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Ophthalmic optics — Contact lenses and contact lens care products — Determination of physical compatibility of contact lens care products with contact lenses

Optique ophtalmique — Lentilles de contact et produits d'entretien des lentilles de contact — Détermination de la compatibilité physique des produits d'entretien des lentilles de contact avec les lentilles de contact

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

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 11981 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

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Ophthalmic optics — Contact lenses and contact lens care products — Determination of physical compatibility of contact lens care products with contact lenses

1 Scope

This International Standard describes the general procedure and performance criteria for assessing the physical compatibility of contact lens care products with contact lenses and for determining whether the observed changes are reversible.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 8320-1:—[1)], *Ophthalmic optics — Vocabulary on contact lenses and contact lens care products — Part 1: Contact lenses.*

ISO 8320-2:—[1)], *Ophthalmic optics — Vocabulary on contact lenses and contact lens care products — Part 2: Contact lens care products.*

ISO 8321-1:1991, *Optics and optical instruments — Contact lenses — Part 1: Specifications for rigid corneal and scleral contact lenses.*

ISO 8321-2:—[2)], *Optics and optical instruments — Contact lenses — Part 2: Specifications for single-vision hydrogel contact lenses.*

ISO 8599:1994, *Optics and optical instruments — Contact lenses — Determination of the spectral and luminous transmittances.*

ISO 9337-1:1999, *Ophthalmic optics — Contact lenses — Determination of back vertex power — Part 1: Method using focimeter with manual focusing.*

ISO 9338:1996, *Optics and optical instruments — Contact lenses — Determination of diameters.*

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

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1) To be published (Revision of ISO 8320:1986).

2) To be published.

ISO 10338:1996, *Optics and optical instruments — Contact lenses — Determination of curvature.*

ISO 10344:1996, *Optics and optical instruments — Contact lenses — Saline solution for contact lens testing.*

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 8320-1 and ISO 8320-2 and the following apply.

3.1
cycle
sequence of events, following instructions for use or recommendations by the manufacturer of the contact lens care product, to occur between the time the contact lens is removed from the eye and before it is placed back into the eye

3.2
active control
contact lens that is cycled according to the test procedure using standard saline solution or appropriate justified contact lens care product(s) instead of the contact lens care product under evaluation

NOTE Active controls are not required to comply with this International Standard, but may be used to gain further information about the test.

4 Principle

4.1 Detection of changes in contact lens characteristics (see flow chart shown in Figure 1)

4.1.1 Before cycling, contact lenses shall be equilibrated in isotonic standard saline solution (ISO 10344) for at least 15 min or for the time necessary to stabilize the contact lens parameters.

NOTE Equilibration times of up to 24 h may be required for some hydrogel lenses.

4.1.2 Contact lenses shall be cycled in a manner which simulates the procedures given in the manufacturer's instructions for use of the product(s) to be tested.

4.1.3 Where a range of contact times is permitted, the cycle giving rise to the most arduous conditions should be used.

4.1.4 Before and after cycling, certain physical parameters shall be measured to determine any changes. Changes shall be evaluated with reference to the manufacturer's finished product specifications and relevant specifications and tolerances given in ISO 8321-1 or ISO 8321-2.

NOTE 1 Contact lens care products should be tested using types of material representative of those with which these products are intended to be used.

NOTE 2 It may be advisable to check contact lens parameters mid-way through the test cycles.

