SLOVENSKI STANDARD
SIST EN ISO 10340:2000

01-januar-2000

Optika in optiļ ni instrumenti - Kontaktne leļ e - Metoda za ugotavljanje izloļ ljivih snovi (ISO 10340:1995)

Optics and optical instruments - Contact lenses - Method for determining the extractable substances (ISO 10340:1995)

Optik und optische Instrumente - Kontaktlinsen - Prüfverfahren zur Bestimmung extrahierbarer Anteile (ISO 10340:1995)

Optique et instruments d'optique - Lentilles de contact - Méthode pour la détermination des substances extractibles (ISO 10340:1995)

Ta slovenski standard je istoveten z: **EN ISO 10340:1996**

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English version

Optics and optical instruments - Contact lenses - Method for determining the extractable substances (ISO 10340:1995)

Optique et instruments d'optique - Lentilles de contact - Méthode pour la détermination des substances extractibles (ISO 10340:1995)

Optik und optische Instrumente - Kontaktlinsen - Prüfverfahren zur Bestimmung extrahierbarer Anteile (ISO 10340:1995)

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart,36 B-1050 Brussels

Foreword

The text of the International Standard from ISO/TC 172 „Optics and optical instruments" of the International Organization for Standardization (ISO) has been taken over as a European Standard by the 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of an identical text or by endorsement, at the latest by December 1996, and conflicting national standards shall be withdrawn at the latest by December 1996.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, 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 10340:1995 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 corresponding European publications

This European Standard incorporates by dated or undated references, 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.

publication/year	title	EN/year
ISO 3696: 1987	Water for analytical laboratory use - Specification and test methods	EN ISO 3696: 1995

INTERNATIONAL STANDARD

ISO 10340

First edition
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Optics and optical instruments — Contact lenses — Method for determining the extractable substances

Optique et instruments d'optique — Lentilles de contact — Méthode pour la détermination des substances extractibles

Reference number
ISO 10340:1995(E)

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.

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.

International Standard ISO 10340 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Optics and ophthalmic instruments*.

Annex A of this International Standard is for information only.

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Optics and optical instruments — Contact lenses — Method for determining the extractable substances

1 Scope

This International Standard specifies an analytical method for the quantitative determination of the substances extractable from contact lenses by Soxhlet extraction with different solvents.

2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods.*

3 Principle

The contact lenses are extracted with various solvents by Soxhlet extraction. The lenses are dried to constant mass and the difference between the original dry mass of the lens and the extracted dry mass determines the quantity of extractable substances.

NOTES

1 The method of extraction specified in this International Standard uses the normal Soxhlet apparatus. However, it describes the particular precautions necessary when handling contact lenses, and also gives guidance to the range of solvents that may be employed. Water and at least one suitable organic solvent are used for extraction. In selecting the organic solvent(s) to be used, consideration should be made as to the effect of the solvent upon the matrix of the material. Ideally a solvent should not swell or degrade the contact lens material. However, in the development of new contact lens materials, a solvent that causes reversible swelling may give valuable information relating to the possibility for extraction over extended periods of time.

2 A knowledge of the quantity and identity of extractable substances is of particular help in evaluating new contact lens materials, and determining the subsequent pre-clinical examination programme. The material extracted from the contact lenses may be examined by appropriate chromatographic, spectrophotometric and wet analysis methods, to identify residual monomers, cross-linking agents and catalysts that were employed in the polymerization process.

3 The laboratory carrying out this test should follow the OECD guidelines for "Good Laboratory Practice in the Testing of Chemicals". Any deviation should be clearly stated in the test report.

4 Reagents

4.1 Water, distilled or deionized, complying with grade 3 of ISO 3696.

4.2 Organic solvent, analytical grade (see table 1).

4.3 Boiling stones or anti-bumping granules, laboratory grade.

4.4 Active desiccant.

NOTE 4 Selection of a suitable desiccant will depend upon the characteristics of the test material.

5 Apparatus

5.1 Soxhlet extraction apparatus, comprising a round-bottom flask of capacity 100 ml, a 30 ml Soxhlet extractor and a condenser of borosilicate glass (see figure 1).