process Engineering, Chinese Academy of Sciences, and Sichuan Provincial Institute for Drug Control. (Sichuan Provincial Medical Device Testing Center), Guangzhou Chuang'er Biotechnology Co., Ltd., Hebei Kaolisen Biotechnology Co., Ltd., Wuxi Bei Dibio Biotechnology Co., Ltd., Institute of Genetics and Developmental Biology, Chinese Academy of Sciences, Technical Institute of Physics and Chemistry, Chinese Academy of Sciences, China Medical The Institute of Biomedical Engineering, College of Science and Technology, Sichuan University, College of Light Industry Science and Engineering, and Zhejiang Keruikang Biomedical Technology Co., Ltd. The main drafters of this document are. Chen Liang, Ke Linan, Zhang Guifeng, Liu Xinglan, Li Guoying, Shao Mingfei, Zhao Yannan, Zhang Qiqing, and Ye Chunting. Cheng Yongmei, Liu Guobao, Xu Songcheng, Fu Bufang, Huang Yuanli, Gao Jianping, Xing Fangyu, Wang Xiaoliang, Lan Wanling, Luo Sishi, Li Yiheng, Lu Jinting Chen Liyuan, Dai Jianwu, Guo Yanchuan, Xu Liming.

Collagen is the main protein of the extracellular matrix and a functional protein closely related to the function of cells, tissues, and organs in the body. White collagen possesses good biocompatibility, biodegradability, and low immunogenicity. With increasing research into the structure and function of collagen... As research progresses, collagen is increasingly used in the medical field, including hemostatic sponges, dressings, soft tissue filler injections, and tissue engineering. Matrix for medical devices and cell-based products, as well as carriers for drug delivery. Meanwhile, the physicochemical properties, biological, immunological, or toxicological characteristics of tissue-extracted collagen may vary depending on the source and extraction process. Because the properties of collagen vary with the source material and extraction process, a thorough study of collagen from different sources and processes is needed. The properties of prepared collagen were studied, and different collagens were compared by performing specific characterization. Although collagen has multiple functions and is widely used in the medical field, the practical application of collagen requires material-based approaches. The design and development of biocompatibility and functional indicators (including data from physical, chemical and biological detection and evaluation) for specific intended applications are carried out. Therefore, the regulations require performance indicators related to collagen protein quality and safety, and the establishment of corresponding detection and evaluation methods. This is crucial for collagen research. It is of great significance for production, quality control, testing and evaluation, and technical review. Tissue-engineered medical devices collagen

1 Scope

YY/T 1985 governs collagen as a raw material for tissue engineered medical devices. It sets out the process control requirements for collagen extracted from tissue, the detection indicators it has to meet and the biological evaluation it has to undergo, and it describes the corresponding test methods. Collagen used in devices is a biologically sourced material whose properties depend on how it was extracted as much as on what it was extracted from, which is why the standard reaches back into the process rather than testing only the finished substance. At 26,000 words it is one of the longest documents in the tissue engineering series. For a manufacturer of collagen scaffolds, dermal fillers, haemostats or wound matrices intended for China, this is the material standard the supplier qualification and the incoming inspection specification are written against.

This document specifies the requirements for process control, detection indicators, and biological evaluation of collagen extracted from tissues, and describes the corresponding detection methods. method. This document applies to the characterization and quality evaluation of collagen for tissue-engineered medical devices. Note

1.The detection indicators and requirements listed in this document are mainly based on purified type I collagen and may not be applicable to all collagen types. Note

2.This document provides reference for the characterization and quality evaluation of

collagen for other medical devices. Note

3.Collagen extracted from cultured cells should be characterized in accordance with this document, and quality control should be based on risk analysis.

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.

GB 5009.6 National Food Safety Standard - Determination of Fat in Food

GB/T 6682 Specifications and test methods for water used in analytical laboratories

GB/T 16886.1 Biological evaluation of medical devices - Part

3 Terms and Definitions

The terms and definitions defined in YY/T 1955 and the following terms and definitions apply to this document.

10 Irritation and skin sensitization tests

GB/T 16886.20 Biological evaluation of medical devices - Part

20 Principles and methods for immunotoxicological testing of medical devices

GB/T 44353.1 Animal-derived medical devices - Part