

# **GOOD MANUFACTURING PRACTICES MANUAL**

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# PROLOGUE

The Royal Decree 1599/1997, of 17th October, dealing with cosmetic products, (BOE of 31st October) defines “cosmetic product” and determines the technical-health conditions and requirements with which, not only the installations as well as the products, their labelling and the publicity must comply.

Said Royal Decree reflects the Spanish the normative in force since 1988. Likewise, it transposes the Directive 93/35/EEC, which modifies the framework of the Directive 76/768/EEC.

In its article 6 is set out the obligation of responsibility of putting on the market and of making accessible and putting at the disposition of the corresponding authorities a technical report.

Of notable importance, due to its novel character, which article 8 acquires in which the person responsible for the commercialization has the obligation to supply to the General Direction of Pharmaceutical and Health Products the corresponding indications for the rapid and adequate treatment in the case of the appearance of problems as a consequence caused by the use or consumption of the cosmetic in question.

The manufacturer of cosmetic products, as well as the importers from third party countries, must be authorised by the General Direction of Pharmaceutical and Health Products. For this motive they must comply with the following conditions (article 18):

- Have sufficient personnel and with adequate qualifications to execute the following controls.
- Have a technician in charge with the necessary level of qualifications, whose employment will be communicated to the General Direction of Pharmaceutical and Health Products.
- Have the necessary premises and equipment for the manufacture, control and conservation of the cosmetics manufactured or imported.
- With regards to the aforementioned they will have the following different areas:
  - Manufacturing area: installations and means necessary for the manufacture and packaging of cosmetic products in the adequate technical-health conditions.
  - Control area: with the necessary means, apparatuses, utensils, reactants and patterns to guarantee the quality of the raw materials, intermediate products and finished products, likewise the packaging and labelling material.
  - Storage area: for raw materials, intermediate products and finished products, likewise the packaging and labelling material.
- Have the manufacturing procedures and controls which permit the establishment of a system to guarantee the quality.

Subsequently, the General Direction of Pharmaceutical and Health Products emitted the circular n° 2/99, in which it details and clarifies what was established in article 18.

In it the period of validity of the authorization of activities is for five years. Also it refers to the entities/installations of cosmetic products, which possess health authorization issued by General Direction of Pharmaceutical and Health Products previous to it coming into force, the Royal Decree 1599/1997, they must adapt to the present legislation and update the authorization issued.

The aim of this document is to orientate the manufacturers of cosmetic products about the way to organize and carry out the manufacture of said products safely, in such a way that products which are put on the market do not harm peoples' health when they are used in normal conditions or put to a reasonably foreseeable use.

At the time of describing the characteristics of a system to guarantee quality, the guidelines used as a reference are those taken from the international standards of the series ISO 9000 of the year 2000. Each organisation must adapt these practices to their specific conditions.

# 1 GENERAL INTRODUCTION

The Good manufacturing Practices are the part of the insurance of quality which guarantees that the products are produced and controlled efficiently to achieve the specific levels of quality for their intended use. The production must have a high level and comply totally with the requirements of the European Union legislation.

The aim of this document is to orientate the manufacturers of cosmetic products as to the manner of organizing and carrying out the manufacture of said products. They are inspired by a management system of total quality and have been considered the basic concepts for quality control. The aim of said control is the reduction, elimination and anticipation of any deficiency in the assurance of quality.

This guide has been prepared specifically with the cosmetic industry in mind, bearing in mind the specific needs of this sector.

The guide has been realized so as to offer help to the industry in accord with the requirements of the Cosmetic Directive 76/768/EEC, particularly with regards to the responsibility of the manufacturers to apply the Good Manufacturing Practices in accord with the requirements of Article 7a.

This guide has been formulated based on the existing Good manufacturing Practices which had been previously developed for the cosmetic sector.

