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Ögonoptik – Skötselprodukter för kontaktlinser – Provning av antimikrobiell effekt och vägledning för fastställande av utgångsdatum (ISO 14730:2014)

Ophthalmic optics – Contact lens care products – Antimicrobial preservative efficacy testing and guidance on determining discard date (ISO 14730:2014)

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Denna standard ersätter SS-EN ISO 14730, utgåva 1.

The European Standard EN ISO 14730:2014 has the status of a Swedish Standard. This document contains the official version of EN ISO 14730:2014.

This standard supersedes the Swedish Standard SS-EN ISO 14730, edition 1.

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Denna standard är framtagen av kommittén för Ögonoptik, SIS/TK 336.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 14730

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Supersedes EN ISO 14730:2000

English Version

Ophthalmic optics - Contact lens care products - Antimicrobial preservative efficacy testing and guidance on determining discard date (ISO 14730:2014)

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 14730:2014)

Augenoptik - Kontaktlinsenpflegemittel - Konservierungsmittelbelastungstest und Anleitung zur Feststellung der Aufbrauchfrist (ISO 14730:2014)

This European Standard was approved by CEN on 23 July 2014.

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Foreword

This document (EN ISO 14730:2014) has been prepared by Technical Committee ISO/TC 172 “Optics and photonics” 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of an identical text or by endorsement, at the latest by April 2015, and conflicting national standards shall be withdrawn at the latest by April 2015.

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This document supersedes EN ISO 14730:2000.

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Endorsement notice

The text of ISO 14730:2014 has been approved by CEN as EN ISO 14730:2014 without any modification.

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.

4.3 The antimicrobial preservative properties of the product are adequate if, in the conditions of the test, there is significant reduction of bacteria and no increase in yeasts and moulds in the inoculated preparation after the times and at the temperatures specified. The performance criteria are given in 5.6.

4.4 Appropriate measures shall be taken to inactivate or remove residual antimicrobial agents during culturing and counting of survivors. The effectiveness of these measures shall be validated.

5 Test methods

5.1 Materials and reagents

5.1.1 Test organisms

The strains listed in Table 1 shall be used.

NOTE Test organisms from other culture collections that can be used are listed in Annex F.

Table 1 — Test organisms

Pseudomonas aeruginosa	ATCC 9027
Staphylococcus aureus	ATCC 6538
Escherichia coli	ATCC 8739
Candida albicans	ATCC 10231
Aspergillus brasiliensis	ATCC 16404

5.1.2 Culture media and reagents

5.1.2.1 Tryptone Soya Agar (TSA).

5.1.2.2 Sabouraud Dextrose Agar (SDA).

5.1.2.3 Dulbecco's Phosphate-Buffered Saline, without calcium chloride and magnesium chloride (DPBS).

Combine 200 mg/l KCl, 200 mg/l KH_2PO_4, 8 000 mg/l NaCl, and 2 160 mg/l $Na_2HPO_4 \cdot 7H_2O$ or suitable diluent.

5.1.2.4 Dulbecco's Phosphate Buffered Saline, plus 0,05 % volumic mass polysorbate 80 (DPBST) or suitable diluent.

5.1.2.5 Validated neutralizing agents/media as required, for example, Dey-Engley Neutralizing Broth (DEB) and Letheen Broth.

5.1.3 Laboratory equipment

The following common laboratory equipment is required*:* sterile pipettes, swabs, tubes, petri dishes (90 mm to 100 mm × 20 mm), etc. and suitable instruments for spectrophotometric determination of cell density, for colony counting and for centrifugation.

5.2 Test sampling and culture maintenance

The product to be tested shall be representative of the product to be marketed. Aliquots should be taken directly from the final product container immediately prior to testing.

Three lots of product shall be tested. Each lot of product shall be tested with a separate inoculum preparation for each challenge organism.

Maintain the test cultures as recommended by the curator of the appropriate culture collection.

Cultures should be no greater than five passes removed from the depository stock (ATCC, NCIB, NCTC, NCPF or other recognized culture depository; see Annex F). Each pass is a subculture of the previous pass.

5.3 Preparation of microbial challenge (Inoculum)

Culture each test organism on agar slopes under the conditions given in Table 2.

Table 2 — Media and incubation conditions for growth of challenge organisms

Organism	Medium	Temperature °C	Incubation time
P. aeruginosa	TSA	30 to 35	18 h to 24 h
S. aureus	TSA	30 to 35	18 h to 24 h
E. coli	TSA	30 to 35	18 h to 24 h
C. albicans	SDA	either 20 to 25	42 h to 48 h
		or 30 to 35	18 h to 24 h
A. brasiliensis	SDA	20 to 25	7 d to 10 d

Use sterile DPBST or suitable diluent to harvest each culture; wash the surface growth, transfer it to a suitable vessel and vortex. Filter the spore suspensions through sterile glass wool, cheesecloth or gauze to remove hyphal fragments.

After harvesting, the cultured organisms can be washed using centrifugation. The bacterial suspensions can be filtered (e.g. 3 µm to 5 µm pore size) to produce a single cell dispersion. Then, adjust all challenge cell suspensions with DPBST or other suitable diluent to a concentration of between $1{,}0 \times 10^7$ cfu/ml and $1{,}0 \times 10^8$ cfu/ml. Estimate the approximate cell concentration of each suspension by measuring the turbidity of the suspension or a dilution of the suspension using a spectrophotometer. The actual concentration of colony-forming units per millilitre shall be determined for each suspension, e.g. by the plate-count method, at the time of the test.

If centrifugation is used, each centrifugation should be conducted at 20 °C to 25 °C for no longer than the equivalent of 10 min at 4 000 g or less.

Use bacterial and yeast cell suspensions on the day of preparation.

NOTE 1 Longer centrifugation times might be required at lower speeds.

NOTE 2 Spore suspensions can be used up to seven days following preparation by storage under refrigeration (2 °C to 8 °C).

5.4 Inoculum challenge test procedure

5.4.1 Prepare one or more tube*s* (for each lot tested) containing a minimum of 10 ml of test solution per challenge organism.

NOTE Sample tubes are used rather than lens cases to allow effective technical execution of the test. Since incompatibilities can exist between solution ingredients and tube materials, tubes of an appropriate material which is compatible with the ingredients should be considered.

Inoculate the sample tube of the product to be tested with a suspension of test organisms sufficient to provide a final count of between $1{,}0 \times 10^5$ cfu/ml and $1{,}0 \times 10^6$ cfu/ml. Ensure that the volume of inoculum does not exceed 1 % of the sample volume. Ensure complete dispersion of the inoculum by adequate mixing.