ICS 11.040.70
CCS C40

NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 28539-2023

Replacing GB/T 28539-2012

Ophthalmic optics - Contact lenses and contact lens care products - Determination of preservative uptake and release

眼科光学 接触镜和接触镜护理产品 防腐剂摄入和释放的测定

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

Issued by: State Administration for Market Regulation;
Standardization Administration of the PRC

Table of Contents

Foreword

This document was issued on 7 September 2023 by the State Administration for Market Regulation; Standardization Administration of the PRC and takes effect on 1 October 2024.

It is a GB/T standard: recommended rather than compulsory, but it is the text a Chinese reviewer applies when assessing a submission.

It is classified under ICS 11.040.70, Chinese classification C40.

It replaces GB/T 28539-2012, which is superseded.

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.

This document replaces GB/T 28539-2012 "Intake and release of preservatives in ophthalmic optical contact lenses and contact lens care products"

"Measurement Guide", compared with GB/T 28539-2012, in addition to structural adjustments and editorial changes, the main technical changes are as follows.

---Changed the release time and process (see Chapter 4, Chapter 3 of the.2012 edition);

---Added the requirements for the volume of test fluid and changed the requirements for the number of contact lenses (see 5.1, 4.1 of the.2012 edition);

---Changed the process of extracting the test fluid for the ingestion test (see 5.2, 4.2 of the.2012 edition);

---Changed the process of extracting the standard salt solution for the release test (see 5.3, 4.3 of the.2012 version);

---Added the formula for calculating the preservative intake and release rate. The preservative intake and release amounts in the test report are expressed in "ug/piece"

expression, as well as the expression of preservative uptake and release rates in the test report (see Chapter 6, Chapter 5 of the.2012 edition).

This document has been modified to adopt ISO 11986.2017 "Preservative uptake and release in ophthalmic optical contact lenses and contact lens care products"

Determination".

The technical differences between this document and ISO 11986.2017 and their reasons are as follows.

---Replaced ISO 18369-3.2017 with normatively cited GB/T 11417.4 (see Chapter 4, 5.3, ISO 11986.2017

Chapter 4, 5.3), to adapt to my country's technical conditions;

---Change "maximum diameter -3.00D single vision lens" to "maximum diameter lens (-3.00D or typical application lens)"

(See 6.7, 6.7 of ISO 11986.2017);

---Change "reference to this document, namely ISO 11986.2017" to "test basis" and delete "such as hydrogel material group or silicone hydrogel"

Identification and surface modification of gluon groups" (see Chapter 7, Chapter 7 of ISO 11986.2017).

The following editorial changes have been made to this document.

---"Hydrogel contact lens" is changed to "soft contact lens" (see 5.2.1, 5.2.1.1 and 5.2.1.2 of ISO 11986.2017).

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

This document is proposed and managed by the National Medical Products Administration.

This document was drafted by. Zhejiang Medical Device Inspection Institute.

The main drafters of this document. Xu Pinghua, Zhang Li, Xu Chang, Bao Jiaohui, Luo Yongjie, Xia Zhongcheng, Chen Jingyun, Zhu Dan.

The previous versions of this document and the documents it replaces are as follows.

---First published as GB/T 28539-2012 in.2012;

---This is the first revision.

Introduction

This document is consistent with GB/T 11417 "Ophthalmic Optical Contact Lenses" and GB/T 28538 "Ophthalmic Optical Contact Lenses and Contact Lens Care Products"

Rabbit Eye Compatibility Research Test" together constitute a series of national standards for contact lenses.

Contact lens care products are complex mixtures of organic and inorganic substances. For microbiological safety reasons, contact lens disinfectants and

Care products in multipurpose containers contain antibacterial active substances. Based on many years of experience wearing contact lenses, we know that due to the absorption of the contact lens matrix,

These preservatives are absorbed and released, sometimes causing irritation and sensitization problems. Therefore, it is necessary to evaluate the extent of preservative uptake and release from contact lenses.

to evaluate.

The Preservative Uptake and Release Test provides a means of measuring preservative uptake by contact lenses in solution and preservative release by contact lenses in aqueous media.

general method of administration. Analytical methods for quantification of specific preservatives are not specified here. When selecting an appropriate analytical method, consider preservatives.

The chemical identity of the agent, its concentration in contact lens care products, and the extent of contact lens ingestion. Contact lens uptake and release data are used to characterize

The possibility of toxic or irritant reactions from potential new or modified contact lens materials derived from currently marketed contact lens materials

Ingesting, binding or releasing preservatives in lens care products.

Ophthalmic optical contact lenses and contact lens care products

Determination of preservative uptake and release

1 Scope

GB/T 28539-2023 measures how much preservative a contact lens takes up from a care solution and how much of it the lens gives back. The principle is a two-stage soak: the lens sits in the test solution at 25 °C +/- 2 °C and the preservative content is analysed at intervals until it reaches a stable state, after which the lens is moved to a standard salt

solution meeting GB/T 11417.4, one millilitre per lens, at 37 °C +/- 2 °C, and what comes out is analysed at intervals up to sixteen hours. The test method clause covers choosing an analytical method suited to the particular preservative, preparing the samples and running the work; result expression and the test report close the document. Only new, unused lenses are in scope, because the organic and inorganic deposits a lens picks up during wear cannot be handled reproducibly. Care solutions have to be preserved to stay microbiologically safe, but a lens is a sponge that concentrates that preservative and then delivers it to the cornea for hours after insertion, which is where the stinging and the epithelial damage come from. It replaces the 2012 edition and belongs with GB/T 11417 and GB/T 28538. Lens and care product manufacturers and their laboratories are the readers.

This document specifies general procedures for the selection of test methods, sample preparation and experimental guidance for preservative uptake and release from contact lenses.

This document applies to testing of preservative uptake and release from contact lenses and contact lens care products.

Note 1.Due to the difficulty of dealing with the inorganic and organic deposits covering contact lenses that are encountered during wear, these methods are only applicable to new and unused lenses.

of contact lenses.

Note 2.The disinfection effect of contact lenses may be affected when preservatives are consumed within the limited volume of the lens case. This document does not measure disinfection effectiveness.

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.

GB/T 11417.4 Ophthalmic optical contact lenses Part 4.Standard salt solution for testing (GB/T 11417.4-2012, ISO 18369-3.

2006,NEQ)

3 Terms and definitions