International

ISO 11986

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

Optique ophtalmique — Lentilles de contact et produits d'entretien pour lentilles de contact — Détermination de l'absorption et de la libération des conservateurs

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This fourth edition cancels and replaces the third edition (ISO 11986:2017), which has been technically revised.

The main changes are as follows:

— Editorial update of the whole document.

— An additional sentence in the Scope clarifies the circumstances when the test method is to be applied. In particular this test method is only considered for use during the development phase of new or modified contact lens materials or new contact lens care products.

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Contact lens care products are a complex mixture of organic and inorganic substances. For reasons of microbiological safety, contact lens disinfecting solutions, as well as care products in multi-use containers, contain substances with antimicrobial activity. From many years of experience in contact lens wear, it is known that irritation and sensitization problems sometimes occur due to these preservatives being absorbed and released by the matrix of the contact lens. For these reasons, it is necessary to be able to estimate the extent of preservative uptake and release by contact lenses.

The preservative uptake and release test provides a general method for measuring the uptake of preservatives in solution by contact lenses and the release of preservatives from contact lenses in an aqueous medium. The analytical method to be used for quantification of specific preservatives is not indicated here. Chemical characteristics of the preservative, as well as concentration in the contact lens care product and degree of uptake by the contact lens, can be taken into consideration in selecting an appropriate analytical method. Contact lens uptake and release data can be useful in characterizing the potential for a new or modified contact lens material to produce a toxic or irritating reaction in the eye from the uptake and binding or release of preservatives from currently marketed contact lens care products.