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Edition 1

# ISO 22716:2007
Edition 1

# SOUTH AFRICAN NATIONAL STANDARD

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

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**Table of changes**

| Change No. | Date | Scope |
|---|---|---|
| | | |

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This South African standard was prepared by National Committee SABS/TC 217, *Cosmetics*, in accordance with procedures of the South African Bureau of Standards, in compliance with annex 3 of the WTO/TBT agreement.

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INTERNATIONAL STANDARD

**ISO 22716**

First edition
2007-11-15

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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

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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.


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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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# 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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**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


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**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

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**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.


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#### 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.

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**3.4.2.5** Training should be regarded as a constant and on-going process that is subject to regular updates.

### 3.4.3 Newly recruited personnel

Besides basic training on the theory and practice of Good Manufacturing Practices, newly recruited personnel should receive training appropriate to the duties assigned to them.

### 3.4.4 Personnel training evaluations

Knowledge accumulated by personnel should be evaluated during and/or after training.

## 3.5 Personnel hygiene and health

### 3.5.1 Personnel hygiene

**3.5.1.1** Hygiene programmes should be established and adapted to the needs of the plant. These requirements should be understood and followed by every person whose activities take them into production, control and storage areas.

**3.5.1.2** Personnel should be instructed to use hand washing facilities.

**3.5.1.3** Every person entering production, control and storage areas should wear appropriate clothing and protective garments to avoid contamination of cosmetic products.

**3.5.1.4** Eating, drinking, chewing, smoking or the storage of food, drink or smoking materials or personal medication in the production, control and storage areas should be avoided.

**3.5.1.5** Any unhygienic practice within the production, control and storage areas or in any other area where the product might be adversely affected should be forbidden.

### 3.5.2 Personnel health

Steps should be taken to ensure, as far as is practicable, that any person affected by an apparent illness or having open lesions on the exposed body surface should be excluded from direct contact with product until the condition is corrected or determined by medical personnel that the quality of cosmetic products will not be compromised.

## 3.6 Visitors and untrained personnel

Visitors or untrained personnel should preferably not be taken into production, control and storage areas. If this is unavoidable, they should be given information in advance, particularly about personal hygiene and the prescribed protective clothing. They should be closely supervised.

# 4 Premises

## 4.1 Principle

**4.1.1** Premises should be located, designed, constructed and utilized so as:

a) to ensure protection of the product;

b) to permit efficient cleaning, if necessary, sanitizing and maintenance;

c) to minimize the risk of mix-up of products, raw materials and packaging materials.


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**4.1.2** Premises design recommendations are described in these guidelines. Design decisions should be based on the type of cosmetic product produced, existing conditions, cleaning and, if necessary, sanitizing measures used.

## 4.2 Types of area

Separate or defined areas should be provided for storage, production, quality control, ancillary, washing and toilets.

## 4.3 Space

Sufficient space should be provided to facilitate operations such as receipt, storage and production.

## 4.4 Flow

Flow of materials, products and personnel through the building or buildings should be defined in order to prevent mix-ups.

## 4.5 Floors, walls, ceilings, windows

**4.5.1** Floors, walls, ceilings and windows in production areas should be designed or constructed for ease of cleaning and, if necessary, sanitization and be kept clean and in good repair.

**4.5.2** Windows should be of non-opening design where ventilation is adequate. If windows are opened to the outside environment, they should be properly screened.

**4.5.3** New construction of production areas should incorporate considerations for proper cleaning and maintenance. Design of new construction should include smooth surfaces if appropriate and these surfaces should allow for resistance to corrosive cleaning and sanitizing agents.

## 4.6 Washing and toilet facilities

Adequate, clean, washing and toilet facilities should be provided for personnel. The washing and toilet facilities should be differentiated from, but accessible to, production areas. Adequate facilities for showering and changing clothes should be provided when appropriate.

## 4.7 Lighting

**4.7.1** Adequate lighting, that is sufficient for operations, should be installed in all areas.

**4.7.2** Lighting should be installed in a manner to ensure containment of any debris from potential breakage. Alternatively, measures should be taken to protect the product.

