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STANDARD

**ISO**  
**10340**

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

**iTeh STANDARD PREVIEW**

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

ISO 10340:1995

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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**.

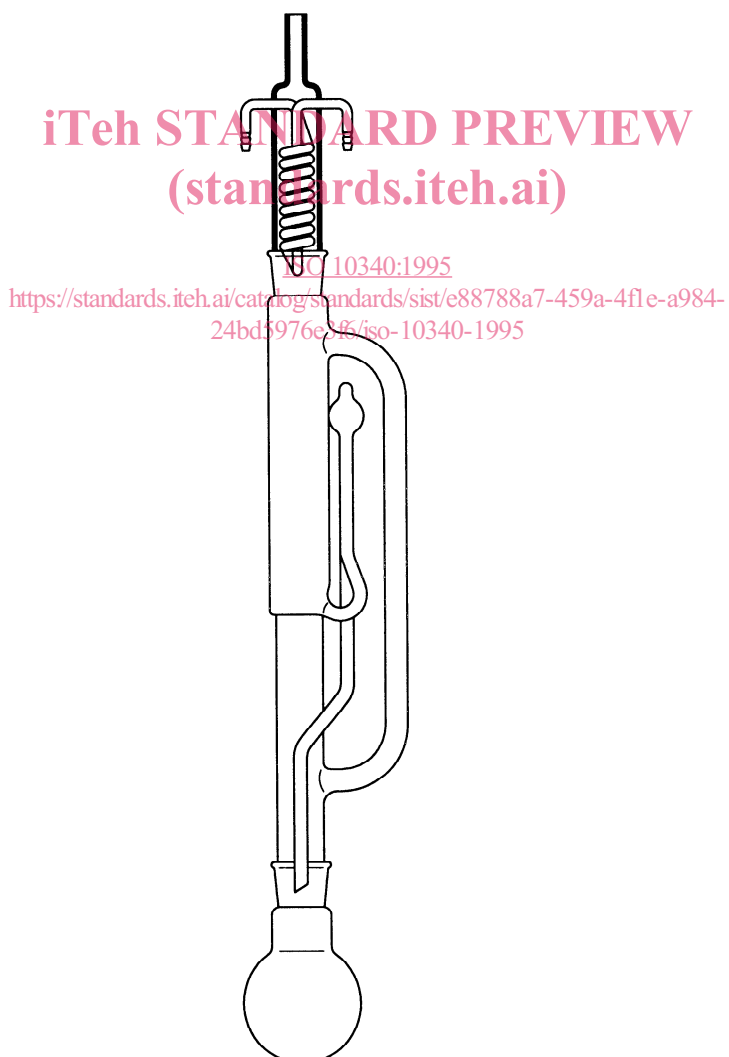
NOTE 4 Selection of a suitable desiccant will depend upon the characteristics of the test material.

## 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).

**Table 1 — Guide to the selection of solvents for use in extraction of contact lenses**

Material	Solvent	Corresponds to
Hydrogels	Water (distilled or deionized)	Mild extraction (simulates in-eye extraction)
	<i>n</i> -Hexane	Mild extraction (non-polar solvent)
	Ethanol or methanol	Extraction of majority of uncrosslinked material (but swells and may degrade material)
	Dichloromethane or chloroform	Extraction of all uncrosslinked material (but swells and is likely to degrade material)
Hard and GP (rigid) and silicone elastomers	Water (distilled or deionized)	Mild extraction (simulates in-eye extraction)
	<i>n</i> -Hexane	Mild extraction (non-polar solvent)
	Dichloromethane or chloroform	Extraction of all uncrosslinked material (but swells and is likely to degrade material)

**Figure 1 — Extraction apparatus**

## 5.2 Heating mantle.

**5.3 Extraction thimble**, of perforated stainless steel, sintered glass, paper or equivalent, fitted with a glass wool plug or suitable closure.

