
**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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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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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.

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