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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1947-2025

Recombinant collagen dressing

重组胶原蛋白敷料

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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 of the contents of this document may involve patents. The issuing organization of this document does not assume the responsibility for identifying patents. This document is proposed by the State Food and Drug Administration. This document is under the jurisdiction of the National Medical Protective Equipment Standardization Working Group (SAC/SWG30). This document was drafted by: Shandong Medical Device and Drug Packaging Inspection Institute, Sichuan Drug Inspection Institute (Sichuan Medical Device Medical Device Testing Center), Jiangsu Chuangjian Medical Technology Co., Ltd., Zhejiang Zhuji Juyuan Biotechnology Co., Ltd., Shanxi Jinbo Biopharmaceutical Co., Ltd. Co., Ltd., Shaanxi Juzi Biotechnology Co., Ltd., Shanghai Deepai Biotechnology Co., Ltd., and Huaxi Biotechnology Co., Ltd. The main drafters of this document are. Liu Xueting, Zhang Bo, Liu Bin, Zhao Dengwei, Ma Heng, Wang Shuai, Meng Xiaoyi, Li Chong, Gai Xiaoxiao, Wang Jian, Fan Daidi, Liu Xinglan, Jin Jian, and Fu Jie. Recombinant collagen dressing

1 Scope

YY/T 1947 is the product standard for the recombinant collagen dressing, the wound care product built on engineered collagen rather than animal-derived material. It specifies the requirements, the markings and the packaging for these dressings and describes the corresponding test methods, applying to recombinant collagen dressings used on wounds that are not deeply penetrating. Recombinant collagen has become a substantial Chinese product category, sold both as a medical dressing and adjacent to cosmetics, and the standard is what separates the regulated device from the rest. It sits above YY/T 1954, the peptide fingerprinting method that establishes the material identity. For a manufacturer or an importer of recombinant collagen dressings seeking Chinese registration, this is the standard the specification and the registration testing follow.

YY/T 1849 Recombinant collagen

YY/T 1888 Recombinant humanized collagen Pharmacopoeia of the People's Republic of China (2020 Edition, Part IV)

2 Normative references

The contents of the following documents constitute the essential clauses of this document through normative references in this document. For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to This document.

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 1849 apply to this document.

4 Product Type

Recombinant collagen dressings are usually in the form of gels, liquids, patches, pastes or fibers.

5 Requirements

5.1 Materials The recombinant collagen added to recombinant collagen dressings should comply with the requirements of YY/T 1849 or YY/T 1888.

5.2 Appearance There should be no visible foreign matter on the surface.