Each company should use the guide reflected in this document to develop their own internal systems and practices. Obviously, such considerations should take into account the size, capacity and the resources available pertaining to the company. It is accepted that there exist other methods and systems other than the ones described here which can be used together with these, or in place of the ones proposed. This presents no problem, if they produce the same or a superior level of guarantee than that supplied in this present guide.

The commitment and responsibility for the application of the Good Manufacturing Practices falls upon the management of the company who must make available all the resources, training and means necessary to comply with the requirements described in this document.

## 2 QUALITY MANAGEMENT SYSTEMS

**Quality management:** management of activities which determine the policy regarding quality, objectives, responsibilities, implanted through plans regarding quality, quality control, insure quality and improve the quality within the quality system.

### 2.1 Introduction

To achieve the objectives of quality set by the organisation, one should design, establish and maintain a documented quality management system which is adapted to its activities and the nature of its products. It should count on the total support of the management of the company.

The implantation of quality management system is the responsibility of the management and requires the participation and commitment of the personnel of the different departments and at all levels within the company, the suppliers and the subcontracted party.

The Quality Management System requires the control of the process of manufacture, managing the arrivals and the departures; identifying and correcting the anomalies, and redefining the processes to avoid their repetition.

### 2.2 ORGANIZATIONAL STRUCTURE

The organizational structure should be clearly defined with the objective of understanding the organization and functioning of the company. It should be in accord with the size and the diversity of the products of the company.

Objective	measures which should be taken	Examples
Understanding the organization and the functioning of the company.	Defining the organizational structure.	Approval of the organization chart
	Determining the functions and responsibilities of each member of the organization.	Descriptions of the job positions or work files, job profiles etc.

- Is there an organization chart?
- Is there a description of the job positions?

### 2.3 Recourses

The company should count on the adequate and appropriate resources with regards to the executive teams, personnel, premises, equipment and machinery

#### 2.3.1 Personnel

Each company, in function to the quantity and diversity of its production, should insure an organizational structure and employ an adequate work force in the different fields of its activity.

The work force should be made up of people whose knowledge, experience, competence and motivation is adapted to the tasks and responsibilities which they are designated. There should be no suppositions or unexplainable lapses regarding the responsibilities of the personnel who are participating in the application of Good Manufacturing Practices.

Objective	Measures which should be taken	Examples
Have an adequate staff in the different fields of the activity	Inform the personnel of the organizational chart	Inform the personnel on joining the company of the organization chart. Inform the personnel of the profile of their job.
	Make sure the tasks are understood	
	training programmes are available	Informal chat on joining the company Annual training programmes.

- Do the personnel know their responsibilities and tasks?
- Do they have access to instructions, information and data about their area?
- Do the personnel know their responsibilities and tasks?
- Have they access to instructions, information and data about their area?
- Is there an adequate staff for the size and diversity of the company?
- Is there a responsible Technician available?
- Are there enough trained personnel to insure the quality of the activities?

### 2.3.2 Premises

The premises should be designed, constructed or adapted and maintained with the aim of satisfying the conditions established to carry out the activities for which they are destined.

objective	Measures which should be taken	Examples
Have available adequate premises for the safe manufacture of the cosmetic products.	Design of the premises and the selection of the adequate materials	Smooth surfaces, use of non-porous materials
	Carry out the maintenance of premises Establish programmes for industrial hygiene	Plans for maintenance corrective and/or preventive. Maintenance contracts with external organizations. Documented cleaning programmes
Establish the different areas in such a way that does not interfere negatively with the quality of the products	Define the activities to be carried out in the different areas. Avoid the cross flow of material or personnel	
	identify the different areas with signs	Signboards, signs on the floor, plans of the installations, physical separations by means of walls, partitions, doors.

- Are the installations suitability designed for the activity for which they are destined?
- Are there procedures for internal or external?
- Are the different areas of the work process clearly distinguishable?
- Are the conditions of ventilation, temperature and illumination sufficient?
- Are there sufficient installations to facilitate adequate personal hygiene?

