AMERICAN NATIONAL STANDARD

OLA®

for Ophthalmics –

Contact Lens Care Products – Vocabulary, Performance Specifications and Test Methodology

ANSI®
Z80.18-2003

American National Standard
for Ophthalmics –

Contact Lens Care Products – Vocabulary, Performance Specifications and Test Methodology

Secretariat

Optical Laboratories Association

Approved May 1, 2003

American National Standards Institute, Inc.

American National Standard

Approval of an American National Standard requires review by ANSI that the requirements for due process, consensus, and other criteria for approval have been met by the standards developer.

Consensus is established when, in the judgement of the ANSI Board of Standards Review, substantial agreement has been reached by directly and materially affected interests. Substantial agreement means much more than a simple majority, but not necessarily unanimity. Consensus requires that all views and objections be considered, and that a concerted effort be made towards their resolution.

The use of American National Standards is completely voluntary; their existence does not in any respect preclude anyone, whether he has approved the standards or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standards.

The American National Standards Institute does not develop standards and will in no circumstances give an interpretation of any American National Standard. Moreover, no person shall have the right or authority to issue an interpretation of an American National Standard in the name of the American National Standards Institute. Requests for interpretations should be addressed to the secretariat or sponsor whose name appears on the title page of this standard.

CAUTION NOTICE: This American National Standard may be revised or withdrawn at any time. The procedures of the American National Standards Institute require that action be taken periodically to reaffirm, revise, or withdraw this standard. Purchasers of American National Standards may receive current information on all standards by calling or writing the American National Standards Institute.

Developed by

The Accredited Committee Z80 for Ophthalmic Standards -

Optical Laboratories Association
Z80 Secretariat
P. O. Box 2000
Merrifield, VA 22116-2000

Published by

Optical Laboratories Association
P. O. Box 2000
Merrifield, VA 22116-2000

Printed in the United States of America

Contents

Page

Foreword ii

1 Scope 1

2 Normative References 1

3 Vocabulary 3

3.1 General Terms Relating to Contact Lens Care Products - ISO 8320-2 3

3.2 Specific Terms Relating to Contact Lens Care Products - ISO 8320-2 4

4 General Specifications of Contact Lens Care Products 7

5 Standard Test Methods 8

5.1 Physicochemical Methods 8

5.1.1 Preservative Uptake and Release - ISO 11986 8

5.1.2 Determination of Shelf-life - ISO 13212 8

5.1.3 Lens Compatibility - ISO 11981 8

5.1.4 Cleaning Effectiveness - FDA Guidance 9

5.2 Toxicology 9

5.2.1 *In vitro* Cytotoxicity - ISO 10993-5 9

5.2.2 Acute Ocular Irritation - ISO 9394 or USP/NF XXII 10

5.2.3 Acute Oral Toxicity - FDA Guidance 10

5.2.4 Sensitization (Guinea Pig Maximization) - FDA Guidance 10

5.2.5 *In vivo* Ocular Biocompatibility - ISO 9394 11

5.2.6 Toxicology Tests for Containers and Plastic Accessories - USP24 11

5.3 Microbiology 11

5.3.1 Sterility - FDA Guidance 11

5.3.2 Validation of Sterilization of Solutions and Containers 12

5.3.3 Microbial Limits Non-sterile Solids - ISO 14534 & USP24 12

5.3.4 Preservative Effectiveness - ISO 14730 12

5.3.5 Disinfection Effectiveness - ISO 14729 13

Foreword (This foreword is not part of American National Standard ANSI Z80.18-2003.)

The Z80 Committee for Ophthalmic Standards was organized in 1956, and the committee's initial standard was issued in 1964 as *American National Standard Institute Requirements for First Quality Glass Ophthalmic Lenses*, ANSI Z80.1-1964. Through the years, a number of changes in the scope of the committee were made. Subsequently the scope of the subcommittee has been broadened to the establishment of standards that shall apply to ophthalmic lenses and to equipment, instruments and to processes used in the final fabrication level that may affect their performance; to ophthalmic frames, sunglasses, and fashion eyewear; to contact lenses and their accessories for use; to intraocular implant lenses; to low vision aids and ophthalmic procedures and vision evaluation.

In 1982, the Optical Laboratories Association (OLA) assumed the responsibilities of the Secretariat, and, in 1985, the Z80 Committee became an Accredited Standards Committee. Currently, ophthalmic standards are drafted by subcommittees of the Z80 committee, which in turn may establish working groups to address specific detailed areas of interest.

In the past decade, the Subcommittee for Contact Lenses has provided delegates to the International Standards Organization to represent the American National Standards Institute's role in developing and approving contact lens care products standards for the international community. During the many sessions to accomplish this task, it became apparent to these delegates that an approved American position regarding standards for contact lenses and contact lens products is a necessity before an international standard can be approved by these delegates. As a result of this observation, the delegates began the task of supplying information to the various ISO working groups and, at the same time, including this information and other information that will appear in ISO standards in an American document that would receive the consensus approval of the Z80 Committee on Ophthalmic Standards. The culmination of this dual project is seen here as ANSI Z80.18-2003. Future reviews or revisions of this standard will ensure that the continued participation of American delegates to ISO will be supported by a document that has received a consensus by Z80 Committee for Ophthalmic Standards.

