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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 14730 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

Annexes A to F of this International Standard are for information only.

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## 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, whilst 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 must 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 may be added to the product to inhibit the growth of microorganisms that may 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 for use 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 days. 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 days.

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# 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 to be used 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 may be used to extend discard dating beyond 28 days. 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 may 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 normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 8320-2:—<sup>1)</sup>, *Contact lenses and contact lens care products — Vocabulary — Part 2: Contact lens care products*.

ISO 14534:1997, *Ophthalmic optics — Contact lenses and contact lens care products — Fundamental requirements*.

## 3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 8320-2 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

<sup>1)</sup> To be published.