

BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

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भारतीय मानक मसौदा

नेत्र विज्ञान ऑप्टिक्स — संपर्क लेंस देखभाल उत्पाद — शेल्फ-जीवन के निर्धारण के लिए दिशानिर्देश
(ISO 13212:2014)

Draft Indian Standard

**Ophthalmic Optics — Contact Lens Care Products — Guidelines for
Determination of Shelf-Life
(ISO 13212: 2014)**

[ICS 11.040.70]

Ophthalmic Instruments and Appliances Sectional Committee,
MHD 05

Last Date for Comments:
17 May 2025

NATIONAL FOREWORD

(Adoption clause will be added later)

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are however not identical to those used in Indian Standards. Attention is particularly drawn to the following:

- a) Wherever the words ‘International Standard’ appear referring to this standard, they should be read as ‘Indian Standard’.
- b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards, which are to be substituted in their respective places, are listed below along with their degree of equivalence for the editions indicated

<i>International Standards</i>	<i>Corresponding Indian Standards</i>	<i>Degree of equivalence</i>
ISO 14729, Ophthalmic optics — Contact lens care products — Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses	MHD/05/27611, Ophthalmic optics Contact lens care products Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses	Identical
ISO 14730, Ophthalmic optics — Contact lens care products — Antimicrobial preservative efficacy testing and guidance on determining discard date	MHD/05/27627, Ophthalmic optics Contact lens care products Antimicrobial preservative efficacy testing and guidance on determining discard date	Identical
ISO 18369-1, Ophthalmic optics — Contact lenses — Part 1: Vocabulary, classification system and recommendations for labelling specifications	IS/ISO 18369 (Part 1), Ophthalmic optics Contact lenses Part 1 Vocabulary classification system and recommendations for labelling specifications	Identical

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2: 2022 ‘Rules for rounding off numerical values (*second revision*)’. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

This standard also makes a reference to the BIS Certification Marking of the product. Details of which is given in National Annex A

NATIONAL ANNEX A
(National Foreword)

A-1 BIS CERTIFICATION MARKING

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards* Act, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

Note: The technical content of the document has not been included as it is identical with the corresponding ISO standard. For details, please refer to (ISO 13212:2014) or kindly contact:

Head (MHD)
Bureau of Indian Standards
Manak Bhawan
9, Bahadur Shah Zafar Marg
New Delhi-110002
Email: mhd5@bis.gov.in, harshadak@bis.gov.in

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.