INTERNATIONAL STANDARD

ISO 11987

Second edition
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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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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

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

This second edition cancels and replaces the first edition (ISO 11987:1997), which has been technically revised. It also incorporates the Technical Corrigendum ISO 11987:1997/Cor.1:1998.

Introduction

The tests included in this International Standard are designed to obtain information that enables proposals to be made for the shelf-life of a contact lens, and 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 that 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 specifies test procedures for determining the stability of contact lenses once they are 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 referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 18369-1, *Ophthalmic optics — Contact lenses — Part 1: Vocabulary, classification system and recommendations for labelling specifications*

ISO 18369-2, *Ophthalmic optics — Contact lenses — Part 2: Tolerances*

ISO 18369-3, *Ophthalmic optics — Contact lenses — Part 3: Measurement methods*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 18369-1 apply.

4 Principle

The stability of contact lenses, packaging solution and packaging is established under controlled storage conditions in order to determine their shelf-life under those conditions.

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

5 General requirements and recommendations

A risk assessment shall be performed to evaluate the critical properties and parameters, and a test protocol prepared.

NOTE 1 A knowledge of the quantity and identity of extractable substances (see ISO 18369-4) is of particular help in evaluating new contact lens materials and in determining the information that needs to be obtained from the stability testing.

The specifications of the properties and parameters evaluated in the stability study, which are 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.

In designing stability tests, the manufacturer should consider any sterility requirements.

NOTE 2 Requirements for the development, validation and routine control of sterilization processes are described in other International Standards. Additionally, sterility testing is described in monographs in various pharmacopoeias.

6 Test and measurement media

6.1 The test medium shall be the contact lens storage solution, if any, that is used by the manufacturer for packaging the contact lens.

6.2 Measurements shall be made either in the test medium (packaging solution), or in the standard saline solution specified in ISO 18369-3 after equilibration in this solution, or dry. The same measurement medium shall be used at all test stages. The choice of measurement medium shall be discussed in the risk assessment and test protocol.

7 Apparatus

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

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

Low relative humidity, for example 10 % RH to 20 % RH, can adversely affect products packed in semi-permeable containers; consideration should be given to appropriate testing under such conditions.

7.2 **Lens/lens packaging measuring equipment**, as required, for the determination of back vertex power, total diameter, curvature, spectral transmittance and other parameters of the lens and packaging system (to be determined from the risk assessment). The equipment shall incorporate, if necessary, the ability to condition the contact lens within the measurement media before and during measurement, under the controlled conditions specified in the measurement method.

7.3 **Solution measuring equipment**, as required, to measure the properties of the packaging solution (to be determined from the risk assessment).

8 Test samples

8.1 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. Additional properties, e.g. ultraviolet light transmittance, shall be considered for measurement, depending on the nature of the contact lens and the outcome of the risk assessment. If supplied sterile, the contact lenses shall have been subjected to the sterilization process that has been validated.

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, an additional risk assessment should be conducted which utilizes the data from the existing study to determine whether the stability study should be continued with contact lenses from the extreme back vertex powers of the new production range.

The selection of power ranges may be adjusted to the requirements of specific test methods.

8.2 The contact lenses to be studied shall be randomly selected from not less than two different traceable 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 can indicate the need to select more than two batches for this stability study.

8.3. 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 shall maintain the sterility until opened, or until the shelf-life has expired.

There is a possibility that substances might be extracted from the packaging itself and that these might interfere with the safety or performance of the contact lenses. The manufacturer should recognize this possibility when selecting the packaging materials and either carry out a risk assessment, perform suitable testing, or use packaging that meets a relevant national or international specification or a specification of a national pharmacopoeia.

8.4 The stability of the packaging solution shall also be monitored. The parameters monitored shall be those included in the solution specification (e.g. pH, osmolality), and additional ingredients added for performance and/or label claims.

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

9 Test procedure

9.1 Real-time studies

9.1.1 Measure and record the initial properties, parameters and solution properties of a sufficient number of contact lenses from each test lot. Identify each test lot with a unique identifier. Each lens should be traceable with respect to identity and source through the lot number or unique identifier.

Sufficient samples from each lot should be stored in a controlled storage chamber and conditioned (see 7.2) to allow the measurement of properties and parameters at designated time intervals. The parameters and properties from these representative samples are used to determine stability.

Additional properties, for example ultraviolet-light transmittance, should be considered for measurement, depending on the nature of the contact lens and the outcome of the risk assessment.

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

NOTE Low relative humidity (e.g. 10 % RH to 20 % RH) can adversely affect products packed in semi-permeable containers; consideration will therefore have to be given to appropriate testing under such conditions.

9.1.3 Periodically remove a sufficient number of contact lenses from each test lot and perform the following steps.

a) Allow the contact lenses within the original packaging to equilibrate before removing the contact lens. Lenses shall then be equilibrated in the measurement medium identified in the risk assessment and documented in the protocol prior to determining the properties and parameters.

b) Measure the back vertex power, diameter, curvature, and other properties and parameters determined by the risk assessment and documented in the protocol.

c) Record the properties and parameters obtained for each lens.

