INTERNATIONAL STANDARD

ISO 10339

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Ophthalmic optics — Contact lenses — Determination of water content of hydrogel lenses

Optique ophtalmique — Lentilles de contact — Détermination de la teneur en eau des lentilles en hydrogel

Reference number
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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.

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 10339 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

Annex A forms an integral part of this International Standard. Annexes B and C are for information only.

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Ophthalmic optics — Contact lenses — Determination of water content of hydrogel lenses

1 Scope

This International Standard describes methods for the determination of water content of hydrogel contact lenses. It specifies the procedures for making the measurements and establishes the conditions under which the measurements are to be made.

2 Normatives references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. 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 8320:1986, *Optics and optical instruments — Contact lenses — Vocabulary and symbols.*

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

3 Definitions

For the purposes of this International Standard, the definitions given in ISO 8320:1986 and the following definition apply.

3.1 water content, w_{H_2O}

Amount of water (expressed as percent by mass fraction) present in a hydrated hydrogel contact lens which is fully equilibrated with saline solution under specified conditions of temperature.

$$w_{H_2O}\ (\%) = \frac{m_{H_2O}}{m_{lens}} \times 100$$

where

m_{H_2O} is the mass of water;

m_{lens} is the mass of the hydrated lens.

NOTE — In this context, dissolved solutes such as sodium chloride and buffers contribute to the mass of the hydrated lens.

4 Procedure

The water content shall be determined by the method given in annex A.

NOTE — The methods given in annexes B and C are informative and may be used for quality control purposes only.

5 Test report

The test report shall include the following information:

a) a reference to this International Standard, i.e. ISO 10339;

b) the test method used, i.e. method given in annex A as well as, if used, the method given in annex B or C;

c) identification of the material under test;

d) the mean water content (result) of the sample, in percent (mass fraction);

e) the number of samples tested and the number of determinations per sample;

f) the date of the test.

Annex A
(normative)

Gravimetric determination of water content of hydrogel lens by loss on drying using conventional oven

A.1 Principle

Test hydrogel lenses in their fully hydrated state are weighed on an analytical balance. The lenses are then dried in an oven and weighed again. The difference in masses is the mass of water lost by evaporation and represents the mass of water present in the fully hydrated lens.

A.2 Precision

The accuracy of this method is limited by the difficulty of reliably "wet-blotting" the lens before determining the hydrated mass. To minimize the error in blotting technique, the mass of the hydrated sample should be between 100 mg and 300 mg.

The result of a ring test demonstrated that multiple (3) determinations on thick polymer discs gave a tolerance of ± 0,4 % water content. For a lens of the mass stated in this International Standard, a reproducibility on the order of ± 1,0 % water content was likely. If the sample mass is less than 100 mg, more samples may be required for measurement in order to obtain the stated reproducibility.

A.3 Apparatus

A.3.1 Analytical balance, capable of weighing to 0,1 mg.

A.3.2 Laboratory oven, capable of being maintained at (105 ± 5) °C.

A.3.3 Glass microscope slides.

A.3.4 Desiccator containing active desiccant (e.g. anhydrous calcium sulfate, $CaSO_4$).

A.3.5 Water bath, capable of being maintained at (20 ± 0,5) °C.

A.3.6 Saline solution complying with ISO 10344.

A.3.7 Whatman No. 1 **filter paper** [1]; or clean dry cloth of lint-free cotton, linen or microfibre.

1) Whatman No. 1 filter paper is the tradename of a product supplied by Whatman, Inc., 9 Bridewell Place, Clifton N.J., USA 07014. This information is given for the convenience of users of this International Standard and does not constitute an endorsement by ISO of the product named. Equivalent products may be used if they can be shown to lead to the same results.

A.4 Procedure

A.4.1 Equilibrate the test lenses, suspended in saline solution, at the temperature of the water bath (20 ± 0,5) °C for at least 1 h.

A.4.2 For each test lens, dry one glass slide to constant mass in the oven. Store the dried slide in the desiccator. Weigh the slide immediately before use (m_0).

A.4.3 Carry out the test at a room temperature of (20 ± 0,5) °C. Carefully blot each test sample by one of the following methods (see note below);

a) Place the sample on a clean dry lint-free cotton, linen or microfibre cloth. Fold the cloth over the sample and absorb unimbibed water by lightly pressing three times with a finger tip.

b) Place the sample between two sheets of barely dampened Whatman No. 1 filter paper.

NOTE — The purpose of blotting is to remove unimbibed water from the surface of the test sample. It is necessary to avoid partial dehydration of the surface by over-blotting. Evaporation can also occur if the procedure is not carried out rapidly.

The likelihood of over-blotting is more prevalent with the dry cloth technique [A.4.3 a)] which could lead to an underestimate of the true water content. Conversely, blotting with the dampened paper [A.4.3 b)] may not remove all surface droplets and could lead to an overestimate of the true water content.

Thus the accuracy of the method is limited by difficulty in reliably carrying out the blotting procedure. Hence, the operator should become proficient at the blotting technique before proceeding.

A.4.4 Immediately place the blotted lens on the previously dried and weighed glass slide. Weigh the slide and the sample (m_1).

Perform the blotting and weighing steps as quickly as possible to minimize loss of water by evaporation.