### 2.3.3 Equipment

The equipment and machinery should be efficiently maintained and cleaned in such a way that it complies with the purpose for which it is destined.

Objective	Measures which should be taken	Examples
Have suitable equipment and machinery for the safe manufacture of cosmetic products.	Selection of suitable materials	Materials not susceptible to corrosion, compatible with the cosmetic and cleaning products.
	Selection of suitable machinery.	Listing of machinery (or related machinery).
	Realize the maintenance and cleaning of machinery and equipment.	Plans for corrective and/or preventive maintenance, scales of maintenance. Contracts for maintenance with external institutions. Programmes for cleaning, programmes for disinfection if necessary.
	Control the safekeeping of equipment	cover cupboards, shelves and equipment

- Are the machines, utensils and accessories easy to clean and disinfect in accord with the requirements of each one?
- Is there compatibility among the components of the machinery and equipment and the products and materials used for the cleaning and disinfection? Are the cosmetic products compatible with the equipment they come into contact with?
- Are the clearing and disinfection procedures simple and easily understandable?
- Is the machinery and equipment designed in such a way as to prevent possible contamination during the manufacturing processes?
- Is there a programme for the maintenance of equipment and machinery?

## 2.4 Procedures

Each company should implant its own procedures and instructions for manufacturing, taking into account the nature of the production and organizational structure. The procedures and the instructions should be appropriately defined and formalized, the operations should be described in detail on being realized, the precautions to be taken into account and the applicable measures of the different activities related with the manufacture.

The instructions related to the formulations, production, dosage and filling should be kept in writing.

All the procedures and instructions should be at all times easily accessible to the appropriate personnel.

Objective	Measures which should be taken	Examples
Realize all the procedures in a controlled way so that the quality of the cosmetic products can not be affected	Determine the type and extension of the necessary documents. Determine the medium to be used for each document.	Manuals, general procedures, normalized work protocols, instructions, specifications, safety files, analytic methods, etc .paper, computer programmes, etc.
	Determine the form of keeping control of the documents.	See chapter 10 on documentation.

- Are there written instructions related to the processes?
- Are the documents checked and approved before their distribution?
- Are the documents available in the work places where their use is necessary?

## 2.5 Processes

**Process:** any operation involving the manufacture of a determinate product.

**Process:** Various operations may be involved in the manufacturing processes for a determinate product and can be combined in the same procedure. These processes should be previously tested before the product is launched onto the market. Any notable modification of one or various processes should be submitted to an evaluation.

Objective	Measures which should be taken	Examples
Carry out the processes which intervene in the manufacture of cosmetic products in a controlled way.	Define the different processes necessary with an adequate level of detail.	Instructions for manufacturing, filling, packaging, etc.
	Determine the responsibilities for the approval of modifications of the processes.	Modifications signed by the persons involved in the process.

- Are the manufacturing processes defined in writing?
- Have the responsibilities for their approval been determined?
- Are the instructions for the processes available in the places for the use for the personnel involved?
- Is any modification approved before it is put into practise, previous testing that it does not affect the quality of cosmetic products?

## 3 MANUFACTURING

Manufacturing: conjunction of operations of a technical nature (transformation of products, processed, filled and packaged, storage, maintenance controls, inspection, etc.) necessary to obtain the finished product, as well as any related administrative or economic operation.

### 3.1. Introduction

In each phase of manufacturing, the appropriate measures must be taken to assure that the finished product fulfils the required conditions which ensure their conformity.

Measures must be taken to ensure the application and compliance of procedures and instructions applicable to each phase of manufacturing process. At all times it should be possible a piece of equipment, an instrument, some raw material/component or materials. The material/components and packaging material not pertinent to the production should be kept separately from the heavy raw materials and bulk products to avoid cross contamination. The personnel should have instructions, information and data available in their work places, about the manufacturing operations, nomenclature, necessary equipment and packaging operations.

The production may be carried out by the selfsame company or through subcontracted parties.

