

ICS 11.040.30

CCS C30

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

YY/T 1888-2023

Recombinant humanized collagen protein

重组人源化胶原蛋白

Issued on: January 18, 2023

Implemented on: July 20, 2023

Issued by: National Medical Products Administration

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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. Publishing of this document The Agency assumes no responsibility for identifying patents. This document is proposed by the State Drug Administration. This document is under the jurisdiction of the Medical Device Technology Evaluation Center of the State Food and Drug Administration. This document was drafted by: Fudan University, Sichuan University, Institute of Biophysics, Chinese Academy of Sciences, Second Affiliated Hospital of Chongqing Medical University, Sichuan Medical Device Biomaterials and Products Inspection Center Co., Ltd. (Sichuan Medical Devices Biomaterials and Products Inspection Center), Shaanxi Provincial Food Institute for Drug Control, Shandong Institute for Medical Device and Drug Packaging Inspection, Sichuan Institute for Drug Control (Sichuan Medical Device Testing Center), Shanxi Jinbo Biomedicine Co., Ltd., Jiangsu Chuangjian Medical Technology Co., Ltd., Shanghai Zhongke New Life Biology Co., Ltd. Technology Co., Ltd. The main drafters of this document. Lu Lu, Wang Yunbing, Zhu Yun, Yang Li, Lin Hai, Dong Xiaojing, Liang Jie, Cai Hu, Zhang Min, Liu Xinglan, Wang Jian, Li Haihang, Ruan Hongqiang, Jiang Shibo, Deng Xiang, Wang Changhe, Hou Li, Zhao Daiguo, Yu Yufeng, Fan Xiaoju, Liu Jingtang, Hua Chen. Recombinant Humanized Collagen

1 Scope

YY/T 1888 is the Chinese standard for recombinant humanized collagen, collagen produced by engineered cells rather than extracted from animal tissue. The point of making it recombinantly is to remove what animal-derived collagen carries with it: viral and prion risk, batch variability, and the immunogenicity of a non-human sequence. This document specifies what such a protein has to be, covering the identity and purity of the material, the characterisation that establishes it, the residuals from the expression system and the labelling. Recombinant collagen is a Chinese industrial strength, used in wound dressings,

dermal fillers, tissue scaffolds and cosmetics, and China moved early to standardise it. For a manufacturer or a purchaser of the raw material, this is the specification a Chinese registration and a supply contract refer to.

This document specifies the quality control, technical requirements, test methods, stability, biological evaluation and packaging of recombinant humanized collagen. Packing, transportation and storage etc. This document applies to the quality of recombinant humanized collagen that does not contain the amino acid sequence of non-human collagen as a raw material for medical devices control. NOTE. The samples validated in this document are based on recombinant type III humanized collagen raw material. Other recombinant humanized collagen raw materials, if applicable, can be referred to Exam document.

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 16886.1 Biological evaluation of medical devices Part

3 Terms and Definitions

YY/T 1849-2022 and the following terms and definitions apply to this document.

3.1 The full-length or partial amino acid sequence fragments encoded by human collagen-specific type genes prepared by DNA recombinant technology, or human collagen-containing A combination of functional fragments of collagen.

3.2 Human collagen types humancolagentypes Genetically, it can be divided into more than 20 different species, which differ in amino acid sequence, molecular assembly form or tissue distribution characteristics.

Note. Different types of human collagen are generally named sequentially by Roman numerals, such as humanTypeIcollagen means human typeIcollagen. each type Human collagen is assembled by one or more collagen genes, for example, human type I collagen is composed of human COL1A1 and COL1A2 genes coded assembly.

3.3 human collagen fragment humancolagenfragment It is an amino acid sequence fragment with a certain continuous length that can form a stable structure within the same amino acid sequence of human collagen.

4 Quality Control

Due to the different human collagen types and amino acid sequence fragments selected for recombinant humanized collagen, and the differences in expression systems, the amino acid sequence and physical and chemical properties are quite different. Used as raw materials for medical devices, it is necessary to establish a suitable method for quality control of products between different batches.