NATIONAL STANDARD OF THE

PEOPLE'S REPUBLIC OF CHINA

GB/T 16886.16-2021

Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables

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Foreword

This Document was drafted as per the rules specified in GB/T 1.1-2020 Directives for Standardization - Part 1: Rules for the Structure and Drafting of Standardizing Documents.

This Document is the Part 16 of GB/T 16886 Biological Evaluation of Medical Devices. GB/T

16886 has issued 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 for Tests for Interactions with Blood;

--- Part 5: Tests for Cytotoxicity: in Vitro Methods;

--- 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;

--- Part 10: Tests for Irritation and Skin Sensitization;

--- 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: Physico-Chemical, Morphological and Topographical Characterization of Materials;

--- Part 20: Principles and Methods for Immunotoxicology Testing of Medical Devices.

This Document replaced GB/T 16886.16-2013 Biological Evaluation of Medical Devices - Part 16: Toxicokinetic Study Design for Degradation Products and Leachables. Compared with GB/T 16886.16-2013, the major technical changes of this Document are as follows besides the editorial modifications:

--- Modify the definition of term "Absorption" (see 3.1 of this Edition; 3.1 of 2013 Edition);

--- Modify "Principles for design of toxicokinetic studies" (see Clause 4 of this Edition; Clause 4 of 2013 Edition);

--- Modify the "Guidance on test methods" (see Clause 5 of this Edition; Clause 5 of 2013 Edition);

--- Add information on toxicokinetic studies of nanomaterials (see A.4 of this Edition);

--- Modify the circumstances that shall be considered in toxicokinetic studies (see A.4 of this Edition; A.4 of 2013 Edition).

This Document used translation method to equivalently adopt ISO 10993-16:2017 Biological

Evaluation of Medical Devices - Part 16: Toxicokinetic Study Design for Degradation Products

and Leachables.

The Chinese document that has a consistent correspondence with the international documents

normatively cited in this document is 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).

Please note some contents of this Document may involve patents. The issuing agency of this

Document shall not assume the responsibility to identify these patents.

This Document was proposed by National Medical Products Administration.

This Document shall be under the jurisdiction of National Technical Committee on Biological

Evaluation on Medical Device of Standardization Administration of China (SAC/TC 248).

Drafting organizations of this Document: Shandong Quality Inspection Center for Medical

Device; and Shandong University.

Chief drafting staffs of this Document: Fan Chunguang, Liu Chenghu, Hou Li, Zhang Na, Liu

Xiangdong, and Dong Xiuli.

The historical editions replaced by this Document are as follows:

--- GB/T 16886.16-2003 was first-time published in 2003; first-time revised in 2013;

Biological Evaluation of Medical Devices - Part 16:

Toxicokinetic Study Design for Degradation Products and

Leachables

1 Scope

This Document provides principles on designing and performing toxicokinetic studies relevant

to medical devices. Annex A describes the considerations for inclusion of toxicokinetic

studies

in the biological evaluation of medical devices.

This Document applies to toxicokinetic studies of medical device degradation products and leachables.

2 Normative References

The provisions in following documents become the essential provisions of this Document through reference in this Document. For the dated documents, only the versions with the dates

indicated are applicable to this Document; for the undated documents, only the latest version

(including all the amendments) is applicable to this Document.

ISO 10993-1 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process

3 Terms and Definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

--- IEC Electropedia: available at http://www.electropedia.org/;

--- ISO Online browsing platform: available at http://www.iso.org/obp.

3.1 Absorption

Process of uptake of substance into or across tissue, blood and/or lymph system.

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