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

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NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 11986:2010 sisaldab Euroopa standardi EN ISO 11986:2010 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 11986:2010 consists of the English text of the European standard EN ISO 11986:2010.
Standard on kinnitatud Eesti Standardikeskuse 30.11.2010 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 30.11.2010 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
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English Version

Ophthalmic optics - Contact lenses and contact lens care products - Determination of preservative uptake and release (ISO 11986:2010)

Optique ophtalmique - Lentilles de contact et produits d'entretien pour lentilles de contact - Détermination de l'absorption/adsorption et du relargage des conservateurs (ISO 11986:2010)

Augenoptik - Kontaktlinsen und Kontaktlinsenpflegemittel - Bestimmung der Aufnahme und Wiederfreisetzung von Konservierungsmitteln (ISO 11986:2010)

This European Standard was approved by CEN on 31 October 2010.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

Foreword

This document (EN ISO 11986:2010) has been prepared by Technical Committee ISO/TC 172 “Optics and photonics” in collaboration with Technical Committee CEN/TC 170 “Ophthalmic optics” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2011, and conflicting national standards shall be withdrawn at the latest by May 2011.

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Endorsement notice

The text of ISO 11986:2010 has been approved by CEN as a EN ISO 11986:2010 without any modification.

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, must be taken into consideration in selecting an appropriate analytical method. Contact lens uptake and release data may 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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1 Scope

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

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 International Standard does not measure disinfection performance.

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 18369-3:2006, *Ophthalmic optics — Contact lenses — Part 3: Measurement methods*

3 Principle

The contact lenses to be tested are immersed in the test product at 25 °C ± 2 °C and the preservative content 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 prepared in accordance with ISO 18369-3:2006, 4.7, 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.

4 Procedure

4.1 General

The following information shall be obtained before commencing the estimation:

a) evidence that the selected test method is suitable for the detection and estimation of the particular preservative;

   NOTE 1 Examples of methods suitable for analysing some preservatives are presented in US FDA guidelines (see Reference [2]).

b) evidence that the test method has the required repeatability and reproducibility, and a detection limit suitable for the assay;