INTERNATIONAL STANDARD

ISO 11986

Third edition
2017-11

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/adsorption et du relargage des conservateurs

Reference number
ISO 11986:2017(E)

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This third edition cancels and replaces the second edition (ISO 11986:2010), which has been technically revised.

The main changes compared to the previous edition are as follows:

— the cross references were aligned with the revised editions of ISO 18369-1 and ISO 18369-3;

— the expression of results in the test report has been clarified;

— editorial corrections have been applied.

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.

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.

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 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

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 is 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.

5 Procedure

5.1 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;

c) the number of determinations required to satisfy b);

NOTE 2 Multiple determinations might be necessary when the analysis result is close to the limit of detection and/or when the analysis method has a low precision.

d) the criteria needed to confirm that equilibrium has been achieved in the extraction process;

e) the volume of test solution used will need to ensure that the quantity of absorbed preservative does not reduce the concentration of the preservative in the test solution to less than 25 % of the initial preservative concentration in the test solution;

f) a sufficient number of contact lenses of each material type shall be used to ensure that the quantity of absorbed and released preservative is higher than the detection limit of the method of analysis, and also ensure that enough lenses are available for preservative release measurement at each time point.

5.2 Uptake of preservatives from test product

5.2.1 Select the appropriate contact lens care product and/or the appropriate contact lens material for testing.

5.2.1.1 To determine the preservative uptake of a new or modified contact lens material, select the appropriate contact lens care product based on the intended use of the contact lens care product (e.g. recommended for use with hydrogel contact lenses or rigid gas-permeable contact lenses).

5.2.1.2 To determine the uptake of a new or modified preservative in the contact lens care product, select the appropriate contact lens materials for testing from currently marketed contact lenses based on the intended use of the contact lens care product (e.g. recommended for use with hydrogel contact lenses or rigid gas-permeable contact lenses).

The selection of test lenses and lens care products should be justified. For hydrogel lenses, representatives from low water and medium/high water ionic and non-ionic lens groups (Groups 1 to 4) and from silicone hydrogel lenses (Group 5) should be included. For rigid lenses, representative lenses from silicone, fluorine and silicon-fluorine lens groups should be included. See ISO 18369-1:2017, Table 2 and Table 3 for the classification and group descriptions.

5.2.2 Determine the initial preservative level in the test solution.

5.2.3 Record the volume of soak solution and immerse the test lenses in the test solution in a suitable closed container (see the following paragraph) at 25 °C ± 2 °C, and shake occasionally (to ensure adequate mixing of the solution surrounding the contact lens during the study). Take aliquot portions of the test solution at different time intervals and analyse each for its preservative content. During day 1, take aliquot portions at the proposed regimen time, at 8 h and at 24 h. Continue the procedure at intervals of not less than 24 h until the aliquot portions show that no more preservative has been absorbed, or the maximum recommended storage time for the lenses in the contact lens care product has been reached. Additional time points during the first day can be included to determine the uptake profile.

It is preferable to use containers that have been demonstrated to absorb insignificant amounts of the preservative. However, if the container does absorb the preservative, this should be allowed for when

carrying out the test procedure. In this case, for example, an appropriate control solution should also be monitored to determine the amount of preservative absorbed by the container.

NOTE 1 Alternatively, the amount of preservative taken up by the contact lens can be determined directly by methods that provide reproducible quantitative extraction from the contact lens, using a suitable solvent and measuring the amount of preservative found in the extraction solvent.

If the aliquot portions taken are large enough to significantly alter the ratio between the volume of the test solution and the mass of the test lenses, additional test lenses and containers should be used for each sampling interval.

NOTE 2 If the percentage of the preservative absorbed by the test lenses exceeds 75 % of the available preservative, it might be necessary to repeat the test with an increased ratio of the test solution volume to number/mass of test lenses.

5.3 Release of preservatives from test lenses

After reaching a steady-state condition (see 5.2.3), remove the test lenses from the test solution and remove any excess solution by gently touching each test lens with an absorbent tissue without using excessive force or contact time.

Immerse the test lenses in saline solution, prepared in accordance with ISO 18369-3:2017, 4.9, at a ratio of one lens per millilitre of saline solution, in a closed container. Leave the test lenses immersed at 37 °C ± 2 °C and shake occasionally.

Take aliquot portions of the saline solution at different times and analyse each for its preservative content. Measure aliquot portions of the saline solution at 1 h, 2 h, 4 h and 16 h and until no additional release (steady-state) is observed.

NOTE If the aliquot portions taken are large enough to significantly alter the ratio between the test solution and the mass of the test lenses, use additional test lenses and containers for each sampling interval.

If 1 ml of saline solution (see ISO 18369-3:2017, 4.9) is not sufficient to immerse the test lens, then an additional minimal known quantity of saline solution may be added to ensure that the lens is fully immersed, and the volume is recorded. The total volume of saline solution shall be used to calculate the concentration of preservative in the extracting saline solution.

6 Expression of results

6.1 The quantity of preservative absorbed by the contact lenses at each measured time point shall be determined by either

a) calculating the difference between the preservative content in the test solution before the contact lenses were immersed, and the concentration in the test solution after each time point or after reaching the equilibrium of the preservative uptake, or

b) a direct measurement method of the quantitative amount of preservative taken up by the contact lens.

6.2 If no preservative uptake is detected by direct measurement, the results shall be expressed as a preservative uptake that is less than the limit of detection of the test method. If no preservative uptake is detected by the difference method, the results shall be expressed as less than the limit of detection of the test method.

6.3 The preservative uptake is calculated using each measured time point and plotted as the uptake of preservative versus time.