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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1754.4-2024

Preclinical animal study of medical devices - Part 4: Acute trauma model for evaluating the healing promoting performance of dressings

医疗器械临床前动物研究 第4部分：用于评价敷料促愈合的急性创伤模型

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Table of Contents

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. This document is part 4 of YY/T 1754 "Preclinical Animal Studies of Medical Devices". YY/T 1754 has been published in the following parts.

1.General requirements;

2.Inducing diabetic rat skin defect model;

3.Animal abdominal wall incisional hernia model for evaluating the histological response and biomechanical properties of the patch;

4.Acute wound model for evaluating dressings promoting healing. 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 Technical Committee for Biological Evaluation of Medical Devices (SAC/TC248). This document was drafted by: Shandong Medical Device and Drug Packaging Inspection Institute, Shenzhen Drug Inspection Institute (Shenzhen Medical Device Medical Device Testing Center), Jiangsu Kebiao Medical Testing Co., Ltd., and Saikesaisi Biotechnology Co., Ltd. The main drafters of this document are. Liu Chenghu, Lin Zhenhua, Wang Shuhan, Zhang Qi, Xia Yiran, Zang Deyue, Zhou Yangfei, Liu Changfeng and Wei Zhenxi.

YY/T 1754 aims to establish specific test methods for preclinical animal research of medical devices and is intended to consist of four parts.

1.General requirements. The purpose is to provide general requirements for preclinical animal studies of medical devices.

2.Induced diabetic rat skin defect model. The purpose is to provide the construction of the diabetic rat skin defect model. Build method.

3.Animal abdominal wall incisional hernia model for evaluating the histological response and biomechanical properties of the patch. Testing and evaluation methods for the histological response and biomechanical properties of intraperitoneal patches.

4.Acute wound model for evaluating wound healing performance of dressings. Testing and evaluation methods for acute trauma models. Medical Device Preclinical Animal Research Part

1 Scope

YY/T 1754.4 standardises the animal model used to show that a dressing actually promotes healing. It is Part 4 of the Chinese series on preclinical animal studies of medical devices, and it defines the acute trauma model for evaluating the healing-promoting performance of a dressing: how the wound is created, how the study is run and how the outcome is assessed. Wound healing claims are notoriously hard to compare because every laboratory has its own model, and a defined model is what turns a marketing statement into evidence a reviewer can weigh. It applies to the growing category of active dressings, including the collagen and hyaluronate products covered by YY/T 1947 and YY/T 1938. For a manufacturer making a healing claim in China, this is the study design the evidence should follow.

This document describes the preparation of a porcine dorsal full-thickness acute wound model for experimental use. This document is applicable to the testing and evaluation of the healing performance of wound dressings.

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 16886.2 Biological evaluation of medical devices Part

3 Terms and definitions

The terms and definitions defined in GB/T 16886.2 apply to this document.

4 Animal selection

It is advisable to use healthy, non-pregnant, adult miniature pigs with an initial weight of

25kg to 30kg, regardless of gender. The suitability of the experiment should be explained. The experimental animals should be of qualified quality and their skin should be intact. The number of animals should be selected in combination with the purpose of the experiment, design type, evaluation index and The accuracy of the evaluation method and other statistical factors should be considered comprehensively to determine the result. It is generally recommended that the sample size of the test samples and control samples that complete the effective test at the final observation point should be no less than 10 each, so the number of animals There should be no less than 4.

5 Main instruments and equipment

Commonly used surgical instruments, animal anesthesia monitoring equipment, pathological examination equipment, etc.

6 Surgical Procedure

6.1 Selection of control samples It is advisable to select similar domestically marketed products with similar materials, structural design, and working principles as control samples. For products, reasonable reasons and evidence for the selection of control samples should be provided.