Suggestions for improvement of this standard will be welcome. They should be sent to the Optical Laboratories Association, P.O. Box 2000, Merrifield, VA 22116-2000, U.S.A.

This standard was processed and approved for submittal to ANSI by the Accredited Standards Committee on Ophthalmic Standards, Z80. Committee approval of this standard does not necessarily imply that all committee members voted for its approval. At the time it approved this standard, the Z80 Committee had the following members:

Thomas C. White, M.D., Chairman
Quido A. Cappelli, P.E., Vice-Chairman
Robert Rosenberg, O.D., Secretary

Organization Represented	*Name of Representative*
AR Council	Scott Rickert
	Lee K. Anderson (Alt.)
	Mark Imus (Alt.)
	Don Quinn (Alt.)
Advance Medical Technologies Association	Douglas J. Fortunato
	Carolyn Jones (Alt.)
	Glenn Davies (Alt.)
	Stanley J. Rogaski (Alt.)
American Acadamy of Optometry	David S. Loshin
American Academy of Ophthalmology	Thomas C. White
	Gerhard Cibis (Alt.)
	Keith Baratz (Alt.)
	Paul F. Vinger (Alt.)
American Optometric Association	Donald Pitts
	William J. Benjamin (Alt.)
	Robert Rosenberg (Alt.)
	Jeffrey Weaver (Alt.)
American Society of Cateract and Refractive Surgery	John J. Alpar
	Jack T. Holladay (Alt.)
	Stephen H. Johnson (Alt.)
Contact Lens Institute	Ed Schilling
Contact Lens Manufacturers Association	Quido Cappelli
Food & Drug Administration	David Whipple
	Donald Calogero (Alt.)
	Robert Landry (Alt.)
	Ashley Boam (Alt.)
National Association of Optometrists & Opticians	Arthur Newman
National Academy of Opticianry	Jeffrey C. Snodgrass
	Floyd Holmgrain (Alt.)
Optical Laboratories Association	Daniel Torgersen
	Henry A. Hart (Alt.)
Optical Society of America	Richard A. Phillips
Opticians Association of America	Mike Robey
Prevent Blindness	Jeff Todd
Sunglass Association of America	Thomas Loomis
	Kenneth L. Frederick (Alt.)
	James Pritts (Alt.)
	Rick Van Arnam (Alt.)
US Leader to ISO TC 172/SC7	Charles E. Campbell
Veterans Administration	John Townsend
	Sharon R. Atkin (Alt.)
Vision Council of America	Kenneth O. Wood
	Steve Drake (Alt.)
	Michelle Princi (Alt.)
	Neil Roche (Alt.)
	Dick Whitney (Alt.)

The subcommittee on Ophthalmic Instruments, which modified the ISO standard, had the following members:

Quido A. Cappelli, Chairman

Claude Anger
William Joe Benjamin
Genn Davies
Douglas Fortunato
Michael Miller
Mary Mowrey McKee
Arthur Newman
Paul Nowacki
Michael Pfleger
C. Richard Sanders
Karen Warburton
David Whipple
Barry Van Duzee

American National Standard
for Ophthalmics –

Contact Lens Care Products – Vocabulary, Performance Specifications and Test Methodology

1 Scope

This American National Standard applies to contact lens care products (CLCP) that are marketed for use with hard (PMMA), rigid gas permeable (RGP), and soft hydrophilic contact lenses. These products are intended for use in the care of contact lenses: e.g., rinsing, storing, disinfection, conditioning, neutralization, cleaning, hydration, and/or for alleviating discomfort of lens wear and improving lens tolerance by physical means.

This standard provides test methodology to be used in developing performance specifications of CLCP by function and, where appropriate, provides acceptable performance specifications for specific products. It also addresses general requirements for CLCP based upon physical state of the marketed product (solutions, granules, and tablets), the packaging configuration (including conventional plastic container, aerosol container, form-fill-seal, or blister pack), and mode of use (unit dose or multi-dose).

2 Normative References

The following standards contain provisions which, through reference in this text, constitute provisions of this American National Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards listed below. Members of IEC and ISO maintain registers of currently valid standards.

ANSI Z80.20-1998, *Ophthalmics – Contact Lenses – Standard Terminology, Tolerances, Measurements and Physicochemical Properties*

ANSI/AAMI/ISO 11134:1993, *Sterilization of health care products – Requirements for validation and routine control – Industrial moist heat sterilization*

ANSI/AAMI/ISO 11135:1993, *Medical devices – Validation and routine control of ethylene oxide sterilization*

ANSI/AAMI/ISO 11137:1995, *Sterilization of health care products – Requirements for validation and routine control – Radiation sterilization*

ISO 8320-2:2001, *Contact lenses and contact lens care products - Vocabulary - Part 2: Contact lens care products*

ISO 9363-1:1994, *Optics and optical instruments – Contact lenses – Determination of cytotoxicity of contact lens material – Part 1: Agar overlay test and growth inhibition test*