### 3.2. Purchases

This important element consists of the management of resources which are essential for the manufacture and which come from outside the company. These elements are:

- Raw materials, components and packaging material purchased from suppliers and, where applicable, manufacturing machinery.
- Partial or total subcontracting of production operations to a company which has one or various factories specialized in the corresponding activity.
- Partial or total subcontracting of packaging operations. The requirements of quality should be specified in close collaboration with the different departments affected, which may include Research and Development, Production, Quality Control, etc.

Responsibilities should clearly be defined for the principle activities such as,  
For example:

- Establish specifications for raw materials, components, packaging material, and manufacturing equipment.
- Approval of suppliers and subcontractors to ensure the quality (purchases should only be made from suppliers who have been previously selected), subcontracting should be forbidden without the agreement of the person in charge of purchases.
- Establish the conditions for the client-supplier relations (assistance, auditing, etc.)
- Establish the inspections to be carried out by the supplier or the subcontractor
  - Compile technical contractual clauses (type of inspection to be carried out, criteria for acceptance or rejection and steps to be taken in the case of unacceptability, or modifications...).

The purchase documents should contain data which clearly describe the product. Moreover a procedure should be established which clearly defines the responsibility with regard to the preparation of the orders, the type of information and the requirements which should be mentioned.

<b>Objective</b>	<b>Measures which should be taken</b>	<b>Examples</b>
Carry out the purchase of equipment, Materials/components and the subcontracting of services, in such a way that the quality of the finished cosmetic products is not affected.	Determine the criteria for the selection of materials/components and equipment.	Catalogues or files of products, realization of pilot tests.
	Determine the criteria for the selection of suppliers.	Systems of specified quality, certified products, Previous experiences, audits of the suppliers, Despatch of questionnaires to the suppliers, references from other firm in the sector, sample orders...

Objective	Measures which should be taken	Examples
	Determine criteria for the evaluation and follow-up of the suppliers and subcontractors.	Index of rejections, reliability of meeting the delivery deadline, merchandize received with the number of the lot merchandize received with the analytic bulletin.
	Establish documents which describe unmistakably the requirements requested for the purchased products.	Specifications of the raw materials, Specifications of the packaging material, contracts with the subcontractors.

**Selection of materials/components**

- Are there specifications of the materials/components?
- Are there lists of approved raw materials?
- Are there lists of approved packaging materials?

**Selection of suppliers**

- Are there lists of approved suppliers for each area?
- Are there lists of approved subcontractors?
- Are the purchases and subcontracting services realized by approved suppliers/subcontractors?

**Criteria of evaluation and follow-up**

- Are the capabilities of the suppliers to comply with the requirements requested evaluated?
- Are evaluations and follow-ups periodically carried out?
- Is the criteria for the evaluation clear?

**Documents**

- Are the purchases documented?
- Is the documentation traceable?
- Are the orders filed?
- Is a follow-up of the said documents carried out?

### 3.3. Reception and manipulation of Materials/components

#### 3.3.1. Quality of the water

Special attention should be given to the water, since it is an important raw material. The quality of the water must have a standard as it guarantees the safety of the finished product.

The installations and systems for the treatment of the water should always provide a quality of water which guarantees the conformity of the finished products.

The chemical and microbiological quality of the water should be regularly controlled in accord with the written procedures. Any deviation from the specified requirements should be immediately corrected.

- The systems for the treatment of the water should permit disinfection in accordance with the established procedures.
- The canalization system should be constructed in such a way as to avoid stagnation and risks of contamination of the water.
- The materials should be selected so that the quality of the water is not affected.
- Adequate signs should be visible to allow the identification of the water pipes, such as hot, cold, demineralised, water or steam for cleaning.

Objective	Measures which should be taken	Examples
Insure that quality of the water guarantees the conformity of the finished cosmetic products.	Define the Physicochemical and microbiological characteristics necessary for the water.	Different specifications if necessary, depending on the product to be manufactured.
	Determine the necessary system of treatment in accord with the characteristics required.	Distillers, osmosis, tap water, etc.

