NATIONAL STANDARD OF THE

PEOPLE'S REPUBLIC OF CHINA

GB/T 16886.5-2017

Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity

Issued on: December 29, 2017 **Implemented on: July 1, 2018**

Issued by: AQSIQ; SAC

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Foreword

GB/T 16886 "Biological evaluation of medical devices" consists of the following parts.

- Part 1.Evaluation and testing within a risk management process;
- Part 2.Animal welfare requirements;
- Part 3.Tests for genotoxicity, carcinogenicity and reproductive toxicity;
- Part 4.Selection of tests for interactions with blood;
- Part 5.Tests for in vitro cytotoxicity;
- Part 6.Tests for local effects after implantation;
- Part 7.Ethylene oxide sterilization residuals;
- Part 9.Framework for identification and quantification of potential

degradation products;

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- Part 11.Tests for systemic toxicity;

- Part 12.Sample preparation and reference materials;

- Part 13.Identification and quantification of degradation products from polymeric medical devices;

- Part 14.Identification and quantification of degradation products from ceramics;

- Part 15.Identification and quantification of degradation products from metals and alloys;

- Part 16.Toxicokinetic study design for degradation products and leachables;

- Part 17.Establishment of allowable limits for leachable substances;

- Part 18.Chemical characterization of materials;

- Part 19.Physicochemical, morphological and topographical characterization of materials;

- Part 20.Principles and methods for immunotoxicology testing of medical devices.

This Part is Part 5 of GB/T 16886.

This Part is drafted in accordance with the rules given in GB/T 1.1-2009.

This Part replaces GB/T 16886.5-2003 "Biological evaluation of medical devices - Part 5.Test for in vitro cytotoxicity". Compared with GB/T 16886.5-2003, the main technical changes are as follows.

- MODIFY the relevant content of "preparation of liquid extracts of material", "test procedures" and "assessment of results", and GIVE the qualitative and quantitative evaluation indicators of cytotoxicity (see 4.2, Clause 8 and Clause 10 of this Part, 4.2, Clause 8 and Clause 10 of 2003 edition);

- ADD the neutral red uptake (NRU) cytotoxicity test (see Annex A);

- ADD the colony formation cytotoxicity test (see Annex B);

- ADD the MTT cytotoxicity test (see Annex C);

- ADD the XTT cytotoxicity test (see Annex D).

This Part uses the translation method to be identical to ISO 10993-5.2009 "Biological evaluation of medical devices - Part 5.Test for in vitro cytotoxicity".

The documents of China that have a consistent correspondence with the international documents referenced in this Part are as follows.

GB/T 16886.1-2011 Biological evaluation of medical devices - Part 1. Evaluation and testing within a risk management process (ISO 10993-1.2009, IDT)

GB/T 16886.12-2017 Biological evaluation of medical devices - Part 12. Sample preparation and reference materials (ISO 10993-12.2012, IDT)

This Part was proposed by China Food and Drug Administration.

This Part shall be under the jurisdiction of National Technical Committee on Biological Evaluation of Medical Devices of Standardization Administration of China (SAC/TC 248).

Drafting organizations of this Part. China Food and Drug Administration Jinan Quality Supervision and Inspection Center for Medical Devices, China Food and Drug Administration Beijing Quality Supervision and Inspection Center for Medical Devices, Jiangsu Institute of Medical Device Testing, Shanghai Biomaterials Research and Testing Center.

Main drafters of this Part. Hou Li, Sun Xiaoxia, Wang Rui, He Xueying, Gao Jingxian, Wang Shasha, Sun Jiao, Huang Xhewei.

The previous versions of the standards replaced by this Part are.

- GB/T 16886.5-1997;

- GB/T 16886.5-2003.

1 Scope

This Part of GB/T 16886 describes test methods to assess the in vitro cytotoxicity of medical devices.

This Part specifies the incubation of cultured cells in contact with a device and/or extracts of a device either directly or through diffusion.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10993-1 Biological evaluation of medical devices - Part 1.Evaluation and testing within a risk management system

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 10993-1 and the following apply.

3.1

culture vessels

Vessels appropriate for cell culture including glass petri dishes, plastic culture flasks or plastic multiwells and microtitre plates.

4.1 General

The test shall be performed on

a) an extract of the test sample; and/or

b) the test sample itself.

5 Cell lines

Established cell lines are preferred and where used shall be obtained from recognised repositories.

Where specific sensitivity is required, primary cell cultures, cell lines and organotypic cultures obtained directly from living tissues shall only be used if reproducibility and accuracy of the response can be demonstrated.