## 4.8 Ventilation

Ventilation should be sufficient for the intended production operations. Alternatively, specific measures should be taken to protect the product.

## 4.9 Pipework, drains and ducts

**4.9.1** Pipework, drains and ducts should be installed in such a manner so that drip or condensation does not contaminate materials, products, surfaces and equipment.

**4.9.2** Drains should be kept clean and should not allow back flow.

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**4.9.3** Design considerations should be given to the following:

a) exposed overhead roof beams, pipes and ducts should be avoided;

b) exposed pipes should not touch walls, but be suspended from or supported by brackets, sufficiently separated to allow thorough cleaning;

c) alternatively, specific measures should be taken to protect the product.

### 4.10 Cleaning and sanitization

**4.10.1** Premises used for activities described in these guidelines should be maintained in a clean condition.

**4.10.2** Cleaning and, if necessary, sanitization should be carried out to achieve the objective of protecting each product.

**4.10.3** Cleaning and, if necessary, sanitizing agents to be used should be specified and effective.

**4.10.4** There should be cleaning and, if necessary, sanitization programmes corresponding to specific needs of each area.

### 4.11 Maintenance

Premises used in activities described in these guidelines should be maintained in a good state of repair.

### 4.12 Consumables

Consumables used for premises should not affect the quality of the product.

### 4.13 Pest control

**4.13.1** Premises should be designed, constructed and maintained so as to restrict access to insects, birds, rodents, pests and other vermin.

**4.13.2** There should be a pest control programme appropriate for the premises.

**4.13.3** Measures should be taken to control the exterior of the premises to prevent attracting or harbouring pests.

## 5 Equipment

### 5.1 Principle

Equipment should be suitable for the intended purpose and capable of being cleaned and, if necessary, sanitized and maintained. This clause applies to all equipment within the scope of these guidelines. If automated systems are introduced into activities described in these guidelines, they should take into account the application of the given relevant principles.

### 5.2 Equipment design

**5.2.1** Production equipment should be designed to prevent contamination of the product.

**5.2.2** Bulk product containers should be protected from air contaminants, such as dust and moisture.

**5.2.3** Transfer hoses and accessories that are not in use should be cleaned and, if necessary sanitized, kept dry and protected from dust, splash or other contamination.


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**5.2.4** The material used in the construction of equipment should be compatible with products and the cleaning and sanitizing agents.

## 5.3 Installation

**5.3.1** The design and the installation of equipment should ease its drainage in order to facilitate cleaning and sanitization.

**5.3.2** Equipment should be placed so that movement of materials, mobile equipment and personnel do not pose a risk to quality.

**5.3.3** Reasonable access under, inside and around equipment should be provided for maintenance and cleaning.

**5.3.4** Major equipment should be readily identifiable.

## 5.4 Calibration

**5.4.1** Laboratory and production measuring instruments that are important for the quality of the product, should be calibrated regularly.

**5.4.2** If results of calibration are out-of-acceptance criteria, measuring instruments should be appropriately identified and removed from service.

**5.4.3** An out-of-calibration condition should be investigated to determine if there is any impact to the quality of the product and appropriate steps taken based on this investigation.

## 5.5 Cleaning and sanitization

**5.5.1** All equipment should be subject to an appropriate cleaning and, if necessary, sanitization programme.

**5.5.2** Cleaning and sanitizing agents should be specified and effective.

**5.5.3** Where equipment is assigned to continuous production or production of successive batches of the same product, equipment should be cleaned and, if necessary, sanitized at appropriate intervals.

## 5.6 Maintenance

**5.6.1** Equipment should be regularly maintained.

**5.6.2** Maintenance operations should not affect the quality of the product.

**5.6.3** Defective equipment should be identified accordingly, excluded from use and isolated if possible.

## 5.7 Consumables

Consumables used for equipment should not affect the quality of the product.

