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## **Cosmetics — Guidelines on the stability testing of cosmetic products**

*Cosmétiques — Lignes directrices relatives aux essais de stabilité des  
produits cosmétiques*



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ISO copyright office  
CP 401 • Ch. de Blandonnet 8  
CH-1214 Vernier, Geneva, Switzerland  
Tel. +41 22 749 01 11  
Fax +41 22 749 09 47  
copyright@iso.org  
www.iso.org

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# Contents

Page

<b>Foreword</b>	<b>iv</b>
<b>Introduction</b>	<b>v</b>
<b>1 Scope</b>	<b>1</b>
<b>2 Normative references</b>	<b>1</b>
<b>3 Terms and definitions</b>	<b>1</b>
<b>4 Basic principles of cosmetic stability</b>	<b>2</b>
<b>5 Aspects to be addressed during stability testing</b>	<b>3</b>
5.1 General	3
5.2 Stage/scale of tested batches	3
5.3 Test procedures and conditions	4
5.3.1 Principle	4
5.3.2 Temperature and humidity	4
5.3.3 Cycling of temperature and/or humidity	5
5.3.4 Vibration	6
5.3.5 Centrifugation	6
5.3.6 Exposure to light (photostability)	6
5.4 Physical, physico-chemical and chemical alterations	7
5.4.1 Physical destabilization phenomena of different product types	7
5.4.2 Chemical destabilization processes	8
5.4.3 Destabilization phenomena	9
5.4.4 Specific test methods	10
5.5 Microbiological aspects	12
5.5.1 General	12
5.5.2 Microbiological parameters	12
5.5.3 Testing conditions	12
5.5.4 Microbiological specifications	13
5.5.5 Interpretation of results	13
5.6 Interaction with packaging	13
5.6.1 General information	13
5.6.2 Types of packing materials and main possible evaluations	13
5.6.3 Pressure vessels (aerosols)	14
<b>6 Stability test conclusions</b>	<b>14</b>
6.1 Evaluation	14
6.2 Report	14
<b>Bibliography</b>	<b>15</b>

## 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.

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](http://www.iso.org/directives)).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 217, *Cosmetics*.

## Introduction

Stability studies are aimed at assessing the ability of a product to maintain the desired physical, chemical and microbiological properties, as well as functionality and sensorial properties when stored and used under appropriate conditions by the consumer. More simply, the objective of a stability study is to determine the shelf life of a product and to evaluate whether a product in the package is stable when subjected to the market conditions in which it is sold and used. The “market conditions” encompass distribution (transportation), warehouse storage and conditions during use.

Thus, the stability study may be seen as a prerequisite for ensuring product quality. Stability tests on cosmetic products are required for

- obtaining a guidance on the formulation of the product, and the appropriate packaging material,
- optimizing the formulation and manufacturing process,
- determining conditions of transportation, storage, display and manner of use,
- estimating and confirming shelf life, and
- ensuring customer safety.

This document identifies readily available references to assess the stability of cosmetic products on the market. Its purpose is to provide a resource for the selection of the appropriate stability tests. Although these guidelines provide a helpful starting point to evaluate new products and technologies, adapting the testing to reflect differences between product types and formulations may still be necessary.



# Cosmetics — Guidelines on the stability testing of cosmetic products

## 1 Scope

This document gives guidelines for the stability testing of cosmetic products. It reviews readily available bibliographic references that provide a resource for the assessment of the stability of cosmetic products. This review of the available guidelines that assess the stability of cosmetic products can serve as a technical/scientific framework to identify the most suitable methods for the assessment of the stability of cosmetic products.

This document does not aim to specify the conditions, parameters or criteria of stability testing.

Considering the wide variety of cosmetic products, storage and use conditions, it is not possible to define a single way to assess product stability. Therefore, it is up to the manufacturer to specify and justify the stability protocol to cover test methods, specifications and conditions at which products will be tested.

## 2 Normative references

There are no normative references in this document.

## 3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <https://www.iso.org/obp>

### 3.1

#### **accelerated stability evaluation**

study designed to speed up naturally occurring destabilization processes due to intrinsic or extrinsic factors and which predicts the behaviour over the long term

Note 1 to entry: Typically, physico-chemical, mechanical or thermal procedures are employed.

### 3.2

#### **real time stability evaluation**

study that monitors the state of a product to determine the time course of any alteration to it under reasonably expected conditions of storage and use

Note 1 to entry: Often called “long term test” or “standard stability test”.

### 3.3

#### **stability**

ability of a cosmetic product to resist change or variation of its initial properties over time under stated or reasonably foreseeable conditions of storage and use

Note 1 to entry: See Reference [1].