INTERNATIONAL STANDARD

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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

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

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Contents

Page

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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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 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*.

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.

Log reductions will be evaluated for all exposure times.

The data generated from this method should be assessed in conjunction with preservative uptake and release data (ISO 11986).

5 Rationale

These studies are designed to simulate the recommended soaking and storage periods wherein the contaminating microorganisms are introduced by patient handling.

6 Methodology

6.1 General

Use ISO 14729 for media, challenge organisms, culture maintenance, test equipment, and other details for conducting the Stand Alone Test with the exception of using lens cases for the microbial challenge.

6.2 Test procedure

6.2.1 Conduct the test using lens types representative of those with which the solution is intended to be used, e.g. low-water non-ionic lens (Group I), high-water ionic lens (Group IV), and representative silicone hydrogel lens (Group V). Use −3,00 D lenses. New and unused lenses shall be used unless otherwise justified.

The lens cases recommended for use with the test solution shall be evaluated at a minimum. The lens cases used in this test shall be new and unused with no preconditioning unless otherwise justified. Prepare three lens case wells per lens type per time point to be examined for the test samples; additionally, prepare control lens cases for each evaluation time point without lenses. Therefore, for the evaluation of one lens case with one solution and one lens type, a total of 6 lens case wells (three wells for the test and three wells for the control) will be prepared for each of the five challenge organisms for each time point or 24 lens case wells for a minimum of four time points per challenge organism are to be evaluated. Additional time points can be evaluated.

If more than one lens type is evaluated in a test, only one set of control lens cases is required per inoculum preparation.

The inoculum shall be prepared using organic soil as specified in Annex A.

6.2.2 Aseptically remove a new, unused lens from its sterile packaging. Aseptically blot the lens on sterile gauze. Each lens will be soaked for 24 h ± 1 h in ≥10 ml ISO saline/lens directly out of the blister pack prior to use in the assay. See ISO 18369-3 for ISO saline formulation.

6.2.3 Prepare the lens cases (test and control) by removing the caps. Aseptically remove a lens soaked in ISO saline and aseptically blot the lens on sterile gauze and place one lens inside each test well with the concave side up. Prepare three lens case wells without lenses for use as controls.

Care should be taken to keep the shape of the lens concave.

6.2.4 Inoculate each test and control well with 0,10 ml of the inoculum suspension prepared with organic soil to result in a final count of between $1,0 \times 10^5$ and $1,0 \times 10^6$ cfu per well. Gently dispense the inoculum directly onto the concave surface of the lens for the test wells and into the well for each control well then cover the wells.

6.2.5 Leave the inoculum in contact with the test lens for 3 min to 10 min and then aseptically dispense a known volume of the test solution gently into each test and control lens case well so that each lens