## 5.8 Authorizations

Equipment or automated systems used in production and control should be accessed and used by authorized personnel.

## 5.9 Back-up systems

Adequate alternative arrangements should be available for systems which need to be operated in the event of a failure or breakdown.

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# 6 Raw materials and packaging materials

## 6.1 Principle

Raw materials and packaging materials that are purchased should meet defined acceptance criteria relevant to the quality of finished products.

## 6.2 Purchasing

Purchasing of raw materials and packaging materials should be based on:

a) evaluation and selection of the supplier;

b) establishment of technical clauses such as type of selection to be conducted, acceptance criteria, actions in the case of defect or modifications, transport conditions;

c) setting of relations and exchanges between the company and supplier such as questionnaire, assistance and audits.

## 6.3 Receipt

**6.3.1** The purchase order, the delivery note and the delivered materials should match.

**6.3.2** The integrity of the raw materials and packaging materials shipping containers should be checked visually. If necessary, additional checks of transport data should be performed.

## 6.4 Identification and status

**6.4.1** Containers of raw materials and packaging materials should be labelled in order to identify the material and the batch information.

**6.4.2** Raw materials and packaging materials showing defects that might affect product quality should be held pending a decision.

**6.4.3** Raw materials and packaging materials should be identified in an appropriate way according to their status such as accepted, rejected or quarantined. Other systems can replace this physical system of identification, if they ensure the same level of assurance.

**6.4.4** Identification of raw materials and packaging materials should contain the following information:

a) name of the product marked on the delivery note;

b) name of the product as given by the company, if different from the name given by the supplier and/or its code number;

c) date or number of receipt, if appropriate;

d) supplier's name;

e) batch reference given by the supplier and the one given at receipt, if different.

## 6.5 Release

**6.5.1** Physical or alternative systems should be set up to ensure that only released raw materials and packaging materials are used.

**6.5.2** The release of materials should be carried out by the authorized personnel responsible for quality.


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**6.5.3** Raw materials and packaging materials can be accepted on the basis of the supplier certificate of analysis only if there are established technical requirements, experience and knowledge of the supplier, supplier audit and agreed supplier's test methods.

### 6.6 Storage

**6.6.1** Storage conditions should be appropriate for each raw material and packaging material.

**6.6.2** Raw materials and packaging materials should be stored and handled in a manner appropriate to their characteristics.

**6.6.3** Specific storage conditions should be respected and monitored, where appropriate.

**6.6.4** Containers of raw materials and packaging materials should be closed and should be stored off the floor.

**6.6.5** When raw materials and packaging materials are repacked, they should carry the same labelling as at origin.

**6.6.6** When raw materials and packaging materials are quarantined or rejected, they should be stored in their respective physical locations or by using any other system providing the same level of assurance.

**6.6.7** Measures should be set up to ensure stock turnover. Except in special circumstances, stock rotation should ensure that the oldest released stock is used first.

**6.6.8** Periodic inventory should be performed to ensure stock reliability. Any significant discrepancy should be investigated and corrective action taken.

### 6.7 Re-evaluation

A system should be set up to re-evaluate materials as appropriate to determining their suitability for use, after a defined period of storage. The system should be set up so as to prevent the use of materials which require re-evaluation.

### 6.8 Quality of water used in production

**6.8.1** The water treatment system should supply a defined quality of water.

**6.8.2** Water quality should be verified by either testing or monitoring of process parameters.

**6.8.3** The water treatment system should permit sanitization.

**6.8.4** Water treatment equipment should be set up so as to avoid stagnation and risks of contamination.

**6.8.5** Materials used in water treatment equipment should be selected to ensure that water quality is not affected.

## 7 Production

### 7.1 Principle

At each stage of manufacturing operations and packaging operations, measures should be taken to produce a finished product that meets the defined characteristics.

