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# Ophthalmic optics — Contact lens care products — Antimicrobial preservative efficacy testing and guidance on determining discard date

*Optique ophtalmique — Produits d'entretien des lentilles de contact — Essais de l'efficacité de conservation antimicrobienne et lignes directrices pour la détermination de la durée d'utilisation après première ouverture*



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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).

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 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* in collaboration with the Technical Committee CEN/TC 170, *Ophthalmic optics*.

This second edition cancels and replaces the first edition (ISO 14730:2000), of which it constitutes a minor revision.



 

# Introduction

Contact lens care products (CLCP) are used with contact lenses. These products rinse, clean, disinfect, store, wet, aid the comfort of, and condition contact lenses. Some products have one function, while others are multifunctional.

Usually, products manufactured for use with hydrogel lenses may be used with rigid gas-permeable (RGP) or poly (methyl methacrylate) (PMMA) lenses, but products specifically used for RGP or PMMA contact lenses are not usually suitable for hydrogel lenses.

Most CLCPs are manufactured as solutions and are commonly packaged and sold in multidose containers. Dry products are sold as tablets or granules and shall be dissolved in a suitable solvent immediately prior to use.

If the contact lens care product solution does not have any antimicrobial activity itself, an antimicrobial preservative can be added to the product to inhibit the growth of microorganisms that might be introduced from repeated dispensing during use and subsequent storage. All antimicrobial agents have the potential for toxicity to the user. For maximum protection to the user, the concentration of the preservative should be such that it provides adequate preservative activity with minimum toxicity.

There are differences between ophthalmic preparations and contact lens care products and some of these differences are significant in relation to preservative efficacy testing. Typically, ophthalmic preparations are packaged in small-volume containers and are used for short periods on compromised eyes. Contact lens care products are distributed in larger volume containers and are used with contact lenses on a long term basis on healthy eyes. The potential risks for contact lens care products are the solution/lens interaction causing ocular irritation and the risks of the solution contamination by the repeated (daily) use of the product.

Thus, when contact lens care products are formulated, the risk of adverse patient reaction due to the lens and/or solution interaction has to be weighed against the benefits of safety derived from the maintenance of the antimicrobial activity of the solution.

This International Standard gives the test procedure and performance criteria for preservative efficacy. It has been adapted from Pharmacopoeias which give a time limitation in their test procedure of 28 d. The informative annexes give four examples of preservative efficacy test procedures developed by contact lens care product manufacturers to show preservative efficacy for products whose discard dates are over 28 d.

# Ophthalmic optics — Contact lens care products — Antimicrobial preservative efficacy testing and guidance on determining discard date



## 1 Scope

This International Standard specifies a procedure to be used in evaluating the antimicrobial preservative activity of all preserved multidose contact lens care products, and provides guidance on methods for determination of discard date as informative annexes.

This test is applicable to products for up to a 28-day discard date.

The test is not applicable to sterile products packaged in unit doses for single use or multidose containers designed with physical barriers to microbial contamination (e.g. aerosol containers).

NOTE 1 Principles of the test can be used to extend discard dating beyond 28 d. See Annexes B, C, D and E.

NOTE 2 Use of multiple or mixed microbial challenges and/or inclusion of contact lenses or other organic load can influence the apparent antimicrobial activity of a particular product. The evaluation of these variables together with testing against a larger panel of microorganisms and testing of samples from partially used containers can be of value in developing a contact lens care product, but are excluded from the scope of this International Standard.

## 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 14534, *Ophthalmic optics — Contact lenses and contact lens care products — Fundamental requirements*

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

## 3 Terms and definitions

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

## 4 Principle

**4.1** The test consists of challenging the preparation with a specified inoculum of suitable microorganisms at the commencement of the test and then rechallenging at day 14. The inoculated preparations are stored at a specified temperature. Samples are withdrawn from the inoculated preparations at specified time intervals and are cultured for determination of viable organisms. The capability of the product to prevent re-growth is confirmed by counting of viable organisms over longer time periods.

**4.2** The size of the microbial challenge chosen in this test is not intended to be representative of the likely challenge in practice, but to provide countable numbers from which estimation of the rate and extent of viability loss can be determined.