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

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Peptide mass fingerprinting analysis of recombinant collagen

重组胶原蛋白肽图指纹图谱分析

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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 China Food and Drug Inspection Institute. This document was drafted by: Sichuan Institute of Drug Control (Sichuan Medical Device Testing Center), China Food and Drug Control Institutes, Shimadzu Enterprise Management (China) Co., Ltd., Institute of Process Engineering, Chinese Academy of Sciences. The main drafters of this document are. Liu Xinglan, Gao Jianping, Ji Feng, Fan Xingliang, Lu Hua, Zhao Dengwei, Xing Fangyu, Huang Yuanli, Zhao Daiguo, Zhang Guifeng, Li Xiaodong and Xu Liming. Peptide fingerprint analysis of recombinant collagen

1 Scope

YY/T 1954 is the identity test for recombinant collagen. It specifies the peptide mass fingerprinting method used to characterise it, covering the peptide map itself, peptide coverage and heterogeneity analysis. Recombinant collagen is not one molecule but a designed sequence expressed in a host organism, so identity, batch consistency and the presence of unintended variants cannot be established by the bulk tests used for animal-derived collagen. Digesting the protein and reading the resulting peptide map is how a manufacturer proves that what came out of the fermenter is what the specification says.

China has moved faster than most jurisdictions in standardising recombinant collagen, and this is the analytical backbone of that framework. For a producer of recombinant collagen for dressings, fillers or scaffolds, this is the method behind the identity and consistency claims.

This document describes the analytical methods for peptide fingerprinting of recombinant collagen, including peptide mapping, peptide coverage, and heterogeneity analysis. This document is applicable to the peptide fingerprint analysis of recombinant collagen.

2 Normative references

The contents of the following documents constitute 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 experiments

YY/T 1849 Recombinant collagen Pharmacopoeia of the People's Republic of China (2020 Edition)

3 Terms and definitions

The terms and definitions defined in YY/T 1849 and the following apply to this document.

3.1 The characteristic spectrum obtained after the protein is cleaved into peptides by appropriate specific enzymes and separated and identified by reliable methods can provide Peptide sequence information of the protein to be tested.

4 Abbreviations

The following abbreviations apply to this document. DTT. Dithiothreitol IAA. Iodoacetamide HCl. Hydrochloric acid

5 Overview

According to 3405 in the Pharmacopoeia of the People's Republic of China (2020 edition), the recombinant collagen sample was enzymatically digested with an appropriate protease (such as pancreatic Protease), separated by high performance liquid chromatography to obtain peptide fingerprints; analyzed by high performance liquid chromatography-high resolution mass spectrometry The primary and secondary spectra of the peptides were obtained, and then matched with the enzymatic peptides of the theoretical amino acid sequence to analyze the coverage of collagen peptides for evaluation. Compliance of recombinant collagen. Peptide fingerprinting can be used to analyze heterogeneity. For

example, N-terminal methionine, signal peptide or leader sequence and other possible

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