INTERNATIONAL STANDARD

ISO 18259

First edition
2014-10-01

Ophthalmic optics — Contact lens care products — Method to assess contact lens care products with contact lenses in a lens case, challenged with bacterial and fungal organisms

Optique ophtalmique — Produits d'entretien de lentilles de contact — Méthode d'évaluation des produits d'entretien des lentilles de contact avec les lentilles de contact dans leur étui, en présence de contamination par des bactéries et champignons

Reference number
ISO 18259:2014(E)

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Published in Switzerland

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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).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

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Ophthalmic optics — Contact lens care products — Method to assess contact lens care products with contact lenses in a lens case, challenged with bacterial and fungal organisms

1 Scope

This International Standard specifies an antimicrobial efficacy end point methodology to determine compatibility of contact lens solutions, lens cases and hydrogel lenses for disinfection. This provides a process for evaluating compatibility of solutions used for disinfection with contact lenses and lens cases using an antimicrobial efficacy end point. Specifically, the microbiological effect of the antimicrobial agent(s) while in the presence of the lens cases and/or lenses will be evaluated as described in the soak step of the label instructions.

For practical purposes, this does not apply to oxidative systems.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14729, *Ophthalmic optics — Contact lens care products — Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses*

ISO 18369-1, *Ophthalmic optics — Contact lenses — Part 1: Vocabulary, classification system and recommendations for labelling specifications*

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 18369-1 apply.

4 Principle

The antimicrobial efficacy of the test solution in combination with a lens and a lens case will be evaluated at various times following inoculation with organisms in the presence of organic soil. New lenses and new lens cases shall be used unless otherwise justified. This test will simulate microbial contamination introduced by patient handling.

Place a lens in a well of a lens case and inoculate each lens with $1{,}0 \times 10^5$ to $1{,}0 \times 10^6$ cfu; leave inoculum in contact with the lens for 3 min to 10 min and dispense the appropriate volume (minimum of 2 ml) of the test solution into each well. The inoculated lenses in solutions will be allowed to soak for various storage times (the labelled regimen soaking period, at 24 h, at 7 days and at the maximum labelled storage in the lens case) in order to evaluate the effects of the lens case and the lens on the antimicrobial activity of the test solution. A separate set of lens case wells shall be prepared for each time point; three wells shall be evaluated for each unique test condition. Additional time points can be evaluated.

A variety of lenses shall be evaluated, e.g. Group I, Group IV, and Group V. The lens case(s) recommended for use with the test solution shall be evaluated at a minimum.

All five challenge organisms specified in ISO 14729 shall be used.

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