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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 11417.8-2023

Replacing GB/T 11417.8-2012

Ophthalmic optics - Contact lenses - Part 8: Determination of shelf-life

Issued on: September 7, 2023 **Implemented on: October 1, 2024**

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1.Structure and Drafting Rules of Standardization Documents"

Drafting.

GB (/T)11417 "Ophthalmic Optical Contact Lenses", GB/T 28538 "Ophthalmic Optical Contact Lenses and Contact Lens Care Products Rabbit Eye Phase"

Capacitance Research Test" and GB/T 28539 "Determination Instructions for Intake and Release of Preservatives in Ophthalmic Optical Contact Lenses and Contact Lens Care Products

"South" together constitute a series of national standards for contact lenses.

This document is Part 8 of GB (/T)11417 "Ophthalmic Optical Contact Lenses". GB (/T)11417 has released the following parts.

---Part 1.Vocabulary, classification and recommended identification specifications;

---Part 2.Rigid contact lenses;

---Part 3.Soft contact lenses;

---Part 4.Standard salt solution for testing;

---Part 5.Optical performance test methods;

---Part 6.Mechanical property test methods;

---Part 7.Physical and chemical property test methods;

---Part 8.Determination of validity period;

---Part 9.Ultraviolet and visible light radiation aging test (in vitro method).

This document replaces GB/T 11417.8-2012 "Ophthalmic optical contact lenses - Part

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8.Determination of validity period" and is consistent with GB/T 11417.8-

Compared with.2012, in addition to structural adjustments and editorial changes, the main technical changes are as follows.

---Changed the "scope" (see Chapter 1, Chapter 1 of the.2012 edition);

---Added "Terms and Definitions" (see Chapter 3);

---Changed the "principle" (see Chapter 4, Chapter 3 of the.2012 edition);

---Deleted "preservation solution" (see Chapter 4 of the.2012 edition);

---Added "General requirements and recommendations" (see Chapter 5);

---Added "test medium" (see Chapter 6);

---Changed the "test device" (see Chapter 7, Chapter 5 of the.2012 edition);

---Changed the "test sample" (see Chapter 8, Chapter 6 of the.2012 edition);

---Changed the "Test Procedure" (see Chapter 9, Chapter 7 of the.2012 edition);

---Changed the "result expression" (see Chapter 10, Chapter 8 of the.2012 edition);

---Changed the "Test Report" (see Chapter 11, Chapter 9 of the.2012 edition).

This document has been modified to adopt ISO 11987.2012 "Determination of validity period of ophthalmic optical contact lenses".

The technical differences between this document and ISO 11987.2012 and their reasons are as follows.

---Changed the "scope" (see Chapter 1) to make it more clear;

---Replaced ISO 18369-1 (see Chapter 3) with normatively cited GB/T 11417.1 to adapt to my country's technical conditions, adding

Increase operability;

---Replaced ISO 18369-3 (see 6.2) with normatively cited GB/T 11417.4 to adapt to my country's technical conditions and increase the availability

operability;

---Replaced ISO 18369-3 (see 9.1.6, 9.2.7) with normatively quoted GB/T 11417.5 to adapt to my country's technical conditions

parts to increase operability;

--- Added normative references to GB 11417.2, GB 11417.3, and GB/T 11417.6 (see 9.1.4, 9.2.5, 9.1.5, 9.2.6), deleted

In addition to ISO 18369-2, to adapt to my country's technical conditions and increase

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operability;

---Changed the content of "test medium" (see 6.2) to make it clearer;

---Changed the content of "light transmission performance" (see 7.2, 9.1.6, 9.2.7) to make it more clear;

--- Added packaging requirements for contact lenses provided in non-sterile ways (see 8.3) to make the regulations clearer;

---Contact lenses provided in a sterile manner (see 9.1.7, 9.2.8) have been changed to make their provisions clearer.

This document also has the following editorial changes.

---Change the name of the standard to "Ophthalmic Optical Contact Lenses Part 8.Determination of Validity Period";

---Changed the expression of monitoring parameters (see 8.4);

---Added "Chinese Pharmacopoeia" (see 9.1.7, 9.2.8);

---Changed "References".

Please note that some content in this document may be subject to patents. The publisher of this document assumes no responsibility for identifying patents.

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Introduction

GB (/T)11417 "Ophthalmic Optical Contact Lenses" is planned to be divided into the following parts.

---Part 1.Vocabulary, classification and recommended identification specifications. The purpose is to prescribe the terms and definitions for contact lenses;

---Part 2.Rigid contact lenses. The purpose is to specify performance requirements for rigid contact lenses;

---Part 3.Soft contact lenses. The purpose is to specify the performance requirements for soft contact lenses;

---Part 4.Standard salt solution for testing. The purpose is to provide specifications for standard salt solutions for contact lens testing;

---Part 5.Optical performance test methods. The purpose is to specify test methods for the optical properties of contact lenses;

---Part 6.Mechanical property test methods. The purpose is to specify test methods for the mechanical properties of contact lenses;

---Part 7.Physical and chemical property test methods. The purpose is to specify test

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methods for the physical and chemical properties of contact lens materials;

---Part 8.Determination of validity period. The purpose is to specify test procedures for the stability of contact lenses during storage;

---Part 9.Ultraviolet and visible light radiation aging test (in vitro method). The purpose is to regulate the aging of contact lenses under simulated sunlight exposure.

chemical in vitro test methods.

The tests covered in this document were designed to obtain information to enable recommendations to be made on the shelf life and recommended storage conditions of contact lenses. Ran

However, in reality, what needs to be tested is the stability of the materials used in the contact lenses and the integrity of the packaging to maintain the environment required by the contact lenses. stability

The purpose of the study was to determine how contact lens quality changes over time and under the influence of various environmental factors. According to the information obtained

information, recommending storage conditions to ensure that the quality of contact lenses is safe throughout the expected period of validity (e.g. during storage, until the time of prescription).

safety, effectiveness and acceptability.

Ophthalmic optical contact lenses

Part 8.Determination of validity period

1 Scope

This document establishes testing procedures for the stability of contact lenses during storage after final packaging.

This document applies to contact lenses.

Note. The test results can be used to determine the packaging expiration date of the lens.

2 Normative reference documents

The contents of the following documents constitute essential provisions of this document through normative references in the text. Among them, the dated quotations

For undated referenced documents, only the version corresponding to that date applies to this document; for undated referenced documents, the latest version (including all amendments) applies to

this document.

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