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## 7.2 Manufacturing operations

### 7.2.1 Availability of relevant documents

**7.2.1.1** Relevant documentation should be available at each stage of manufacturing operations.

**7.2.1.2** Manufacturing operations should be carried out according to manufacturing documentation, including:

a) suitable equipment;

b) formula for the product;

c) list of all raw materials identified according to relevant documents indicating batch numbers and quantities;

d) detailed manufacturing operations for each stage, such as addition of raw materials, temperatures, speeds, mixing times, sampling, cleaning and, if necessary, sanitizing of equipment, and bulk product transfer.

### 7.2.2 Start-up checks

Before starting any manufacturing operations, it should be ensured that:

a) all documentation relevant to the manufacturing operations is available;

b) all raw materials are available and released;

c) suitable equipment is available for use, in working order, cleaned and, if necessary, sanitized;

d) clearance of the area has been performed to avoid mixing with materials from previous operations.

### 7.2.3 Assignment of a batch number

A batch number should be assigned to each batch of manufactured bulk product. This number does not need to be identical with the batch number that appears on the label of the finished product, but, if not, it should be easy to relate to that number.

### 7.2.4 Identification of in-process operations

**7.2.4.1** In accordance with the formula, all raw materials should be measured or weighed, into clean and suitable containers labelled with appropriate identification or directly into the equipment used for manufacturing.

**7.2.4.2** At all times, it should be possible to identify major equipment, containers of raw materials and containers of bulk products.

**7.2.4.3** Identification of containers of bulk products should indicate:

a) name or identifying code;

b) batch number;

c) storage conditions when such information is critical to assure the quality of the product.

### 7.2.5 In-process control

**7.2.5.1** In-process controls and their acceptance criteria should be defined.


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**7.2.5.2** In-process controls should be performed according to a defined programme.

**7.2.5.3** Any result outside the acceptance criteria should be reported and appropriately investigated.

#### 7.2.6 Bulk product storage

**7.2.6.1** Bulk product should be stored in suitable containers, in defined areas, and under appropriate conditions.

**7.2.6.2** The maximum bulk product storage duration should be defined.

**7.2.6.3** When this duration is reached, the bulk product should be re-evaluated before use.

#### 7.2.7 Re-stocking raw materials

If raw materials remain unused after weighing and are intended and deemed acceptable to return to stock, their containers should be closed and properly identified.

### 7.3 Packaging operations

#### 7.3.1 Availability of relevant documents

**7.3.1.1** Relevant documentation should be available at each stage of packaging operations.

**7.3.1.2** Packaging operations should be carried out according to packaging documentation including:

a) suitable equipment;

b) list of packaging materials defined for the intended finished product;

c) detailed packaging operations such as filling, closing, labelling, and coding.

#### 7.3.2 Start-up checks

Before starting any packaging operation, it should be ensured that:

a) the area has been cleared of materials to avoid mixing with materials from previous operations;

b) all documentation relevant to the packaging operations, is available;

c) all packaging materials are available;

d) suitable equipment is available for use, in working order, cleaned and, if necessary, sanitized;

e) any coding to permit identification of the product is defined.

#### 7.3.3 Assignment of batch number

**7.3.3.1** A batch number should be assigned to each unit of finished product.

**7.3.3.2** This number does not need to be identical with the batch number that appears on the label of the bulk product, but, if not, it should be easy to relate to that number.

#### 7.3.4 Packaging line identification

At all times, it should be possible to identify the packaging line with its name or identifying code, the name or identifying code of the finished product and the batch number.

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#### 7.3.5 Checks of on-line control equipment

If used, on-line control equipment should be regularly checked according to a defined programme.

#### 7.3.6 In-process control

**7.3.6.1** In-process controls and their acceptance criteria should be defined.

**7.3.6.2** In-process controls should be performed according to a defined programme.

**7.3.6.3** Any result that is outside the acceptance criteria should be reported and appropriately investigated.

#### 7.3.7 Re-stocking of packaging materials

If packaging materials remain unused after packaging operations and are intended and deemed acceptable to return to stock, their containers should be closed and properly identified.

