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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 1889-2023

**Ophthalmic optics - Contact lens care products - Method to
assess contact lens care products with contact lenses in a lens
case, challenged with bacterial and fungal organisms**

眼科光学 接触镜护理产品 镜片盒内接触镜护理产品及接触镜的细菌和真菌挑战
评估方法

(English Translation)

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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.

This document has been modified to adopt ISO 18259:2014 "Ophthalmic optical contact lens care products. Contact lens care products and contacts in lens cases." Bacterial and fungal challenge assessment methods for microscopy.

The technical differences and reasons between this document and ISO 18259:2014 are as follows.

---Deleted the normative reference document ISO 18369-1, and added the normative reference documents GB/T 11417.1 and YY/T 0719.1 (See Chapter 3), in order to adapt to our country's national conditions;

---Replaced ISO 14729 with normatively cited YY/T 0719.3-2009 (see Chapter 4, 6.1, 6.2.8.5, 6.2.10, Chapter 7 Chapter) to adapt to my country's national conditions and increase operability;

---Added the relevant expressions of "typical application lenses" (see 6.2.1) to adapt to my country's national conditions;

---Replaced ISO 18369-3 (see 6.2.2) with normatively cited GB/T 11417.4 to adapt to my country's national conditions and increase operability Doing things.

The following editorial changes have been made to this document.

---Deleted additional instructions related to ISO 11986 and added instructions for additional time points that can be assessed (see 6.2.1).

---Changed title name (see Chapter 7).

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

1 Scope

This document describes an antimicrobial test used to evaluate the compatibility of disinfectant contact lens care products with hydrogel lenses and lens cases.

Biological efficacy endpoint method.

This document applies to contact lens care products with disinfecting functions.

This document does not apply to care products with hydrogen peroxide as the main bactericidal ingredient.

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 11417.1 Ophthalmic optical contact lenses Part 1: Vocabulary, classification and recommended labeling specifications (GB/T 11417.1-2012,ISO 18369-1:2006,MOD) 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) YY/T 0719.1 Ophthalmic optical contact lens care products Part 1: Terminology (YY/T 0719.1-2009, ISO 18369-1.

2006,NEQ)

YY/T 0719.3-2009 Ophthalmic optical contact lens care products Part 3: Microbial requirements and test methods and contact lenses Nursing system (ISO 14729:2001, MOD)

3 Terms and definitions

The terms and definitions defined in GB/T 11417.1 and YY/T 0719.1 apply to this document.

4 General rules

After adding organic test bacteria into the care solution used with the lens and lens case, the antimicrobial properties of the test solution are evaluated at different time points.

Material effectiveness. Unless otherwise specified, new lenses and new lens cases should be used. This test will simulate microscopic exposure caused by contact lens wearer manipulation.

biological contamination.

Place a lens in a lens box hole, and insert $1.0 \times 10^5 \text{CFU} \sim 1.0 \times 10^6 \text{CFU}$ test bacteria into each lens;

After the test bacteria are in contact with the lens for 3 to 10 minutes, add an appropriate volume (at least 2 mL) of care solution into each lens box hole. in order to evaluate to determine the effect of lens cases and lenses on the antimicrobial activity of the care solution, soak the inoculated lenses in the care solution for different times (the marked soaking time time, 24h, 7d and the maximum storage period in the lens box marked). A separate set of lens boxes should be prepared for each time point, with each test strip Pieces should be evaluated for 3 parallel holes. Additional time points may be assessed.