INTERNATIONAL STANDARD

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Ophthalmic optics — Contact lenses — Determination of shelf-life

Optique ophtalmique — Lentilles de contact — Détermination de la durée de conservation

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Foreword

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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 11987 was prepared by ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

Annex A of this International Standard is for information only.

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Introduction

The tests included in this International Standard are designed to obtain information that will enable proposals to be made for the shelf-life of the contact lens, and enable storage conditions to be recommended. However in practical terms it is the stability of the material from which the contact lens is made that is being tested, along with the integrity of the packaging that maintains the environment necessary for the contact lens.

The purpose of the stability studies is to ascertain how the quality of the contact lens 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 can be recommended which will guarantee the maintenance of the quality of the contact lens in relation to its safety, efficacy and acceptability, throughout the proposed shelf-life (i.e. during storage and distribution until the moment of dispensing).

Ophthalmic optics — Contact lenses — Determination of shelf-life

1 Scope

This International Standard describes the testing required in order to determine the stability of contact lenses, once placed in their final packaging, during storage and distribution.

NOTE The results obtained can be used for determining the 'expiry date'.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were 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 editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 8321-1:1991 *Optics and optical instruments - Contact lenses - Part 1: Specification for rigid corneal and scleral contact lenses*

ISO 8599:1994 *Optics and optical instruments - Contact lenses - Determination of spectral and luminous transmittances*

ISO 9337-1:– [1] *Ophthalmic optics - Contact lenses - Determination of back vertex power - Part 1: Focimeter*

ISO 9338:1996 *Optics and optical instruments - Contact lenses - Determination of the diameters*

ISO 9341:1996 *Optics and optical instruments - Contact lenses - Determination of inclusions and surface imperfections for rigid contact lenses*

ISO 10338:1996 *Optics and optical instruments - Contact lenses - Determination of curvature*

3 Principle

Suitable tests are described by which the stability of contact lenses under controlled storage conditions is established and their shelf-life under those conditions determined.

[1] To be published.

The design of the stability tests is based on the known properties of the material from which the contact lens is made, and the recommendations for storage of the contact lens.

NOTE 1 A knowledge of the quantity and identity of extractable substances (see ISO 10340) is of particular help in evaluating new contact lens materials, and in determining the information that needs to be obtained from the stability testing.

NOTE 2 The specifications claimed at the time of manufacture and to the end of the proposed shelf-life should reflect, as far as possible, the results of the stability studies, particularly in relation to any parameters which could have a bearing on efficacy, safety and product acceptability.

NOTE 3 In designing stability tests, the manufacturer should consider any sterility requirement. Validation and requirements of sterilization processes are described in other International Standards. Additionally, sterility testing is described in pharmacopoeia monographs.

4 Reagent

The reagent shall be the contact lens storage solution used by the manufacturer for packing the contact lens.

5 Apparatus

5.1 Controlled storage chamber, capable of being maintained at 25°C ± 2°C, and equipped with means for continuously recording temperature and humidity.

NOTE Additional storage conditions, for example at 35°C ± 2°C and 45°C ± 2°C, may be required for accelerated studies.

5.2 Measuring equipment, as required, for the determination of back vertex power, total diameter, curvature and spectral transmittance. The equipment shall incorporate, if necessary, the facility to condition the contact lens within the storage solution before and during measurement, under the controlled conditions specified in the measurement method.

6 Test samples

6.1 Test lenses shall be representative of the normal production. The parameters of the contact lenses being studied shall be representative of the range of parameters normally produced, in particular high and low back vertex powers (see Table 1). If supplied sterile, the contact lenses shall have been subjected to the sterilization process normally used.

Table 1 - Suitable parameters for test lenses

Parameter	Soft lens	Rigid lens
Diameter (see ISO 9338)	12,0 mm to 16,0 mm	8,0 mm to 11,0 mm
Curvature (see ISO 10338)	7,0 mm to 10,0 mm	7,0 mm to 9,0 mm
Back vertex power (see ISO 9337-1)	-7 D to -10 D 0 D to -4 D +7 D to +10 D	-7 D to -10 D 0 D to -4 D +7 D to +10 D
Visible light transmittance (see ISO 8599 and note 2 below)	0 D to -4 D	0 D to -4 D

NOTE 1 - When contact lenses are made by moulding or casting, the back vertex powers available are frequently limited to the range 0 D to -5 D during initial production runs. In these cases, the stability study should test contact lenses of the extreme back vertex powers available. If the back vertex power range is later increased, the stability study should be continued with contact lenses from the extreme back vertex powers of the new production range.

NOTE 2 - Additional properties, e.g. ultraviolet light transmittance, should be considered for measurement, depending on the nature of the contact lens.