#### 7.3.8 Identification and handling of work-in-process

Filling and labelling is usually a continuous process. Where this is not the case, special measures including segregation and identification should be applied so that no mix-ups or mislabelling can occur.

## 8 Finished products

### 8.1 Principle

Finished products should meet the defined acceptance criteria.

Storage, shipment and returns should be managed in a manner so as to maintain the quality of finished products.

### 8.2 Release

**8.2.1** Prior to being placed on the market, all finished products should be controlled in accordance with established test methods and should comply with acceptance criteria.

**8.2.2** Product release should be carried out by the authorized personnel responsible for quality.

### 8.3 Storage

**8.3.1** Finished products should be stored in defined areas under appropriate conditions for an appropriate length of time. If necessary, finished products should be monitored while stored.

**8.3.2** Storage areas should permit organized storage.

**8.3.3** When finished products are released, quarantined or rejected, they should be stored in their respective physical locations or by using any other system providing the same level of assurance.

**8.3.4** Identification of finished product containers should indicate:

a) name or identifying code;

b) batch number;

c) storage conditions when such information is critical to assure the quality of the product;

d) quantity.


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**8.3.5** Measures should be set up to ensure stock turnover.

Except in special circumstances, stock rotation should ensure that the oldest released stock is used first.

**8.3.6** Periodic inventory checks should be performed to:

a) ensure inventory accuracy;

b) ensure that acceptance criteria are met.

Any significant discrepancy should be investigated.

### 8.4 Shipment

Measures should be taken to ensure the shipment of the defined finished product.

Precautions should be taken to maintain the finished product quality, when appropriate.

### 8.5 Returns

**8.5.1** Returns should be identified in an appropriate way and stored in defined areas.

**8.5.2** Returns need to be evaluated against established criteria to determine their disposition.

**8.5.3** Release should be given before placing returns on the market again.

**8.5.4** Measures should be established to distinguish any reprocessed return. Measures should be taken to avoid the inadvertent redistribution of unreleased finished product.

## 9 Quality control laboratory

### 9.1 Principle

**9.1.1** Principles described for personnel, premises, equipment, subcontracting, and documentation should apply to the quality control laboratory.

**9.1.2** The quality control laboratory is responsible for ensuring that the necessary and relevant controls, within its activity, are carried out for sampling and testing so that materials are released for use and products are released for shipment, only if their quality fulfils the required acceptance criteria.

### 9.2 Test methods

**9.2.1** The quality control laboratory should use all test methods necessary to confirm that the product complies with acceptance criteria.

**9.2.2** Controls should be performed on the basis of defined, appropriate and available test methods.

### 9.3 Acceptance criteria

Acceptance criteria should be established to specify the requirements to be met for raw materials, packaging materials, bulk products and finished products.

### 9.4 Results

All results should be reviewed. After this review, a decision should be made, notably in terms of approval, rejection or pending.

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## 9.5 Out-of-specification results

**9.5.1** Out-of-specification results should be reviewed by authorized personnel and properly investigated.

**9.5.2** There should be sufficient justification for any re-testing to be performed.

**9.5.3** After the investigation, a decision by authorized personnel should be made, notably in terms of deviation, rejection or pending.

## 9.6 Reagents, solutions, reference standards, culture media

Reagents, solutions, reference standards, culture media, etc. should be identified by the following information:

a) the name;

b) its strength or concentration, when appropriate;

c) expiration date, when appropriate;

d) the name and/or signature of the person who prepared it, when appropriate;

e) opening date;

f) storage conditions, when appropriate.

## 9.7 Sampling

**9.7.1** Sampling should be performed by authorized personnel.

**9.7.2** Sampling should be defined in terms of:

a) sampling method;

b) equipment to be used;

c) amounts to be taken;

d) any precautions to be observed to avoid contamination or deterioration;

e) identification of sample;

f) frequency.

**9.7.3** Samples should be identified by:

a) the name or identifying code;

b) the batch number;

c) the date of sampling;

d) the container from which the sample was taken;

e) the sampling point, if applicable.