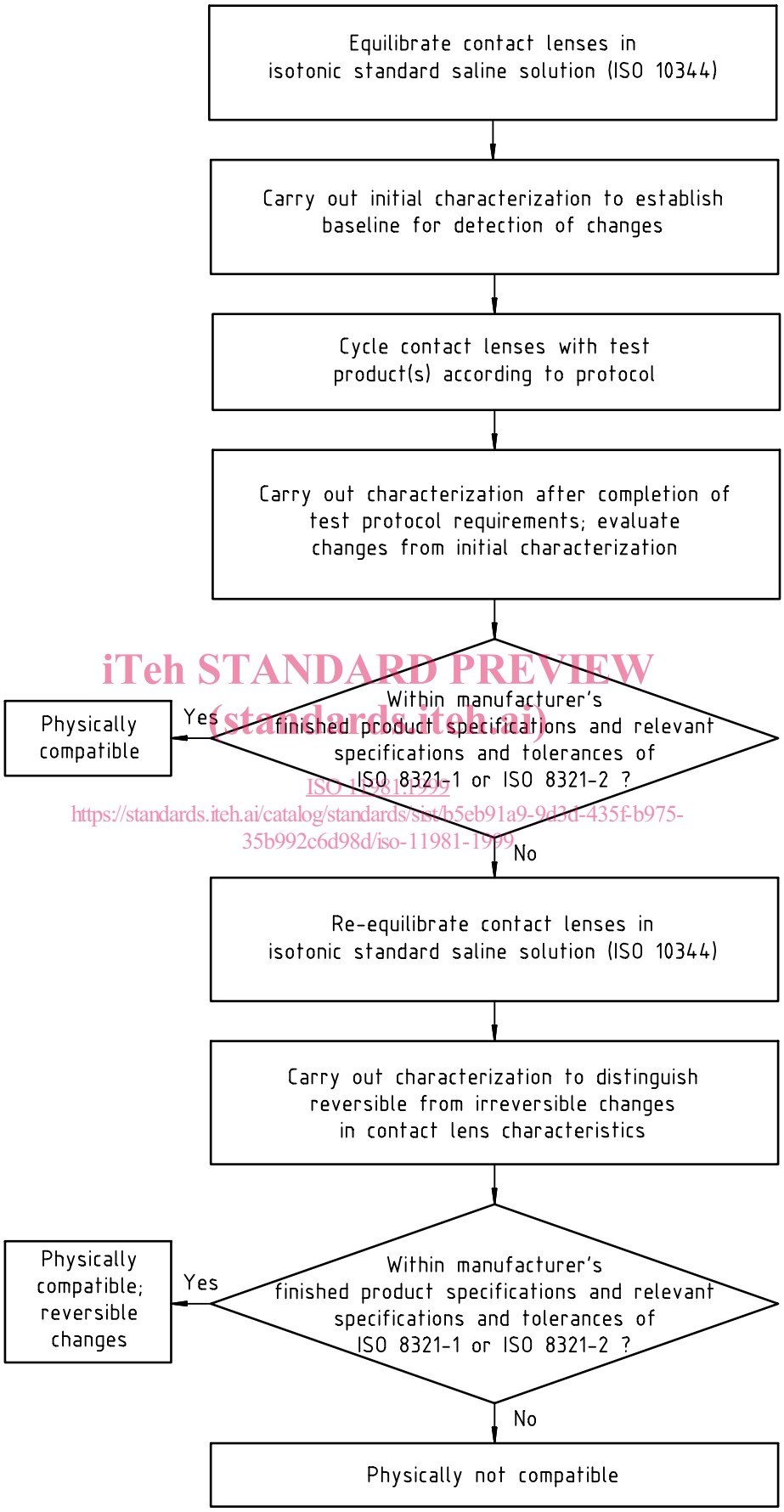

Figure 1 — Flowchart

4.2 Method to distinguish reversible from irreversible changes in contact lens characteristics

4.2.1 This method applies only to contact lens care products for which the changes observed in the contact lens characteristics are outside the manufacturer's finished product specifications and relevant specifications and tolerances given in ISO 8321-1 or ISO 8321-2 after following the test method given in 4.1.

4.2.2 Re-equilibrate the same contact lenses measured in test solution in 4.1 in isotonic standard saline solution (ISO 10344) and measure to distinguish reversible from irreversible changes.

4.2.3 Evaluate contact lens parameters measured in isotonic standard saline solution (ISO 10344) with respect to the manufacturer's finished product specifications and relevant specifications and tolerances given in ISO 8321-1 or ISO 8321-2.

NOTE For certain types of contact lens material, e.g. ionic, the ionic strength of standard saline solution (ISO 10344) may affect the parameters, compared to the label claim.

5 Selection of test lenses

5.1 A suitable number of contact lenses for test and, where necessary, for active controls are required for each type of contact lens material to be studied. The average of the results shall be based on a minimum of at least 10 contact lenses for each lens group tested.

5.2 Contact lens material groups tested shall represent those types of contact lenses for which the contact lens care product is intended to be used. Contact lens material groups are described in ISO 11539.