9.1.4 Check that the parameters measured do not differ from the measurements made initially by more than the tolerance specified in ISO 18369-2.

9.1.5 In accordance with the test method specified in ISO 18369-3, carry out a subjective visual examination of the contact lenses and their surfaces. Note any unusual colour, surface deposit or appearance.

9.1.6 At the beginning and end of the period of study, measure the visible-light transmittance of a sufficient number of contact lenses in accordance with the method specified in ISO 18369-3.

9.1.7 For contact lenses supplied sterile, periodically, and at the end of the period of study for the labelled shelf-life, carry out a validated package integrity test, e.g. physical test or microbial challenge, or a sterility test according to a recognized method (e.g. Ph.Eur., USP, JP).

9.1.8 At the beginning and at each test point, the packaging solution shall be equilibrated to the appropriate temperature and measured for solution properties as determined from the risk assessment and documented in the protocol.

9.1.9 During the period of study, record the actual temperature and humidity.

9.1.10 If, during the period of study, any contact lens is found to be outside the permitted tolerance or to have changed visually, the non-conforming lens should be re-evaluated to confirm the result. If the lens is unsuitable for further evaluation, additional contact lenses from the same test lot should be evaluated to check the validity of the non-conforming contact lens result. The testing requirement for additional testing shall be defined in the test protocol. Any results outside the permitted tolerances shall be reported in the test report.

9.2 Accelerated ageing studies

9.2.1 If accelerated studies are required, select sufficient contact lenses and store at 35 °C ± 2 °C and/or 45 °C ± 2 °C, or another suitable temperature, and at suitable controlled humidity. Such studies shall 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. The same test lots that are used for the real-time studies shall be used for the accelerated studies.

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).

Sufficient samples from each lot should be stored in a controlled storage chamber and conditioned (see 7.2) to allow the measurement of properties and parameters at designated time intervals. The parameters and properties from these representative samples are used to determine stability.

9.2.2 The initial property and parameter values measured in 9.1.1 shall be used for time-zero values for the accelerated studies.

9.2.3 Transfer the contact lenses to the storage chamber maintained at 35 °C ± 2 °C and/or 45 °C ± 2 °C, or another suitable temperature, and at suitable controlled humidity. Record the actual temperature, the humidity and the date.

9.2.4 Periodically remove a sufficient number of contact lenses from each test lot and perform the following steps.

a) Allow the contact lenses within the original packaging to equilibrate before removing the contact lens. Lenses shall then be equilibrated in the measurement medium identified in the risk assessment and documented in the protocol prior to determining the properties and parameters.

b) Measure the back vertex power, diameter, curvature, and other properties and parameters determined by the risk assessment and documented in the protocol.

c) Record the properties and parameters obtained for each lens.

9.2.5 Check that the parameters measured do not differ from the measurements made initially by more than the tolerance specified in ISO 18369-2.

9.2.6 In accordance with the test method specified in ISO 18369-3, carry out a subjective visual examination of the contact lenses and their surfaces. Note any unusual colour, surface deposit or appearance.

9.2.7 At the beginning and end of the period of study, measure the visible-light transmittance of a sufficient number of contact lenses in accordance with the method specified in ISO 18369-3.

9.2.8 For contact lenses supplied sterile, periodically, and at the end of the period of the study for the labelled shelf-life, carry out a validated package integrity test, e.g. physical test or microbial challenge, or a sterility test according to a recognized method (e.g. Ph.Eur., USP, JP).

9.2.9 At the beginning and at each test point the packaging solution shall be equilibrated to the appropriate temperature and measured for solution properties as determined from the risk assessment and documented in the protocol.

9.2.10 During the period of the study, record the actual temperature and humidity.

9.2.11 If, during the period of the study, any contact lens is found to be outside the permitted tolerance or to have changed visually, the non-conforming lens should be re-evaluated to confirm the result. If the lens is unsuitable for further evaluation, additional contact lenses from the same test lot and same testing conditions should be evaluated to check the validity of the non-conforming contact lens result. The testing requirement for additional testing shall be defined in the test protocol. Any results outside the permitted tolerances shall be reported in the test report.

10 Expression of results

Prepare a summary of the results. For each test lot, report for each property and parameter the initial results, the results obtained after storage and the supported shelf-life.

Results of ongoing real-time measurements should be added as they become available.

11 Test report

The following information shall be included:

a) a summary of results for the referenced test protocol and supported shelf-life, including out-of-tolerance test results, results of any re-tests and all deviations from the protocol;

b) identification of the contact lens, including the lot number, type of contact lens material, date of manufacture and name of the manufacturer of the contact lens material;

c) details of the packaging, including the materials used and descriptions of the container and the closure, and the composition of the storage solution (if any);

d) details of the environment used for the storage of the contact lenses, including temperature(s) and humidity conditions;

e) the name and location of the test laboratory, the date(s) of testing and the signature of the person approving the test report;

f) a copy of the protocol or a reference thereto;

g) a reference to the risk assessment document(s).