## 9.8 Retain sample

**9.8.1** Samples of finished product should be retained in an appropriate manner and in designated areas.

**9.8.2** Sample size of finished products should allow analyses to be carried out in accordance with local regulations.


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**9.8.3** Retain samples of finished product should be kept in their primary package for an appropriate time under the recommended storage conditions.

**9.8.4** Samples of raw materials may be retained according to company practice or in accordance with local regulations.

## 10 Treatment of product that is out of specification

### 10.1 Rejected finished products, bulk products, raw materials and packaging materials

**10.1.1** Investigations of rejected product or materials should be performed by personnel authorized to do so.

**10.1.2** Decisions to destroy or to reprocess should be approved by the personnel responsible for quality.

### 10.2 Reprocessed finished products and bulk products

**10.2.1** If all or part of a batch of finished product or bulk product does not meet the defined acceptance criteria, a decision to reprocess in order to obtain the defined quality should be approved by personnel responsible for quality.

**10.2.2** The method of reprocessing should be defined and approved.

**10.2.3** Controls should be performed on the reprocessed finished products or bulk products. Results should be reviewed by authorized personnel in order to verify the conformity of the finished product or bulk product with the acceptance criteria.

## 11 Wastes

### 11.1 Principle

Wastes should be disposed of in a timely and sanitary manner.

### 11.2 Types of waste

The company should define the different types of waste (from production and from the quality control laboratory) that could affect the quality of the product.

### 11.3 Flow

**11.3.1** The flow of waste should not impact on the production and laboratory operations.

**11.3.2** Appropriate measures should be taken concerning collection, transportation, storage and disposal of wastes.

### 11.4 Containers

Containers of waste should be properly identified as to contents and other information, as appropriate.

### 11.5 Disposal

The disposal of waste should be performed in an appropriate way with an adequate level of control.

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## 12 Subcontracting

### 12.1 Principle

A written contract or agreement should be established, mutually confirmed and controlled between the contract giver and the contract acceptor covering subcontracted activities. The objective of this step is to obtain a product or service that complies with the defined contract giver requirements.

### 12.2 Types of subcontracting

This clause concerns subcontracting of:

a) manufacturing;

b) packaging;

c) analysis;

d) cleaning, sanitization of premises;

e) pest control;

f) equipment and premises maintenance.

### 12.3 Contract giver

**12.3.1** The contract giver should assess the contract acceptor's ability and capacity to carry out the contracted operations. Further, the contract giver should ensure that the contract acceptor has all the means available to carry out the contract. The contract giver should assess the contract acceptor’s ability to comply with these guidelines, as appropriate, and to ensure the operations can be performed as agreed.

**12.3.2** The contract giver should provide the contract acceptor with all the information required to carry out the operations correctly.

### 12.4 Contract acceptor

**12.4.1** The contract acceptor should ensure that they have the means, experience and competent personnel to meet the contract requirements.

**12.4.2** The contract acceptor should not pass to a third party any of the work entrusted to them in the contract without the contractor giver’s prior approval and consent. Arrangements should be made between the third party and the contract acceptor to ensure that all information about operations is made available to the contract giver in the same way as in the original contract.

**12.4.3** The contract acceptor should facilitate any checks and audits that the contract giver has defined in the contract.

**12.4.4** The contract acceptor should inform the contract giver of any changes that may affect the quality of the services or products provided prior to implementation unless otherwise specified in the contract.

### 12.5 Contract

**12.5.1** A contract or agreement should be drawn up between the contract giver and the contract acceptor which specifies their respective duties and responsibilities.

**12.5.2** All data should be kept or made available to the contract giver.


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## 13 Deviations

**13.1** Deviations from the specified requirements should be authorized with sufficient data to support the decision.

**13.2** Corrective action should be made to prevent recurrence of the deviation.

## 14 Complaints and recalls

### 14.1 Principle

**14.1.1** All complaints that fall within the scope of these guidelines and are communicated to the plant should be reviewed, investigated and followed-up on, as appropriate.

