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Cosmetics - GMP - Guideline on Good Manufacturing Practices

Cosmétiques - Guide des Bonnes Pratiques de Fabrication

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Foreword

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

Introduction

This guideline is intended to provide guidance regarding Good Manufacturing Practices for cosmetic products. The guideline has been prepared for consideration by the cosmetic industry and takes into account the specific needs of this sector. The guideline offers organizational and practical advice on the management of the human, technical and administrative factors affecting product quality.

The guideline has been written to allow use 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 this GMP guideline 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 - GMP- Guideline on Good Manufacturing Practices

1 Scope

This international standard gives guidance for the production, control, storage and shipment of cosmetic products.

This guideline covers the quality aspects of the product, but as a whole does not cover safety aspects for the personnel engaged in the plant, nor does it 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.

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
A 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 to achieve objectives.

2.3
batch
A 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
A distinctive combination of numbers, letters and/or symbols that specifically identifies a batch.

2.5
bulk product
Any product which has completed processing stages up to, but not including, final packaging.

2.6
calibration
The set of operations which 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 by means of the following combined factors, in variable proportions: chemical action, mechanical action, temperature, duration of application. It is the action of separating and eliminating generally visible dirt from a surface.

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

2.10
contamination
The occurrence of any undesirable matter (chemical, physical and/or microbiological) in the product.

2.11
consumables
Consumables are materials that are used up during cleaning or maintenance operations. These can be cleaning agents and lubricants for example.

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
A 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
A systematic and independent examination made by competent personnel inside the company. The aim is to determine whether activities covered by this guideline and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

2.18
major equipment
Equipment specified in production and laboratory documents that are 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. 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
The 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 and packaging materials.

2.26
production
The 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 processing 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 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 product back to the plant cosmetic product which may or may not present a quality defect.

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. 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 concerned by the implementation of the activities described in this guideline 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 in order to understand the organization and functioning of the company. 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 of the quality department.

3.2.2 Number of people

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

3.3 Key responsibilities

3.3.1 Management responsibilities

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

3.3.1.2 The implementation of Good Manufacturing Practices should be the responsibility of senior 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 authorised personnel are allowed to enter.

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 documents and comply with documents 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 training to perform the assigned responsibilities and activities.

3.4 Training

3.4.1 Training and skills

Personnel involved in production, control and storage 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 this guideline 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 program 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.

3.4.3 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 Training courses

3.4.4.1 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.

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

3.4.5 Personnel training evaluations

Evaluations should be conducted on the knowledge accumulated by personnel during and/or after training.

3.5 Personnel hygiene and health

3.5.1 Personnel hygiene

3.5.1.1 Hygiene programs 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 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 utilised so as:

a. to ensure protection of the product,

b. to permit efficient cleaning and maintenance,

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

4.1.2 Premises design recommendations are described in this guideline. Design decisions should be based on the type of cosmetic product produced, existing conditions and cleaning measures used.

4.2 Types of areas

Separate or defined areas such as storage areas, production areas, quality control areas, ancillary areas, washing and toilet areas, should be provided to prevent error and mix-ups.

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 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 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 should allow for resistance to corrosive cleaning agents.

4.6 Washing and toilet premises

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

4.7 Lighting

4.7.1 Adequate lighting should be installed in all areas sufficient for operations.

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.

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 Any premise used in activities described in this guideline should be maintained in clean conditions.

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

4.10.3 Cleaning and sanitizing agents to be used should be specified and effective.

4.10.4 There should be cleaning and sanitization programs corresponding to specific needs of each area.

4.11 Maintenance

Premises used in activities described in this guideline 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, pest and other vermin.

4.13.2 There should be a pest control program 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, sanitized and maintained. This section applies to all equipment within the scope of this guideline. If automated systems are introduced into activities described in this guideline, 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 Product containers should be protected from environmental dust and moisture.

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

5.2.3 The material used in the construction of equipment should be compatible with products and 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 movements 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 identified.

5.3.5 Defective equipment should be identified accordingly.

5.4 Calibration

5.4.1 Measuring instruments of laboratory and production, that are critical for the quality of the product, should be regularly calibrated.

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 product produced 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 sanitization program.

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 at appropriate intervals.

5.6 Maintenance

Equipment should be regularly maintained. Maintenance operations should not affect the quality of the product.

5.7 Consumables

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

5.8 Authorisations

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

6 Raw materials and packaging materials

6.1 Principle

Raw materials and packaging materials that are purchased should correspond to 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. the 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 assistance and audits.

6.3 Receipt

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

6.3.2 The integrity of the raw and packaging material 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, and quarantined. Other systems can replace this physical system of identification, if they ensure the same level of guarantee.

