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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*



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Foreword

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

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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).