

INTERNATIONAL STANDARD

ISO
10344

First edition
1996-09-01

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)
Documents



Document Sharing Hub

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.

© ISO 1996

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from the publisher.

International Organization for Standardization
Case Postale 56 • CH-1211 Genève 20 • Switzerland

Printed in Switzerland

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 $7,4 \pm 0,1$ 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