6.4.4 Identification of raw materials and packaging materials should be composed of the following information:

a. the name of the product marked on the delivery document and packaging,

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

c. the date or number of receipt, if appropriate,

d. the supplier's name,

e. the 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 and packaging materials are used.

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

6.5.3 Raw 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 and packaging material.

6.6.2 Raw 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 and packaging materials should be closed and should be stored off the floor.

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

6.6.6 When raw and packaging materials are quarantined or rejected, they should be stored in a specific physical area or data processing location.

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.

6.7 Re-evaluation

A system should be set-up to re-evaluate materials as appropriate to determine their suitability for use, after a defined period of storage. The system should be set-up 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 finished product that meets the defined characteristics.

7.2 Manufacturing operations

7.2.1 Availability of relevant documents

7.2.1.1 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. the suitable equipment,

b. the formula of the product,

c. the list of all raw materials identified according to relevant documents indicating batch number and quantities,

d. the detailed manufacturing operations for each stage, such as filling sequences, temperatures, speeds, mixing times, sampling, cleaning of equipment, and bulk transfer.

7.2.2 Start-up checks

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

a. all documentation relevant to the manufacturing is available,

b. all raw materials are available and released,

c. the suitable equipment is available for use, in working order, clean and/or 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. the name or identifying code,

b. the 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.

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

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 controlled before use.

7.2.7 Re-stocking raw materials

If raw materials remain unused after weighing and are intended for return into stock, their container should be closed and properly identified.

7.3 Packaging operations

7.3.1 Availability of relevant documents

7.3.1.1 The 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. the suitable equipment,

b. the list of packaging materials defined for the intended finished product,

c. the 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 operation is available,

c. all packaging materials are available,

d. the suitable equipment is available for use, in working order, clean and/or sanitized,

e. on-line coding permits identification of the product, as 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.

7.3.5 Checks of on-line control equipment

On-line control equipment should be regularly checked according to a defined program.

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 program.

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

7.3.7 Re-stocking packaging materials

If packaging materials remain unused after packaging operations and are intended for return into stock, the 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 their quality.

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 authorised 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. Finished product should be monitored to ensure only acceptable finished product are kept in storage.

8.3.2 Storage areas should permit ordered storage.

8.3.3 When finished products are released, quarantined or rejected, they should be stored in their respective physical or administrative location.

8.3.4 Identification of finished product pallets and other forms of containment should indicate:

a. name or identifying code,

b. the batch number,

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

8.3.5 Measures (precautions) 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, and

b. ensure 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 that meets acceptance criteria.

Pre-cautions 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 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 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.

9.5 Out-of-specification results

9.5.1 Out-of-specification results should be reviewed by authorised 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 authorised 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 with 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 authorised personnel.

9.7.2 Sampling should be defined in terms of:

a. the sampling method,

b. the equipment to be used,

c. the amounts to be taken,

d. any precautions to be observed to avoid contamination or deterioration,

e. the identification of sample,

f. the frequency

9.7.3 Samples should be identified with:

a. the name or identifying code,

b. the batch number,

c. the date of sampling or other suitable date, when appropriate,

d. the container which the sample was taken from

e. 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 as a function of local regulation.

9.8.3 Retain samples of finished product should be kept in their primary package for an appropriate time.

9.8.4 Samples of raw materials may be retained according to company practice or as a function of local regulation.

10 Treatment of product that is out of specification

10.1 Rejected finished product, bulk product, raw and packaging materials

10.1.1 Investigations of rejected product or materials should be performed by personnel authorised 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 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 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 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 with contents and other information, as appropriate.

11.5 Destruction

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

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 which complies with the defined contract giver requirements.

12.2 Types of subcontracting

This chapter concerns subcontracting of:

a. manufacturing,
b. packaging,
c. analysis,
d. cleaning and/or 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 acceptors 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 this guideline, 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 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 The contract

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

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

13 Deviations

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

13.2 Corrective actions 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 this guideline 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 this guideline and to implement corrective actions,

14.1.3 In the case of contracted operations, the contract giver and acceptor should agree on the process for managing complaints (see section 13.1).

14.2 Product complaints

14.2.1 Authorized personnel should centralise all complaints.

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

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

14.2.3 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.

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

14.3 Product recalls

14.3.1 The authorised person 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 or materials should be approved and performed by authorised personnel on the basis of sufficient data.

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 actions.

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 it is responsible for. 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 spoken communication.

17.2 Type of documents

17.2.1 Documents should be notably composed of 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 authorised persons before being used,

c. prepared, updated, withdrawn, distributed, classified,

d. referenced to ensure that obsolete documents are not used,

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

f. accessible to appropriate personnel.

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 regulation.

17.5.3 The storage of original documents should be properly secured.

17.5.4 Documents may be retained as either electronic or hard-copies and their legibility should be assured.

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