Ophthalmic optics - Contact lens care products - Guidelines for determination of shelf-life (ISO 13212:2011)

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NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 13212:2011 sisaldab Euroopa standardi EN ISO 13212:2011 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 13212:2011 consists of the English text of the European standard EN ISO 13212:2011.
Standard on kinnitatud Eesti Standardikeskuse 31.05.2011 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 31.05.2011 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 15.05.2011.	Date of Availability of the European standard text 15.05.2011.
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English Version

Ophthalmic optics - Contact lens care products - Guidelines for determination of shelf-life (ISO 13212:2011)

Optique ophtalmique - Produits d'entretien pour lentilles de contact - Lignes directrices pour la détermination de la durée de conservation (ISO 13212:2011)

Augenoptik - Kontaktlinsenpflegemittel - Leitfaden für die Bestimmung der Lagerdauer (ISO 13212:2011)

This European Standard was approved by CEN on 14 May 2011.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

Foreword

This document (EN ISO 13212:2011) 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of an identical text or by endorsement, at the latest by November 2011, and conflicting national standards shall be withdrawn at the latest by November 2011.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

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Endorsement notice

The text of ISO 13212:2011 has been approved by CEN as a EN ISO 13212:2011 without any modification.

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 for 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 thus 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 referenced documents are indispensable for the application of this document. 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*

3 Terms and definitions

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

4 General requirements

4.1 The specified shelf-life of the contact lens care product shall be based on the evaluation of the results of stability studies.

4.2 Analytical methods that have been validated and are stability-indicating shall be used to assay for active ingredients. Validation includes, but is not limited to, being able to differentiate between the active ingredient and its degradation products. The test methods used shall be described in full.