A.4.5 With the lens on the slide, dry the lens in the oven until constant mass is achieved. Allow to cool in the desiccator for at least 30 min and then reweigh (m_2).

NOTE — Drying to constant mass normally takes 16 h to 18 h.

A.5 Calculation of results

Calculate the water content w_{H_2O} as a percentage (mass fraction) using the following equation:

$$w_{H_2O} = \frac{m_1 - m_2}{m_1 - m_0} \times 100$$

where

m_0 is the mass of the slide;

m_1 is the mass of the hydrated lens and the slide;

m_2 is the mass of the dried lens and the slide.

Annex B
(informative)

Gravimetric determination of water content of hydrogel lens by loss on drying using a microwave oven

B.1 Principle

This method is identical to that described in annex A except that the lenses are dried in a microwave oven rather than in a conventional oven. It offers the advantage of greater speed. However, accuracy is still limited by the reliability of the blotting technique. To minimize the error in blotting technique, the mass of the hydrated sample should be between 100 mg and 300 mg.

B.2 Apparatus

B.2.1 Analytical balance, capable of weighing to 0,1 mg.

B.2.2 Microwave oven fitted with a rotating stage, with a capacity of between 0,015 m^3 and 0,05 m^3 and with a maximum power output of between 500 W and 650 W.

B.2.3 Glass specimen jars (approximately 20 ml volume, 28 mm outside diameter and 58 mm high) with microwave-compatible plastic screw cap closures.

B.2.4 Discs of polytetrafluoroethylene (PTFE).

B.2.5 Desiccator, containing active desiccant (e.g. anhydrous calcium sulfate, $CaSO_4$).

B.2.6 Saline solution complying with ISO 10344.

B.2.7 Water bath, capable of being maintained at (20 ± 0,5) °C.

B.2.8 Whatman No. 1 **filter paper** [1], or clean dry cloth of lint-free cotton, linen, or microfibre.

B.3 Procedure

B.3.1 Equilibrate the test lenses as described in A.4.1.

B.3.2 For each test lens, weigh a dry PTFE disc (m_0).

B.3.3 For each test lens, prepare a specimen jar (B.2.3) by approximately half filling it with active desiccant.

B.3.4 Carry out the test at a room temperature of (20 ± 5) °C. Blot each test lens as described in A.4.3. Immediately place the blotted lens on the previously dried and weighed PTFE disc and weigh the disc and sample (m_1). Perform the blotting and weighing steps as quickly as possible to minimize loss of water by evaporation.

B.3.5 After weighing the disc and hydrated sample, place the disc and sample in the specimen jar (B.3.3). Close the jar and place it in the microwave oven. Run the oven at its maximum power for 10 min. Remove the jar and allow it to cool in the desiccator for at least 30 min. Remove the disc and lens from the jar and reweigh to obtain the dry mass (m_2).

B.3.6 Repeat B.3.5 using another active supply of desiccant until the lens sample reaches constant mass.

B.4 Calculation of results

Calculate the water content as a percentage (mass fraction) using the equation given in A.5.

Annex C
(informative)

Determination of water content of hydrogel lens by refractive index

C.1 Principle

The refractive index of hydrogel contact lens material is a function of its relative water and solid contents. Therefore, measurement of refractive index provides a fast and non-destructive method for determining the water content. Moreover, the method is not dependent on wet-blotting techniques. It has been shown that the standard sucrose solution tables of dissolved solids content as a function of refractive index provide an estimate of the water content of hydrogel contact lenses. For an absolute measurement, the refractive index in both the hydrated and the dehydrated states has to be measured.

C.2 Apparatus

C.2.1 Abbé refractometer, equipped with constant-temperature circulation.

C.2.2 Constant-temperature water bath, capable of being maintained at (20 ± 0,5) °C.

C.2.3 Saline solution complying with ISO 10344.

C.3 Procedure

C.3.1 Equilibrate each test lens, suspended in saline solution, at the temperature of the water bath (20 ± 0,5) °C for at least 1 h.

C.3.2 Clean the refractometer prism surface with methanol and wipe dry with a lint-free tissue.

C.3.3 Carry out the test at room temperature (20 ± 5) °C. Remove the equilibrated test lens from the saline solution and touch slightly with a lint-free cloth or tissue to remove gross excess solution.

C.3.4 Immediately place the test lens on the measurement prism. Close the prism case with care, ensuring complete contact between the mating surfaces of the prism and the test lens.

NOTE — The pliable nature of the hydrogel lens means that, unlike the measurement of refractive index of other solids, no contact liquid is required.

C.3.5 Adjust the illuminator for best contrast in the reflection borderline. Set the borderline on the crosshair intersection and correct for colour dispersion with the compensator.

NOTE — When properly corrected, the borderline should be achromatic in the centre, faintly blue on one end, and faintly red at the other. Achromatic compensations are not needed if monochromatic light is used in the refractometer.

C.3.6 Switch on the scale illumination and read the value for the refractive index or percent total solids.

C.3.7 The tables for sucrose solutions (see tables C.1 and C.2) provide the percent of dissolved solids. Therefore, the water content w_{H_2O} of the test lens is obtained by subtracting the table value from 100.