**14.1.2** When a product recall decision is made, appropriate steps should be taken to complete the recall within the scope of these guidelines and to implement corrective action.

**14.1.3** In the case of contracted operations, the contract giver and acceptor should agree on the process for managing complaints (see 12.1).

### 14.2 Product complaints

**14.2.1** Authorized personnel should centralise all complaints.

**14.2.2** Any complaints concerning a product defect should be kept with the original details and follow-up information.

**14.2.3** Appropriate follow-up on the concerned batch should be completed.

**14.2.4** Complaint investigations and follow-up should include:

a) steps to prevent recurrence of the defect;

b) checking other batches in order to determine whether they are also affected, where appropriate.

**14.2.5** Complaints should be reviewed periodically to check for trends or recurrence of a defect.

### 14.3 Product recalls

**14.3.1** The authorized personnel should coordinate the recall process.

**14.3.2** Product recall operations should be capable of being initiated promptly and in a timely manner.

**14.3.3** The appropriate authorities should be notified of recalls which could have an impact upon consumer safety.

**14.3.4** Recalled products should be identified and stored separately in a secure area while awaiting a decision.

**14.3.5** The product recall process should be periodically evaluated.

## 15 Change control

Changes that could affect the quality of product should be approved and performed by authorized personnel on the basis of sufficient data.

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## 16 Internal audit

### 16.1 Principle

An internal audit is a tool which is designed to monitor the implementation and the status of these cosmetic Good Manufacturing Practices and, if necessary, to propose corrective actions.

### 16.2 Approach

**16.2.1** Specially designated competent personnel should conduct internal audits in an independent and detailed manner, regularly or on demand.

**16.2.2** All observations made during the internal audit should be evaluated and shared with appropriate management.

### 16.3 Follow-up

Internal audit follow-up should confirm the satisfactory completion or implementation of corrective action.

## 17 Documentation

### 17.1 Principle

**17.1.1** Each company should establish, design, install and maintain its own system of documentation that is appropriate to its organizational structure and to the type of products. An electronic system can be used to prepare and manage documents.

**17.1.2** Documentation is an integral part of Good Manufacturing Practices. Therefore, the objective of documentation is to describe activities defined in these guidelines in order to relate the history of these activities and to prevent risks of interpretation, loss of information, confusion or errors inherent to verbal communication.

### 17.2 Type of document

**17.2.1** Documents should be composed of constituents such as procedures, instructions, specifications, protocols, reports, methods, and records appropriate to the activities covered by these guidelines.

**17.2.2** Documents can be hard-copy papers or electronic data processing records.

### 17.3 Writing, approval and distribution

**17.3.1** Documents should be defined and describe, with appropriate detail, the operations to be carried out, precautions to be taken and measures to be applied in all activities connected with these guidelines.

**17.3.2** The title, nature and purpose of documents should be stated.

**17.3.3** Documents should be:

a) written in a legible and comprehensive way;

b) approved, signed and dated by authorized persons before being used;

c) prepared, updated, withdrawn, distributed, classified;

d) referenced to ensure that obsolete documents are not used;

e) accessible to appropriate personnel;

f) removed from the job area and destroyed if they are out-dated.


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**17.3.4** Records which require the entry of handwritten data should:

a) indicate what is to be entered;

b) be written legibly with permanent ink;

c) be signed and dated;

d) be corrected, if needed, leaving the original entry still readable; where appropriate, the reason for the correction should be recorded.

## 17.4 Revision

Documents should be updated, when necessary, and the revision number indicated.

The reason for each revision should be retained.

## 17.5 Archiving

**17.5.1** Only original documents should be archived and only controlled copies should be used.

**17.5.2** The duration of archiving original documents should be defined according to applicable legislation and regulations.

**17.5.3** The storage of original documents should be properly secured.

**17.5.4** Documents may be archived as either electronic or hard-copies and their legibility should be ensured.

**17.5.5** Backup data should be stored at a separate and secure location at regular intervals.

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