Objective	Measures which should be taken	Examples
	Determine the type of maintenance and cleaning for the processing systems of the installations.	Use the information from the supplier of the processing system, cleaning contract with an external company, cleaning and disinfection for the water production plant and all the canalization. Physicochemical controls Microbiological controls.

- Do there exist specifications for water in the same way as other raw materials?
- Do there exist procedures for cleaning and disinfection of the water processing system and/or installations?
- Are the pipes identified?
- Do there exist plans of the route of the water?
- Is the water processing system adequate to supply the required quality of the water?
- Is the quality of the water obtained periodically tested?

### 3.3.2. Reception of raw materials, packaging material and other materials/components

**RAW MATERIAL:** any substance which participates or is implicated in the manufacture/processing of a bulk product.

**Packaging material:** Each element or article which is necessary to contain a final product, and principally to ensure its physical protection, excluding any external packaging for transportation or shipping

The reception of all merchandise destined for production (raw materials, packaging material, bulk/loose products, etc.) should be made according to the established procedure.

Each delivery should be registered, likewise the result of checking its correctness. The discovery of any non-fulfilment which may affect the quality should be made know to the personnel responsible for making the decisions. The irregular material should be identified awaiting a decision.

The raw material and the primary packaging materials should be stored and manipulated in such a way that mixing is prevented, the contamination with micro-organisms and other chemical products or decomposition due to exposure to excessive heat, cold, sunlight or humidity.

The packages, containers, boxes, etc. should be stored closed and not in contact with the floor.

The containers should identify the merchandise container as well as the lots.

The merchandise should be sampled and inspected according to procedures which ensure the absence of micro-organisms and other extraneous substances. Particular attention should be paid to the merchandise of origin animal or vegetable and those used in the production of cosmetics in cold procedures, relative to the possibility of contamination with dirt or micro-organisms.

The raw materials which are purchased should comply with the contractual specifications previously established being important for the quality and safety in the use of the finished product. The necessary requirements relative to the purity required of certain ingredients should be taken into consideration. Also careful attention should be paid to the possible presence of forbidden substances in the cosmetic products, in accordance with those indicated in the legislation in force for cosmetic products. These quantities should be as low as possible within the limits established by the current level of technical development in the industries which supply the substances used in cosmetics.

The merchandise which does not comply with the criteria for the specified acceptance should be identified in such a way as to avoid its use.

The reception register should contain the information which permits the identification of the merchandise. As a guide it should include at the least the following information:

- The name of the merchandise indicated in the delivery documentation and on the container.
- The name given to merchandise within the company (if it is different to the name used by the supplier) and/or its code
- Date of reception
- Name of the supplier
- Batch reference given by the supplier and the one given to reception if it is different
- Total quantity and number of containers received

In the reception a systematic verification of the merchandise should be carried out, not only if it is a new product, a sample, but also if it comes from a known supplier or subcontractor, so as to control possible risks during its use or after the finished product has been put on the market.

The internal identification and transportation of merchandise should follow established procedures

The sampling should be carried out by authorised persons and experts with the object of guaranteeing that the samples taken correspond to the batch received, not only with regards to identity but quality as well.

<b>Objective</b>	<b>Measures which should be taken</b>	<b>Examples</b>
Insure that the reception of all the merchandise destined for production is carried out in accord with the established procedures which guarantee its conformity.	Determine the documentation which must accompany each type of merchandise.	Analytic bulletin, despatch note, etc.

Objective	Measures which should be taken	Examples
	Establish sampling systems, if necessary	the size of samples, utensils, precautions, containers of samples, containers labelled and sealed, identification of samples, etc.
	Establish systems of registration of the merchandise received which facilitates its identification.	Manual or computerized system, labels, roadmaps.