6.2 The contact lenses to be studied shall be randomly selected from not less than two different batches of the contact lens polymer, preferably from production-scale manufacture.

NOTE In practice, a manufacturer would normally have some stability data from contact lenses made from small-scale or research lots of polymer. The examination of the data may indicate that more than two batches should be selected for this stability study.

6.3 The contact lenses shall be packaged in the same manner as that intended when supplied to the purchaser. For contact lenses that are supplied sterile, the package is required to maintain the sterility until opened, or until the shelf-life has expired.

NOTE 1 - The usual limitations on shelf-life are the permeability of the package to moisture and the sensitivity of the contact lens' parameters to change in degree of hydration and /or salinity. A packaging failure is the most common cause of a shortened shelf-life. Therefore sufficient contact lenses should be placed on test to clearly differentiate between a material instability and a packaging failure.

NOTE 2 - There is a possibility that substances could be extracted from the packaging itself and that these might interfere with the safety or performance of contact lenses. The manufacturer should recognize this possibility when selecting the packaging materials and either carry out suitable testing or use packaging that meets a relevant national or international specification or a specification of a National Pharmacopoeia.

7 Test procedure

7.1 Real-time studies

7.1.1 Measure and record the initial parameters of the contact lenses under test (see clause 6) and identify each contact lens with a unique number upon the contact lens packaging.

7.1.2 Transfer the contact lenses to the storage chamber maintained at 25 °C ± 2 °C. Record the actual temperature, the humidity and date.

7.1.3 Periodically remove at least three contact lenses from each of the three back vertex power groups and each polymer batch, i.e. a minimum of eighteen contact lenses (see Table 1). Allow the contact lenses within the original packaging to equilibrate before removing the contact lenses and measuring the parameters, in the following order:

a) back vertex power (see ISO 9337-1);
b) diameter (see ISO 9338);
c) curvature (see ISO 10338).

Record the parameters obtained for each property. Discard the contact lens after completing the measurements.

NOTE For soft lenses, measurements are carried out within a wet cell when determining diameter and radius of curvature. The reagent (see clause 4) used in the wet cell should be taken from the original packaging, but, if this is not possible, measurements should be taken immediately after transferring each contact lens into the measurement cell. This should ensure that the contact lens has insufficient time to equilibrate with the fresh test solution.

7.1.4 For rigid contact lenses, check that the parameters measured do not differ from the measurements made initially by more than the tolerance specified in ISO 8321-1.

For hydrogel contact lenses, it should be checked that the parameters measured do not differ from the measurements made initially by more than the tolerance specified in ISO 8321-2.

7.1.5 Using the test method described in annex A of ISO 9341:1996, carry out a subjective visual examination of the contact lenses and their surfaces, and note any unusual colour, surface deposit or appearance.

7.1.6 At the beginning and end of the period of the study, measure the visible light transmittance of two contact lenses using the method described in ISO 8599.

7.1.7 At the end of the period of the study:

a) check the integrity of the package;
b) for contact lenses supplied sterile, carry out a sterility test according to a recognized method.

NOTE The checking of integrity of the package may be done by measuring moisture vapour permeability (e.g. weight loss or osmolarity determination) and by performing dye penetration tests.

7.1.8 At the end of the period of the study, record the actual temperature and humidity, and record the range of temperatures and mean humidity during the period of the study.

7.1.9 If, during the period of the study, any contact lens is found to be outside the permitted tolerance or to have changed visually, examine additional contact lenses from all back vertex power groups to check the validity of the non-conforming contact lens result.

7.2 Accelerated ageing studies

7.2.1 Measure and record the initial parameters of the contact lenses under test (see clause 6) and identify each contact lens with a unique number upon the contact lens packaging.

NOTE Studies under more extreme test conditions (see note in 5.1) are likely to increase any degradation and permit an extrapolation to the 25°C shelf-life.

Such studies should always be supplemented by long-term real-time studies, and normally at least 6 months real-time study data should be available before marketing the product.

7.2.2 If accelerated studies are required, select sufficient contact lenses and store at 35°C ± 2°C and/or 45°C ± 2°C.

NOTE To a first approximation, each increase of 10°C in storage temperature doubles the rate of any degradation of synthetic polymers (e.g. storage at 35°C for 6 months is equivalent to storage for 12 months at 25°C).

7.2.3 At defined intervals, remove samples from storage and allow them to equilibrate to the same test temperature (e.g. 20°C) as the initial measurement, before re-determining the required parameters.

7.2.4 Record the actual temperature and humidity at the time of the determinations, and the range of temperatures and mean humidity during the period of the study.

7.2.5 If, during the period of the study, any contact lens is found to be outside the permitted tolerance or to have changed visually, examine additional contact lenses from all back vertex power groups, to confirm the validity or otherwise of the non-conforming contact lens result.