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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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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.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

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.

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.

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

2.7
change control
internal organization and responsibilities relative to any planned change of one or several activities covered by the Good Manufacturing Practices in order to ensure that all the manufactured, packaged, controlled and stored products correspond to the defined acceptance criteria

2.8
cleaning
all operations that ensure a level of cleanliness and appearance, consisting of separating and eliminating generally visible dirt from a surface by means of the following combined factors, in variable proportions, such as chemical action, mechanical action, temperature, duration of application

2.9
complaint
external information claiming a product does not meet defined acceptance criteria

2.10
contamination
occurrence of any undesirable matter such as chemical, physical and/or microbiological matter in the product

2.11
consumables
materials such as cleaning agents and lubricants that are used up during cleaning, sanitization or maintenance operations

2.12
contract acceptor
person, company or external organization carrying out an operation on behalf of another person, company or organization

2.13
control
verification that acceptance criteria are met

2.14
deviation
internal organization and responsibilities relative to the authorization to deviate from specified requirements due to a planned or unplanned and, in any case, temporary situation concerning one or several activities covered by the Good Manufacturing Practices

2.15
finished product
cosmetic product that has undergone all stages of production, including packaging in its final container, for shipment

2.16
in-process control
controls performed during production in order to monitor and, if appropriate, to adjust the process to ensure that the product meets the defined acceptance criteria

2.17
internal audit
systematic and independent examination made by competent personnel inside the company, the aim of which is to determine whether activities covered by these guidelines and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable for achieving objectives

2.18
major equipment
equipment specified in production and laboratory documents which is considered essential to the process

2.19
maintenance
any periodic or unplanned support and verification operations designed to keep premises and equipment in proper working condition

2.20
manufacturing operation
set of operations from the weighing of raw materials to the making of the bulk product

2.21
out-of-specification
examination, measurement or test result that does not comply with defined acceptance criteria

2.22
packaging operation
all packaging steps including filling and labelling, which a bulk product has to undergo in order to become a finished product

2.23
packaging material
any material employed in the packaging of a cosmetic product, excluding any outer packaging used for transportation

NOTE Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.

2.24
plant
location for production of cosmetic products

2.25
premises
physical location, buildings and supporting structures used to conduct receipt, storage, manufacturing, packaging, control and shipment of product, raw materials and packaging materials

2.26
production
manufacturing and packaging operations

2.27
quality assurance
all those planned and systematic activities necessary to provide confidence that a product satisfies given acceptance criteria

2.28
raw material
any substance going into or involved in the manufacturing of a bulk product

2.29
recall
decision made by a company to call back a product batch that has been put on the market

2.30
reprocessing
re-treatment of all or part of a batch of finished product or bulk product of an unacceptable quality from a defined stage of production so that its quality may be rendered acceptable by one or more additional operations

2.31
return
sending finished cosmetic products which may or may not present a quality defect back to the plant

2.32
sample
one or more representative elements selected from a set to obtain information about that set

2.33
sampling
set of operations relating to the taking and preparation of samples

2.34
sanitization
operation, used to reduce undesirable micro-organisms on inert contaminated surfaces depending on the objectives set

NOTE It is the action of reducing generally invisible contaminants from a surface.

2.35
shipment
set of operations relative to the preparation of an order and its putting in a transport vehicle

2.36
waste
any residue of a production operation, transformation or use, any substance, material, product that its holder intends for disposal

3 Personnel

3.1 Principle

Persons involved in the implementation of the activities described in these guidelines should have appropriate training to produce, control and store products with a defined quality.

3.2 Organization

3.2.1 Organization chart

3.2.1.1 The organizational structure should be defined such that the organization and functioning of the staff of the company be understood. It should be appropriate for the size of the company and the diversity of its products.

3.2.1.2 Each company should ensure that there are adequate staffing levels in the different scope of activity, according to the diversity of its production.

3.2.1.3 The organization chart should show the independence, from the other units of the plant, of each quality unit, such as quality assurance unit and quality control unit. The quality assurance and quality control responsibilities can be undertaken by a separate quality assurance unit and a quality control unit, or they can be undertaken by a single unit.

3.2.2 Number of people

The company should have an adequate number of properly trained personnel with regards to the defined activities in these guidelines.

3.3 Key responsibilities

3.3.1 Management responsibilities

3.3.1.1 The organization should be supported by the top management of the company.

3.3.1.2 The implementation of Good Manufacturing Practices should be the responsibility of top management and should require the participation and commitment of personnel in all departments and at all levels within the company.

3.3.1.3 Management should define and communicate the areas in which authorized personnel are allowed to access.

3.3.2 Responsibilities of personnel

All personnel should:

a) know their position in the organizational structure;

b) know their defined responsibilities and activities;

c) have access to and comply with documents relevant to their particular responsibility scope;

d) comply with personal hygiene requirements;

e) be encouraged to report irregularities or other non-conformities which may occur at the level of their responsibilities;

f) have adequate education training and skills to perform the assigned responsibilities and activities.

3.4 Training

3.4.1 Training and skills

Personnel involved in production, control, storage and shipment should have skills based on relevant training and experience acquired, or any combination thereof, that are appropriate to their responsibilities and activities.

3.4.2 Training and Good Manufacturing Practices

3.4.2.1 Appropriate Good Manufacturing Practices training relative to the defined activities of these guidelines should be provided for all personnel.

3.4.2.2 The training needs of all personnel, regardless of level or seniority in the company, should be identified and a corresponding training programme should be developed and implemented.

3.4.2.3 Considering the expertise and experience of the respective personnel, training courses should be tailored to be appropriate to the jobs and responsibilities of individuals.

3.4.2.4 According to the needs and in-house resources available, training courses may be designed and executed by the company itself or with the help of expert external organizations, if necessary.