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Ophthalmic optics - Contact lens care products - Guidelines for determination of shelf-life (ISO 13212:2014)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 01/15

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English Version

Ophthalmic optics - Contact lens care products - Guidelines for determination of shelf-life (ISO 13212:2014)

Optique ophtalmique - Produits d'entretien pour lentilles de contact - Lignes directrices pour la détermination de la durée de conservation (ISO 13212:2014)

Augenoptik - Kontaktlinsenpflegemittel - Leitfaden für die Bestimmung der Lagerdauer (ISO 13212:2014)

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Foreword

This document (EN ISO 13212:2014) 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of an identical text or by endorsement, at the latest by March 2015, and conflicting national standards shall be withdrawn at the latest by March 2015.

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Endorsement notice

The text of ISO 13212:2014 has been approved by CEN as EN ISO 13212:2014 without any modification.

Ophthalmic optics — Contact lens care products — Guidelines for determination of shelf-life

*Optique ophtalmique — Produits d'entretien pour lentilles de
contact — Lignes directrices pour la détermination de la durée de
conservation*





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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).

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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*.

This third edition cancels and replaces the second edition (ISO 13212:2011), which has been technically revised.

Introduction

The purpose of stability tests of contact lens care products is to obtain sufficient information to enable the manufacturer to establish an appropriate shelf-life and identify any unique storage conditions required to appear on the labelling of the product.

The quality of a contact lens care product is determined by its content of active ingredient(s), its purity, and its physicochemical and microbiological properties. It is important to take into account the possible interaction of the container/closure with the contents.

The stability studies are intended to ascertain how the quality of a product varies as a function of time and under the influence of a variety of environmental factors.

On the basis of the information obtained, storage conditions are recommended, which will guarantee the maintenance of the quality of the product in relation to its safety, performance, and acceptability throughout the proposed shelf-life.

The design of the finished product stability studies for a care product is based on the knowledge obtained from studies on the active ingredient(s) and from the development studies.

Ophthalmic optics — Contact lens care products — Guidelines for determination of shelf-life

1 Scope

This International Standard provides guidance on the design of stability studies for use in gathering information to enable determination of the shelf-life of contact lens care products.

This International Standard does not address studies designed to obtain information to establish the in-use stability (i.e. notice of discard date) of contact lens care products.

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 14730, *Ophthalmic optics — Contact lens care products — Antimicrobial preservative efficacy testing and guidance on determining discard date*

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

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