

American National Standard

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



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ANSI®
Z80.18-2010
Revision of
ANSI Z80.18-2003

American National Standard
for Ophthalmics –

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

Secretariat
The Vision Council

Approved October 25, 2010
American National Standards Institute, Inc.

American National Standard

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Developed by

The Accredited Committee Z80 for Ophthalmic Standards -

The Vision Council
225 Reinekers Lane
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Alexandria, VA 22314

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Contents

	Page
Foreword	ii
1 Scope.....	1
2 References.....	1
3 Vocabulary	3
3.1 General Terms Relating to Contact Lens Care Products - ISO 18369-1	3
3.2 Specific Terms Relating to Contact Lens Care Products - ISO 18469-1	3
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	9
5.1.4 Cleaning Effectiveness - FDA Guidance	9
5.2 Toxicology.....	9
5.2.1 <i>in vitro</i> Cytotoxicity - ISO 10993-5	9
5.2.2 Acute Ocular Irritation - USFDA, XX, ISO 10993-10.....	10
5.2.3 Acute Oral Toxicity - FDA Guidance.....	10
5.2.4 Sensitization (Guinea Pig Maximization Test) - FDA Guidance, ISO 10993-10	10
5.2.5 <i>in vivo</i> Ocular Biocompatibility - ISO 9394.....	11
5.2.6 Toxicology Tests for Containers and Plastic Accessories - Current USP, ISO 10993-10	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 & Current USP.....	12
5.3.4 Preservative Effectiveness - ISO 14730	13
5.3.5 Disinfection Effectiveness - ISO 14729.....	13

Foreword (This foreword is not part of American National Standard ANSI Z80.18-2010.)

The Z80 Committee for Ophthalmics was organized in 1956, and the committee's initial standard on ophthalmic lenses was issued in 1964. In the ensuing years the committee expanded its scope and organization into a number of subcommittees, each charged with specific areas of responsibility. One of these, The Subcommittee for Contact Lenses, has published two standards (Insert names) which are dutifully reviewed on a five year basis to include any newly established information.

Since 1980, the Subcommittee for Contact Lenses has provided delegates to the International Standards Organization to represent the American Standards Institute's role (for the United States) in developing and approving contact lens and contact lens care products standards for the international community. In providing this service for ANSI it became apparent that the role of the delegates continued to require reaffirmation from the American community as a whole to support their input. Thus in addition to providing information to the international forum the Subcommittee for Contact Lenses continues to process all available information through its ANSI network.

This latest version of Z80.18 meets that objective while ensuring that the US standard is in conformance with the International Standard. Thus this revision of Z80.18 and future reviews or revisions of this standard will ensure that the continued participation of American delegates to ISO will be supported by an American standard that has received a consensus by the Z80 Committee for Ophthalmic standards in addition to other American interests.

Suggestions for improvement of this standard will be welcome. They should be sent to The Vision Council, 225 Reinekers Lane, Suite 700 Alexandria, VA 22314.

At the time it approved this standard, the Z80 Committee had the following members:

Thomas C. White, M.D., Chair
Quido Cappelli, Vice-Chair
Robert Rosenberg, O.D., Secretary
Kenneth Wood, Secretariat

<i>Organization Represented</i>	<i>Name of Representative</i>
Advance Medical Technologies Association	Douglas Fortunato
American Academy of Ophthalmology	Thomas White
American Academy of Optometry	David Loshin
American Ceramic Society	Lyle Rubin
American Glaucoma Society	Steven Gedde
American Optometric Association	Jeffrey Weaver
American Society of Contact and Refractive Ophthalmology.....	Stephen Klyce
Contact Lens Institute	Stan Rogaski
Contact Lens Manufacturers Association	Quido Cappelli
Department of Veterans Affairs	John Townsend
Federated Cornea Societies/ASCRS	Dr. Michael Belin
Food & Drug Administration CDRH/ Division of Federal Agencies	Don Calogero
National Association of Optometrists & Opticians	Nick Mileti
Optical Laboratory Association	Daniel Torgersen
Opticians Association of America	Tom Hicks
Sunglass Association of America	Kenneth L. Frederick
The Vision Council	Jeff Endres
U.S. ISO TC 172/SC7	Charles Campbell

The individuals who worked on the revision of ANSI Z80.18 were:

William J. Benjamin (American Optometric Association)	Ling Huang (Abbott Medical Optics)	Stan Rogaski (Contact Lens Institute)
Roya Borazjani (Alcon Laboratories, Inc.)	Joe Hutter (US Food and Drug Administration)	Karen Sentell (CIBA Vision Corporation)
Gary Collins (Johnson & Johnson Vision Care)	Nia Kao (Abbott Medical Optics)	Megan Shoff (US Food and Drug Administration)
James Cook (Abbott Medical Optics)	Simon Kilvington (Abbott Medical Optics)	Ralph Stone (R. P. Stone Consulting, Inc.)
Richard Courtney (Johnson & Johnson Vision Care)	Kim Kracke (Alcon Laboratories, Inc.)	John Walfort (Contact Lens Manufacturers Association)
Glenn Davies (Bausch & Lomb, Inc.)	John Lally (Alcon Laboratories, Inc.)	Michael Marks (Alcon Laboratories, Inc.)
Doug Fortunato (Bausch & Lomb, Inc.)	Michael Marks (Alcon Laboratories, Inc.)	Karen Warburton (US Food and Drug Administration)
Steve Galas (Johnson & Johnson Vision Care)	Dave Meadows (Alcon Laboratories, Inc.)	Patricia Benz (Benz R&D)
Angelo Greene (US Food and Drug Administration)	Mary Mowry-McKee (CIBA Vision Corporation)	Thomas White (American Academy of Ophthalmology)
Denise Hampton (US Food and Drug Administration)	Sue Norton (Bausch & Lomb, Inc.)	
	James O'Donnell (CIBA Vision Corporation)	
	Samuel Puig (Cooper Vision Corporation)	

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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) which are marketed for use with hard (PMMA), rigid gas permeable (RGP), enhanced oxygen permeable materials, 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 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.

2.1 Normative References

ANSI Z80.20-2010, *Ophthalmics – Contact Lenses – Standard Terminology, Tolerances, Measurements and Physicochemical Properties*

ANSI/AAMI/ISO TIR 11129, *Sterilization of health care products-Vocabulary*

ANSI/AAMI/ISO 11634, *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems, and packaging*

ANSI/AAMI T61, *Sterilization of medical devices – Requirements for products labeled “Sterile”*

ISO 17665, *Sterilization of health care products – Moist heat – Part 1: Requirements for development, validation and routine control of sterilization process for medical devices*

ISO 11135-1, *Medical devices – Validation and routine control of ethylene oxide sterilization*

ISO 11137-1, *Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*