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Ophthalmic optics — Contact lens care products — Method for evaluating Acanthamoeba encystment by contact lens care products

Optique ophtalmique — Produits d'entretien de lentilles de contact — Méthode d'évaluation de l'enkystement de Acanthamoeba au contact des produits d'entretien des lentilles de contact

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT), see the following URL: Foreword — Supplementary Information.

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

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Introduction

Acanthamoeba is a genus of small free-living amoeba common to most soil and aquatic habitats.[1],[2] The organism is characterized by a life cycle of a feeding and dividing trophozoite which, in response to adversity, can transform into a resistant cyst stage.[1],[2] *Acanthamoeba* cysts have been shown to resist extremes of temperature, pH, desiccation, and most chemical disinfectants at normal concentration for use.[1],[2],[3],[4]

Recently, it has been observed that a contact lens disinfecting solution associated with a significant number of *Acanthamoeba* keratitis cases was able to induce trophozoite encystment.[5],[6],[7] Such a phenomenon is of important concern as *Acanthamoeba* cysts can be resistant to contact lens disinfection systems and this can increase the risk of acquiring *Acanthamoeba* keratitis.[3],[4],[7],[8],[9]

This International Standard provides a methodology for assessing the capability of a contact lens disinfecting solution to induce *Acanthamoeba* trophozoite encystment. This method does not describe methodology to assess the efficacy of a contact lens disinfecting product against *Acanthamoeba* spp.

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Ophthalmic optics — Contact lens care products — Method for evaluating Acanthamoeba encystment by contact lens care products

1 Scope

This International Standard specifies a method for evaluating the potential of products for contact lens disinfection to induce encystment of *Acanthamoeba* species. This method excludes the evaluation of oxidative systems that require a special lens case for use. This International Standard does not address the evaluation of disinfection efficacy of contact lens disinfecting products.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1
trophozoite
motile, feeding amoeboid form of *Acanthamoeba*

2.2
encystment
phase in the life cycle of *Acanthamoeba* where the trophozoite stage transforms into the cyst stage

2.3
mature cyst
dormant form of *Acanthamoeba* composed of an inner and outer cell wall, typically more resistant to a range of challenges than *trophozoites* (2.1)

Note 1 to entry: Challenges include heat, dehydration, chemical, etc.

2.4
immature cyst
cyst comprised only of the inner cell wall

2.5
room temperature
temperature defined as 18 °C to 25 °C

2.6
passage
transfer or transplantation of cells, with or without dilution, from one culture vessel to another

Note 1 to entry: It is understood that any time cells are transferred from one vessel to another, a certain portion of the cells may be lost and, therefore, dilution of cells, whether deliberate or not, can occur.

Note 2 to entry: This term is synonymous with the term “subculture”.[10]

2.7
passage number
number of times cells in the culture have been subcultured or *passaged* (2.6)[10]

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