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

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Tissue engineering medical device - Collagen - Terminology

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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 institution does not bear responsibility for identifying patents. This document is proposed by the State Food and Drug Administration. This document is organized by the National Technical Committee for Standardization of Surgical Implants and Orthopedic Devices, Technical Committee for Engineering Medical Device Products (SAC/TC110/SC3) is responsible for this matter. This document was drafted by: China Food and Drug Inspection Institute, Institute of Process Engineering, Chinese Academy of Sciences, Sichuan Institute for Drug Control (Sichuan Medical Device Testing Center), Northwest University. The main drafters of this document are: Shao Anliang, Xu Liming, Zhang Guifeng, Liu Xinglan, Fan Daidi, Wang Xiaoliang and Duan Zhiguang. Tissue Engineering Medical Devices Collagen Terminology

1 Scope

YY/T 1955 is the terminology standard for collagen in tissue engineered medical devices. It specifies the terms and definitions for collagen, and applies to collagen used in preparing tissue engineering scaffold materials and the device products made from them, including collagen extracted from tissue. Collagen is sold under a vocabulary that has grown commercially rather than technically, with atelocollagen, telopeptide-free, native, reconstituted and recombinant all in use and not always meaning the same thing to buyer and seller. Fixing the terms is the precondition for the material and product standards that sit above it, YY/T 1985 on collagen as a raw material and YY/T 0954 on type I collagen implants. For a supplier or a manufacturer working with collagen for the Chinese market, this is the document that settles what each term means.

This document defines the terms and definitions of collagen. This document applies to collagen for the preparation of tissue engineering scaffold materials and their medical device products, including tissue extraction or genetic recombination Collagen. This document does not apply to genetically modified collagen without a triple helix structure.

2 Normative references

This document has no normative references.

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 Collagen A family of secretory proteins containing at least 20 genetically distinct types that primarily provide structural support for the body. A unique triple helical structure consisting of three polypeptide chains (called alpha chains) with certain biological functions. [Source: YY/T 1849-2022, 3.1]

3.2 Collagen polymer Without the introduction of exogenous substances (such as cross-linking agents), collagen molecules are self-assembled or polymerized to form a polymer with a high-level structure. Compound.

3.3 The specific amino acid sequence of the triple helical structure of collagen is the basic sequence of the triple helical structure of natural collagen, usually "glycine-Proline-Hydroxyproline-"(Gly-XY).

3.4 Propeptide The amino- and carboxyl-terminal non-trimeric residues of individual collagen polypeptide chains (alpha chains) that direct triple helical folding and procollagen molecule formation Helical structure area. NOTE. Removal of propeptides is required for collagen fibril formation and self-assembly.

3.5 Tropocollagen The collagen molecule consists of three alpha chains with the amino- and carboxyl-terminal propeptides removed (see Figure 1); the carboxyl- and amino-terminal telopeptides remain. whole.

Note. Tropocollagen can self-assemble to form a fibrotic network.