American National Standard

for Ophthalmics –

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

ANSI Z80.18-2010

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

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Published by

The Vision Council
225 Reinekers Lane
Suite 700
Alexandris, VA 22314

Printed in the United States of America

Contents

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 America 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

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American Ceramic Society	Lyle Rubin
American Glaucoma Society	Steven Gedde
American Optometric Association	Jeffrey Weaver
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Contact Lens Institute	Stan Rogaski
Contact Lens Manufacturers Association	Quido Cappelli
Department of Veterans Affairs	John Townsend
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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 11139, *Sterilization of health care products-Vocabulary*

ANSI/AAMI/ISO 11607-1, *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems, and packaging*

ANSI/AAMI ST67, *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*