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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0606.14-2014

Tissue engineered medical products - Part 14: Standard practice for evaluating the immune response of matrices and scaffolds - ELISA method

组织工程医疗产品 第14部分：评价基质及支架免疫反应的试验方法：ELISA法

Issued on: June 17, 2014 **Implemented on: July 1, 2015**

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Foreword

YY/T 0606 "tissue-engineered medical products" have or plan to release the following sections.

--- Part 2. Terminology;

--- Part 3. General classification;

--- Part 4. skin substitute (object) of the terminology and classification;

--- Part 5. Matrix and stent performance and testing;

--- Part 6. I collagen;

--- Part 7. chitosan;

--- Part 8. sodium alginate;

--- Part 9. sodium hyaluronate;

--- Part 10. In vivo evaluation of the repair or regeneration of articular cartilage implants;

--- Part 12. cells, tissues, organs processing guide;

--- Part 13. automatic cell counting;

--- Part 14. Test methods and evaluation matrix scaffold immune response. ELISA method;

--- Part 15. Test method for evaluating the immune response matrix and bracket. Lymphocyte proliferation assay;

1 Scope

YY/T 0606.14 is Part 14 of the Chinese tissue engineered medical product series, covering the ELISA method for evaluating the immune response a matrix or scaffold provokes. Scaffolds derived from tissue, and even synthetic ones, can trigger a cytokine response that decides whether the implant integrates or is walled off, and measuring the mediators released by cells exposed to the material is how that is assessed quantitatively rather than by histology alone. The immune response of a scaffold is not covered by the general

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cytotoxicity tests, which is why the series treats it separately. For a manufacturer of scaffolds or matrices seeking Chinese registration, this is the method behind the immunological part of the biological evaluation.

YY/T 0606 provisions of this part of the test due to a mammal a humoral immune response evaluation of tissue-engineered medical products matrix or scaffold Test method. ELISA method. This section applies to biological evaluation of medical products for tissue engineering scaffold or matrix. NOTE. This standard may also be used, although the test to detect human specimens or for research purposes, and provides data for clinical track, but not on the human body shape Diagnostic testing conditions. In addition to this part of the selected method, but may adopt other equivalent method. Not all materials and applications are required in accordance with this section for detection and therefore should carefully consider the applicability of the method in this section. in Before the implementation of this part of the recommended test, the test results should be considered GB/T 16886.1 or administration recommended the prompt information.

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2 Normative references

The following documents for the application of this document is essential. For dated references, only the dated version suitable for use herein Member. For undated references, the latest edition (including any amendments) applies to this document.

GB/T 16886.1 Biological evaluation of medical devices - Part 1. Evaluation and testing Tests for local effects after implantation.

GB/T 16886.6 Biological evaluation of medical devices - Part 6

GB/T 16886.10 Biological evaluation of medical devices - Part 10. irritation and delayed-type hypersensitivity test

GB/T 16886.12 Biological evaluation of medical devices - Part 12. Sample preparation and reference materials

YY/T 0606.3 tissue-engineered medical products - Part 3. General Category

YY/T 0606.5 tissue-engineered medical products - Part 5. Matrix and stent performance and testing ISO /T S10993.20 Biological evaluation of medical devices - Part 20. Immune toxicology test principles of medical devices and methods (Bio-logicalevaluationofmedicaldevices-Part 20. Principlesandmethodsforimmunotoxicologytestingof medicaldevices)

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 Matrix substrate Tissue-engineered medical products as the growth of cells or

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biomolecules, support or delivery vehicle of raw materials.

3.2 Bracket scaffold Alternative, repair or regeneration of tissue cells or biologically active factors migration, binding or transporting a support, carrier or matrix release.

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