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Ophthalmic optics — Contact lens care products — Guidelines for determination of shelf-life

Optique ophtalmique — Produits d'entretien pour lentilles de contact — Lignes directrices pour la détermination de la durée de conservation

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Contents

Page

Foreword ... **iv**

Introduction ... **v**

1 Scope ... **1**

2 Normative references ... **1**

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

4 General requirements ... **1**

5 Determination of finished product stability ... **1**

5.1 Objective ... 1
5.2 Study methods ... 2
5.3 Description of the product under study ... 3
5.4 Characteristics ... 3
5.5 Evaluation methods ... 4
5.6 Presentation of results ... 4
5.7 Discussion, interpretation, and conclusions ... 4
5.8 Ongoing stability ... 5

Annex A (informative) **Example of a stability testing plan for the finished contact lens care product** ... **6**

Bibliography ... **7**

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.*

This third edition cancels and replaces the second edition (ISO 13212:2011), which has been technically revised.

Introduction

The purpose of stability tests of contact lens care products is to obtain sufficient information to enable the manufacturer to establish an appropriate shelf-life and identify any unique storage conditions required to appear on the labelling of the product.

The quality of a contact lens care product is determined by its content of active ingredient(s), its purity, and its physicochemical and microbiological properties. It is important to take into account the possible interaction of the container/closure with the contents.

The stability studies are intended to ascertain how the quality of a product varies as a function of time and under the influence of a variety of environmental factors.

On the basis of the information obtained, storage conditions are recommended, which will guarantee the maintenance of the quality of the product in relation to its safety, performance, and acceptability throughout the proposed shelf-life.

The design of the finished product stability studies for a care product is based on the knowledge obtained from studies on the active ingredient(s) and from the development studies.