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I.S. EN ISO 22716:2007

Cosmetics - Good Manufacturing Practices (GMP) - Guidelines on Good Manufacturing Practices (ISO 22716:2007, Corrected version 2008-05-15)

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It has been brought to our attention that this document, issued on 2007-11-14, requires modification.

Please find enclosed the updated English version.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 22716

November 2007

ICS 71.100.70

English Version

Cosmetics - Good Manufacturing Practices (GMP) - Guidelines on Good Manufacturing Practices (ISO 22716:2007, Corrected version 2008-05-15)

Cosmétiques - Bonnes pratiques de fabrication (BPF) - Lignes directrices relatives aux bonnes pratiques de fabrication (ISO 22716:2007)

Kosmetik - Gute Herstellungspraxis (GMP) - Leitfaden zur guten Herstellungspraxis (ISO 22716:2007)

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Foreword

This document (EN ISO 22716:2007, Corrected version 2008-05-15) has been prepared by Technical Committee ISO/TC 217 "Cosmetics" in collaboration with Technical Committee CEN/TC 392 “Cosmetics” the secretariat of which is held by AFNOR.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2008, and conflicting national standards shall be withdrawn at the latest by May 2008.

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INTERNATIONAL STANDARD

ISO 22716

First edition
2007-11-15

Corrected version
2008-05-15

Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices

Cosmétiques — Bonnes Pratiques de Fabrication (BPF) — Lignes directrices relatives aux Bonnes Pratiques de Fabrication

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Reference number
ISO 22716:2007(E)

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

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ISO 22716 was prepared by Technical Committee ISO/TC 217, *Cosmetics*.

This corrected version contains, for the sake of clarity, syntactical changes to subclauses 3.2.1.1 and 11.2.

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Introduction

These guidelines are intended to provide guidance regarding Good Manufacturing Practices for cosmetic products. These guidelines have been prepared for consideration by the cosmetic industry and take into account the specific needs of this sector. These guidelines offer organizational and practical advice on the management of the human, technical and administrative factors affecting product quality.

These guidelines have been written to allow them to be used following the flow of products from receipt to shipment. Additionally, in order to clarify the way this document reaches its objectives, a ‘principle’ is added to each major section.

Good Manufacturing Practices constitute the practical development of the quality assurance concept through the description of the plant activities that are based on sound scientific judgement and risk assessments. The objective of these GMP guidelines is to define the activities that enable you to obtain a product that meets defined characteristics.

Documentation is an integral part of Good Manufacturing Practices.

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INTERNATIONAL STANDARD ISO 22716:2007(E)

Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices

1 Scope

This International Standard gives guidelines for the production, control, storage and shipment of cosmetic products.

These guidelines cover the quality aspects of the product, but as a whole do not cover safety aspects for the personnel engaged in the plant, nor do they cover aspects of protection of the environment. Safety and environmental aspects are inherent responsibilities of the company and could be governed by local legislation and regulation.

These guidelines are not applicable to research and development activities and distribution of finished products.

2 Terms and definitions

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

2.1
acceptance criteria
numerical limits, ranges, or other suitable measures for acceptance of test results

2.2
audit
systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable for achieving objectives

2.3
batch
defined quantity of raw material, packaging material or product issued from one process or series of processes so that it could be expected to be homogeneous

2.4
batch number
distinctive combination of numbers, letters and/or symbols, which specifically identifies a batch

2.5
bulk product
any product which has completed manufacturing stages up to, but not including, final packaging

2.6
calibration
set of operations that establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure, and the corresponding known values of a reference standard

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