SLOVENSKI STANDARD
SIST EN ISO 14730:2001

01-november-2001

Oļ esna optika - Kontaktne leļ e in izdelki za vzdrģevanje kontaktnih leļ - Preskuģanje uļ inkovitosti antimikrobnih sredstev za konzerviranje in napotek za doloļ anje datuma za zavrģenje(ISO 14730:2000)

Ophthalmic optics - Contact lens care products - Antimicrobial preservative efficacy testing and guidance on determining discard date (ISO 14730:2000)

Augenpolitik - Kontaktlinsenpflegemittel - Konservierungsmittlebelastungstest und Anleitung zur Feststellung der Aufbrauchfrist (ISO/FDIS 14730:2000)

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 apres premiere ouverture (ISO/FDIS 14730:2000)

Ta slovenski standard je istoveten z: EN ISO 14730:2000

ICS:

11.040.70	Oftalmološka oprema	Ophthalmic equipment

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EUROPEAN STANDARD

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EUROPÄISCHE NORM

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English version

Ophthalmic optics - Contact lens care products - Antimicrobial preservative efficacy testing and guidance on determining discard date (ISO 14730:2000)

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 (ISO 14730:2000)

Augenoptik - Kontaktlinsenpflegemittel - Konservierungsmittelbelastungstest und Anleitung zur Feststellung der Aufbrauchfrist (ISO 14730:2000)

This European Standard was approved by CEN on 15 September 2000.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

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The text of the International Standard ISO 14730:2000 has been prepared by Technical Committee ISO/TC 172 "Optics and optical instruments" in collaboration with Technical Committee CEN/TC 170 "Ophthalmic optics", the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2001, and conflicting national standards shall be withdrawn at the latest by March 2001.

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

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 14730:2000 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to International Standards are listed in annex ZA (normative).

Annex ZA (normative)
Normative references to international publications with their relevant European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE Where an International Publication has been modified by common modifications, indicated by (mod.), the relevant EN/HD applies.

Publication	Year	Title	EN	Year
ISO 14534	1997	Ophthalmic optics - Contact lenses and contact lens care products - Fundamental requirements	EN ISO 14534	1997

INTERNATIONAL STANDARD

ISO 14730

First edition
2000-09-15

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

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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.

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.