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Ophthalmic optics — Contact lenses and contact lens care products — Cytotoxicity testing of contact lenses in combination with lens care solution to evaluate lens/solution interactions

Optique ophtalmique — Lentilles de contact et produits d'entretien des lentilles de contact — Essais de cytotoxicité des lentilles de contact en association avec une solution d'entretien des lentilles de contact pour évaluer les interactions solution/lentille

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Contents

Page

Foreword ... **iv**

1 Scope ... **1**

2 Normative references ... **1**

3 Terms and definitions ... **1**

4 Principle ... **1**

5 Direct contact cytotoxicity test for lens/lens care solution combination ... **1**
5.1 General ... 1
5.2 Experimental procedure ... 2
5.2.1 Basic procedure ... 2
5.2.2 Material ... 2
5.2.3 Preparation of test sample ... 3
5.2.4 Methods ... 3

6 Assessment of results ... **5**

7 Test report ... **5**

Annex A (normative) **Measurement of zone of cell lysis for the direct contact cytotoxicity test method for testing contact lens in combination with lens care solution** ... **7**

Bibliography ... **9**

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Foreword

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The committee responsible for this document is ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

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Ophthalmic optics — Contact lenses and contact lens care products — Cytotoxicity testing of contact lenses in combination with lens care solution to evaluate lens/solution interactions

1 Scope

This International Standard describes an in vitro test method to assess the potential cytotoxic effects that may arise due to interaction of contact lenses with contact lens care solutions.

NOTE The potential of a contact lens or a contact lens care solution to cause cytotoxicity by itself can be evaluated in accordance with general guidance in ISO 10993-5.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 18369-1, *Ophthalmic optics — Contact lenses — Part 1: Vocabulary, classification system and recommendations for labelling specifications*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 18369-1 and the following apply.

3.1
room temperature
temperature defined as 18 °C to 25 °C

4 Principle

The chemicals in a lens care solution can cause cytotoxic effects by direct contact with ocular tissues or by indirect contact through contact lenses. Uptake of the care product preservative or other solution ingredients by the lens and subsequent release of these chemicals in the ocular environment can compromise ocular biocompatibility. The potential interactions between a lens care product and various contact lens materials should be taken into account in designing the tests to fully evaluate the cytotoxicity potential of a new contact lens or a lens care product.

5 Direct contact cytotoxicity test for lens/lens care solution combination

5.1 General

The following protocol describes the test method for evaluating potential cytotoxic effects of contact lenses exposed to contact lens care solution. The cytotoxicity can result from contact lens/lens care solution interactions.

With the exception of daily disposable contact lenses, the potential interaction of a new contact lens with marketed representative multipurpose solutions to produce cytotoxicity shall be evaluated.

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