NOTE The study should include test lenses of the extreme powers available within the total of a minimum of 10 contact lenses tested for each lens group.

6 Procedure

6.1 Test method to detect changes in contact lens characteristics

6.1.1 Record in detail both the characteristics of contact lenses to be tested and the regimen to be followed. The record shall include contact lens care products/test methods to be used and the sequence and method of their use.

6.1.2 For contact lens care products intended for use on a daily basis, perform 30 test cycles on each material.

6.1.3 For products recommended for use on a scheduled basis as part of a contact lens care regimen (e.g. enzymatic cleaners), the number of cycles shall represent one month's use of the product or at least five exposures to the product.

6.1.4 For each contact lens care regimen being tested, test a minimum of 10 contact lenses for each lens group tested, and when required, a minimum of 10 contact lenses with the active-control regimen.

6.1.5 Allow the contact lenses to equilibrate in isotonic standard saline solution before testing for a minimum of 15 min or the time necessary to stabilize the contact lens parameters. Determine the contact lens characteristics and record the data. As a minimum, the properties listed in Table 1 should be determined.

Table 1 — Properties and test methods

Property	Standard test method according to
Diameter (hydrogel lenses only)	ISO 9338
Curvature (rigid lenses only)	ISO 10338
Back vertex power (spherical lenses)	ISO 9337-1
Spectral transmittance	ISO 8599 (cosmetic tinted and UV-absorbing lenses only)
Physical appearance (e.g. surface defects, colour)	ISO 9341

6.1.6 Cycle the contact lenses and record the time of each cycle.

NOTE Particular attention should be given to recording the times allocated to each of the components of the regimen.

6.1.7 After cycling, again measure the contact lens characteristics in the test solution. Active-control contact lenses should be measured in the active-control solution.

6.1.8 Determine changes in contact lens characteristics and compare to the manufacturer's finished product specifications and relevant specifications and tolerances defined in ISO 8321-1 or ISO 8321-2.

6.2 Test method to distinguish reversible from irreversible changes in contact lens characteristics

6.2.1 Perform this test if the changes observed in the characteristics of the test lenses using the test method in 6.1 fall outside the manufacturer's finished product specifications and relevant specifications and tolerances given in ISO 8321-1 or ISO 8321-2.

6.2.2 Soak the same contact lenses used in 6.1 in isotonic standard saline solution (ISO 10344), and allow to equilibrate at least for 15 min or the time necessary to stabilize the contact lens parameters.

6.2.3 After equilibration and while soaking in isotonic standard saline solution (ISO 10344), measure the contact lens characteristics.

6.2.4 Determine changes from the initial values obtained in isotonic standard saline solution and compare to the manufacturer's finished product specifications and relevant specifications and tolerances defined in ISO 8321-1 or ISO 8321-2.

6.3 Interpretation of results

6.3.1 If the changes observed in the contact lens characteristics are within the manufacturer's finished product specifications and relevant specifications and tolerances defined in ISO 8321-1 or ISO 8321-2 after completing the test described in 6.1, the test product(s) is/are judged to be physically compatible with the contact lens material.

6.3.2 If the changes observed in the contact lens characteristics are within the manufacturer's finished product specifications and relevant specifications and tolerances defined in ISO 8321-1 or ISO 8321-2 after completing the test described in 6.2, the test product(s) is/are judged to be physically compatible with reversible changes with the contact lens material.

6.3.3 If the changes in the contact lens characteristics are outside the manufacturer's finished product specifications and relevant specifications and tolerances defined in ISO 8321-1 or ISO 8321-2 after completing the test described in 6.2, the test product(s) is/are judged to be physically not compatible with the contact lens material.

NOTE Pass/fail criteria for this study should be specified in the test plan.

7 Test report

The test report shall include at least the following information.

a) description of the contact lens material, the lot number and expiry date of the contact lenses;

b) description of the contact lens care product, the lot number and expiry date;

c) test protocol;

d) test results;

e) name and place of the test laboratory;

f) name of the person responsible;

g) date of testing and an approved signature.

Bibliography

[1] ISO 11539:—[3], *Ophthalmic optics — Contact lenses — Classification of contact lenses and contact lens materials.*

3) To be published.