International Standard

ISO 11986

Ophthalmic optics — Contact lenses and contact lens care products — Determination of preservative uptake and release

Optique ophtalmique — Lentilles de contact et produits d'entretien pour lentilles de contact — Détermination de l'absorption et de la libération des conservateurs

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 170, *Ophthalmic optics*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 11986:2017), which has been technically revised.

The main changes are as follows:

— Editorial update of the whole document.

— An additional sentence in the Scope clarifies the circumstances when the test method is to be applied. In particular this test method is only considered for use during the development phase of new or modified contact lens materials or new contact lens care products.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

Contact lens care products are a complex mixture of organic and inorganic substances. For reasons of microbiological safety, contact lens disinfecting solutions, as well as care products in multi-use containers, contain substances with antimicrobial activity. From many years of experience in contact lens wear, it is known that irritation and sensitization problems sometimes occur due to these preservatives being absorbed and released by the matrix of the contact lens. For these reasons, it is necessary to be able to estimate the extent of preservative uptake and release by contact lenses.

The preservative uptake and release test provides a general method for measuring the uptake of preservatives in solution by contact lenses and the release of preservatives from contact lenses in an aqueous medium. The analytical method to be used for quantification of specific preservatives is not indicated here. Chemical characteristics of the preservative, as well as concentration in the contact lens care product and degree of uptake by the contact lens, can be taken into consideration in selecting an appropriate analytical method. Contact lens uptake and release data can be useful in characterizing the potential for a new or modified contact lens material to produce a toxic or irritating reaction in the eye from the uptake and binding or release of preservatives from currently marketed contact lens care products.

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Ophthalmic optics — Contact lenses and contact lens care products — Determination of preservative uptake and release

1 Scope

This document provides general procedures for the selection of methods, preparation of samples, and the conduct of testing for the uptake and release of preservatives from contact lenses.

Preservative uptake and release testing is not intended as a routine test of production contact lenses or contact lens care products nor are testing results meant to establish finished goods specifications in any way.

Such testing is carried out when developing new contact lens materials and/or contact lens care products.

NOTE 1 Due to the manifest difficulties of reproducibility when coating contact lenses with mineral and organic deposits encountered during lens wear, these methods are only applicable to new and unused contact lenses.

NOTE 2 Preservative depletion by a contact lens in the limited volume of a lens case could compromise disinfection performance. This document does not measure disinfection performance.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 18369-3:2017, *Ophthalmic optics — Contact lenses — Part 3: Measurement methods*

3 Terms and definitions

No terms and definitions are listed in this document.

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

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

4 Principle

The contact lenses to be tested are immersed in the test product at 25 °C ± 2 °C and the preservative content is analysed at regular intervals of time until a steady-state condition has been achieved.

After reaching the steady-state condition, each contact lens is immersed in 1 ml of saline solution for contact lens testing, the saline solution shall be prepared in accordance with ISO 18369-3:2017, 4.9, at 37 °C ± 2 °C. At discrete intervals up to and including 16 h, and at intervals until no additional release is observed, if required, the solution is analysed for the amount of preservative that has been extracted at each time point.

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