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Biological Evaluation of Medical Devices – Part 10: Tests for Skin Sensitization

(ISO 10993-10:2021, IDT)

医疗器械生物学评价 第 10 部分：皮肤致敏试验

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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 Part 10 of GB/T (Z) 16886 *Biological Evaluation of Medical Devices*. GB/T (Z) 16886 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;

--- Part 10: Tests for 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 Leachable;

--- Part 17: Establishment of Allowable Limits for Leachable Substances;

--- Part 18: Chemical Characterization of Medical Device Materials within a Risk Management Process;

--- Part 19: Physic-Chemical, Morphological and Topographical Characterization of

Biological Evaluation of Medical Devices – Part 10: Tests for Skin Sensitization

1 Scope

This Document specifies the procedure for the assessment of medical devices and their constituent materials with regard to their potential to induce skin sensitization.

This Document includes:

— details of in vivo skin sensitization test procedures;

— key factors for the interpretation of the results.

NOTE: Instructions for the preparation of materials specifically in relation to the above tests are given in Annex A.

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

NOTE: GB/T 16886.1-2022 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, IDT)

ISO 10993-2 Biological evaluation of medical devices – Part 2: Animal Welfare requirements

NOTE: GB/T 16886.2-2011 Biological evaluation of medical devices – Part 2: Animal Welfare requirements (ISO 10993-2:2006, IDT)

ISO 10993-12 Biological evaluation of medical devices – Part 12: Sample preparation and reference materials

NOTE: GB/T 16886.12-2023 Biological evaluation of medical devices – Part 12: Sample

There are two methods for preparing the test solution from the organic solvent extract.

Method 1 is applicable when the amount of residue obtained by solvent extraction of a test sample and the weight of a test sample are relatively high because sufficient amounts of residue have been obtained. In addition, Method 1 is especially recommended to evaluate the risk for the medical devices which are repeatedly used. See Reference [14].

Method 2 is applicable when the amount of residue obtained by solvent extraction of a test sample or the weight of a test sample is relatively low. Examples of the latter are contact lenses and intraocular lenses.

For both Methods 1 and 2, in parallel to the extraction of the test sample, the amount of solvent equal to the total volume used during the extraction of the test sample is subjected to the same concentration procedure as the test extracts. This solvent blank is used as negative control for each phase of testing.

B.2.2.2 Test sample preparation according to Method 1

For Method 1, the extraction is performed by covering the test sample with a 10- to 20-fold volume of the appropriate solvent (as determined in the preliminary extraction test) and agitating (shaking) at room temperature. The solvent is collected in another flask. The solvent is exchanged three times [e.g. after extraction for (4 ± 1) h, (8 ± 1) h or (24 ± 2) h] and repeated to agitate at room temperature within a 24 h to 72 h period depending on the leaching and stability of the substances extracted from the test material.

A residue is obtained by evaporating the collected solvent. A rotary evaporator is used at the lowest possible temperature that provides controlled evaporation under reduced pressure.

The residue is dissolved in an appropriate vehicle (olive oil/acetone/ethanol/DMSO) as determined by the solubility experiment in the preliminary extraction test, to prepare a mass fraction of mass fraction of 10 % test solution for the intradermal induction phase and a mass fraction of 20 % test solution for the intradermal induction phase and for the topical induction phase in the GPMT.

For the challenge phase in the GPMT, a mass fraction of 10 % solution is prepared in the vehicle. The 10 % solution is further diluted with the vehicle to obtain 1 %, 0.1 %, 0.01 % and 0.001 % test solutions.

B.2.2.3 Test sample preparation according to Method 2

For Method 2, the extraction is performed by covering the test sample with a 10- to 20-fold volume of the appropriate solvent (as determined in the preliminary extraction test) and shaking at room temperature for (24 ± 2) h. The solvent is collected in one flask. The extraction procedure is repeated three times within a 24 h to 72 h period using the same volume of fresh solvent each time. The extracts are pooled in one flask and the solvent is evaporated.

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