**5.4 Vacuum oven**, or other suitable drying apparatus.

**5.5 Analytical balance**, capable of weighing to an accuracy of 0,1 mg.

## 6 Test samples

**6.1** Test samples shall be representative of the finished product. The test samples shall be in finished contact lens form. They shall have been prepared and finished as in the normal production process.

Lenses normally subject to a sterilization process shall be so treated.

**6.2** A sufficient number of lenses shall be selected so that the total dry mass before extraction will be not less than 200 mg.

**6.3** For hydrophilic lens materials, any initial hydration and extraction of the lenses shall be made in the same manner as is used in normal production (see note 7). The composition of the solution shall be stated in the test report.

NOTE 5 If the hydration steps have been correctly carried out then extraction by this test method, using water, would not be expected to extract any material other than the inorganic salts from the hydration solution. This International Standard may therefore be used as a quality control test for production purposes as well as in the development of new materials.

## 7 Procedure

**7.1** Dry the lenses, preferably under vacuum, at 60 °C ± 5 °C to constant mass.

Allow the lenses to cool to room temperature under vacuum before weighing or, if this is not possible, remove the lenses from the oven and allow to cool in a closed container over active desiccant.

**7.2** Check that at least 200 mg of dry lenses are available for the extraction step.

**7.3** Weigh the dry lenses to ± 0,1 mg and record the mass ( $m_1$ ).

**7.4** Put the lenses in the extraction thimble and, if necessary, place the boiling stones in the flask, and part fill the flask to about 70 % of capacity with the appropriate solvent (see table 1). Place the extraction thimble in the Soxhlet extractor and assemble the flask, the Soxhlet extractor and the condenser on the heating mantle.

NOTE 6 When using a very volatile or flammable solvent the equipment should be placed in a fume-cupboard.

**7.5** Extract the lenses for at least 4 h.

**7.6** Allow the solvent to cool to room temperature before removing the lenses from the extraction thimble. Dry the lenses to constant mass as described in 7.1.

**7.7** Weigh the extracted lenses to ± 0,1 mg and record the mass ( $m_2$ ).

NOTE 7 It is usual for hydrophilic lenses to be hydrated and supplied in a solution containing inorganic salts. Hydrophilic lenses used in this test should be supplied in a solution of known composition. Therefore when using water as the extracting solution an allowance should be made for the contribution of the inorganic salt content of the hydrating medium to the result obtained. In order for the effect of salt content upon the calculated result to be accurately determined, the water content of the lenses will need to be known or measured, according to the method specified in ISO 10339. Alternatively, the lenses should be equilibrated in at least two changes of water for 24 h at room temperature prior to beginning the test.

## 8 Expression of results

Calculate the quantity of extracted material as a percentage using the equation:

$$\% \text{ Extracted} = \frac{m_1 - m_2}{m_1} \times 100$$

where

$m_1$  is the mass of non-extracted lenses;

$m_2$  is the mass of extracted lenses.

## 9 Test report

The test report shall contain at least the following information:

- a reference to this International Standard, i.e. ISO 10340;
- the percentage of material extracted from the lenses;

- c) identification of the contact lens lot number, including the type of contact lens material tested;
- d) the number and mass of contact lenses extracted;
- e) the solvent used to extract the lenses, and its purity;
- f) if the material is hydrophilic, the composition of the initial hydrating solution, together with a statement as to whether the percentage of extractable substances has been adjusted for the salt content of the hydrating solution, or if the lenses were equilibrated in water before the beginning of the test;
- g) the name of the test laboratory, date of testing and an approved signature.

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## **Annex A** (informative)

### **Bibliography**

- [1] ISO 10339:—<sup>1)</sup>, *Optics and optical instruments — Contact lenses — Determination of water content of soft lenses*.
- [2] OECD guidelines for “Good Laboratory Practice in the Testing of Chemicals” (OECD, Paris 1982).

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