INTERNATIONAL STANDARD

ISO 10344

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Optics and optical instruments — Contact lenses — Saline solution for contact lens testing

Optique et instruments d'optique — Lentilles de contact — Solution saline pour les essais des lentilles de contact

Reference number
ISO 10344:1996(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 10344 was prepared by Technical Committee 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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Optics and optical instruments — Contact lenses — Saline solution for contact lens testing

1 Scope

This International Standard specifies a saline solution for use when conducting specified standardized test methods to determine dimensional, physical, chemical and biological characteristics of contact lenses and contact lens materials.

The specified solution is applicable to the equilibrating of either a contact lens or a contact lens material prior to testing, and also to the immersion of the test item during testing.

The specified solution is not intended for the purpose of packaging finished contact lenses but is similar to many commercially used contact lens packaging solutions.

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 3696:1987, *Water for analytical laboratory use — Specification and test methods.*

ISO 8320:1986, *Optics and optical instruments — Contact lenses — Vocabulary and symbols.*

3 Definitions

For the purposes of this International Standard, the definitions given in ISO 8320 apply.

4 Requirements

4.1 General

The standard saline solution shall be phosphate buffered at a pH of 7,4 ± 0,1 and have a nominal osmolarity of 310 mOsm/kg.

4.2 Ingredients

The standard saline shall be prepared using hydrated sodium phosphate salts which comply with the requirements of monographs in current official pharmacopoeia such as the US Pharmacopoeia (USP), the European Pharmacopoeia (Ph Eur) or various national pharmacopoeia. The liquid phase is water complying with ISO 3696:1987, grade 3 or any purer standardized grade. Water shall be either freshly prepared or sterilized within 24 h of preparation of the standard solution.

4.3 Formulation in molarities

The following molar concentrations shall be applicable to the finished solution.

a) sodium chloride (NaCl) $1{,}420 \times 10^{-1}$ M

b) sodium dihydrogen phosphate (NaH_2PO_4) $3{,}384 \times 10^{-3}$ M

c) disodium phosphate (Na_2HPO_4) $1{,}673 \times 10^{-2}$ M

4.4 Formula example using USP substances

a) sodium chloride USP (NaCl) 8,300 g

b) monobasic sodium phosphate monohydrate USP ($NaH_2PO_4 \cdot H_2O$) 0,467 g

c) dibasic sodium phosphate heptahydrate USP ($Na_2HPO_4 \cdot 7H_2O$) 4,486 g

d) water according to ISO 3696:1987, grade 3 (H_2O) qs 1 000 ml

4.5 Formula example using Ph Eur substances

a) NATRII CHLORIDUM Ph Eur (NaCl) 8,300 g

b) NATRII DIHYDROGENOPHOSPHAS DIHYDRICUS Ph Eur ($NaH_2PO_4 \cdot 2H_2O$) 0,528 g

c) DINATRII PHOSPHAS DODECAHYDRICUS Ph Eur ($Na_2HPO_4 \cdot 12H_2O$) 5,993 g

d) water according to ISO 3696:1987, grade 3 (H_2O) qs 1 000 ml

4.6 Formula example using anhydrous substances

NOTE 1 As these are not all pharmacopoeial substances, this example is for information only.

a)	NaCl	8,300 g
b)	NaH_2PO_4	0,406 g
c)	Na_2HPO_4	2,376 g
d)	H_2O qs	1 000 ml

5 Preparation procedure

5.1 General

As the hydrated phosphates of sodium may vary in the number of molecules of water of hydration, depending on the type and period of exposure to the atmosphere and thus affecting their formula mass, the formulations given in 4.4 to 4.6 may not achieve the required molarity and therefore the pH of 7,4 ± 0,1. In this sense the saline is not a "standard" until provision has been made to adjust the solution using a standardized pH-meter with standardized reference solutions for calibration (e.g. BS 1647 and BS 3145). To adjust the solution, either aqueous orthophosphoric acid (e.g. 5 M) or aqueous sodium hydroxide (e.g. 5 M) should be added after the ingredients have been dissolved in the water. Only a small amount of adjustment (less than 1 ml/l) is normal.

5.2 Formulating the solution

The three ingredients are sequentially added to 70 percent of the water (700 ml in the examples given in 4.4 to 4.6), ensuring that all are completely dissolved by proper mixing.

This solution is tested with a standardized calibrated pH-meter and adjusted by dropwise addition of either acid or alkali (see 5.1) to a pH of 7,4 ± 0,1. Dilute the adjusted solution with water to a volume of 1 000 ml, mix thoroughly and test the pH again. If necessary, add more acid or alkali.

5.3 Packaging and labelling

If the saline is to be retained, it shall be packaged in autoclavable containers, preferably of neutral glass, and sterilized by a validated process. The closures shall be airtight.

Labelling shall include:

a) reference to this International Standard (i.e. ISO 10344);

b) a description (e.g. standard saline for contact lens testing);

c) the date of preparation.

If the saline is not to be stored, it shall be used within 24 h of preparation and need not be autoclaved.

Annex A
(informative)

Bibliography

[1] BS 1647: *pH measurement*, Part 2:1984(1991), *Specification for reference value standard solutions and operational reference standard solutions.*

[2] BS 3145:1978(1993), *Specification for laboratory pH meters.*

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