- Is the coherence between the delivery/despatch note and the merchandise checked?
- Denomination, quantity, external physical aspect...?
- If identified, are anomalies registered?
- Is the zone where the merchandise must be deposited defined?
- Do reception procedures exist?
- Do sampling procedures exist?
- Are packets and parcels identified on being received?
- Is the data registered? Commercial name of the product, company code, date of reception, name of the supplier, supplier's batch number, etc.
- Is the agreed documentation which must accompany the merchandise verified?

### 3.3.3. Storage

The different merchandise which is required for the production should be stored cleanly and neatly in accord with the safety specifications applicable. The storage conditions must be the appropriate for each type of merchandise.

A system should be established which incorporates the following;

- The incoming and outgoing channels must be clearly distinguishable
- The storage should be realized in conditions which permit the separation of lots and the rotation of stocks.
- The system should avoid the use of nonconforming materials or materials which have not been previously checked; if a product is blocked it must be identified as such
- Follow-ups and periodic inventories to ensure the reliability of the stock;
- If any raw materials or the packaging material is left over after manufacturing and the stock is going to be returned, its designation, lot number and quantity as well as what is going to be returned to the system of stock management it should be clearly indicated;  
The storage conditions of the bulk raw materials should be established in procedures.

All the containers should be kept close and clean and should be according to the special conditions and safety initially established.

Objective	Measures which should be taken	Examples
Ensure that the storage is carried out cleanly and neatly and appropriately for each type of material/component.	Draw up procedures for storage of raw materials, packaging materials, intermediate and bulk products, finished products.	
	Establish special storage conditions should they be necessary.	Humidity, heat, cold, safety.

Objective	Measures which should be taken	Examples
	Identify the materials/components, according to state of acceptance (quarantine, approval, rejection).	Painted lines, separated shelving, labels, signs, Computer systems, etc.
	Establish a system of rotation for the products in the stores.	First In First Out system, Computerised systems.

- Are the materials/components duly differentiated according to the state of manufacture?
- Are the parcels identified and remain sealed?
- Have the necessary environmental conditions been established, when they are applicable and are they periodically checked? Are the results registered when they are obtained?
- Is the material identified, and is its position known in respect to its availability?
- Are the containers especially those which contain intermediate and bulk products identified with information related to them:
  - the name of the product
  - the number of the lot
  - the quantity
  - the date of manufacture
  - the state
- Is there a system to ensure the correct rotation of the material, in such a way that the use of obsolete or out of date material is avoided?
- Is there documentation regarding the storage life of materials, especially intermediate and bulk products?

### 3.4. Weighing and dosage of raw materials

All the raw materials should be identified and quantified in accord with the formula of the product.

The raw materials should be measured, weighed, and dosed, either in suitable clean recipients which contain the necessary information, or directly in the machinery or equipment for the manufacture, whether it is carried out as a continuous or discontinuous process. During the weighing out of raw materials adequate preparations should be made to avoid cross contamination. After the weighing process, all the containers should be returned to stock to avoid any risk of alteration of the raw material.

Objective	Measures which should be taken	Examples
Ensure that all the raw materials for the elaboration are identified and quantified in accord with the formula of the product.	Design areas for weighing/dosage with adequate equipment for the quantities to be weighed and dosed.	Scales and balances with different weight ranges.
	Have at the disposal of the person responsible for weighing the quantified formulas.	Formula index, Computer screen, etc.
	Identify the raw materials once weighed.	Labels with name, Number of lot, product for which it has been weighed, etc.
	Identify all the raw materials for the same manufacturing order.	Placing them all on the same pallet, in the same site, etc.

- Is there suitable balance to carry out the weighing?
- Is it accurate?
- Are there documented procedures for the weighing and dosing of raw materials, including the formula?
- Are the utensils, recipients and the equipment necessary for weighing and dosage clean and correctly tested beforehand?
- Is the identification of the raw materials and their availability previously checked (approval for its use)?
- Are the raw materials once weighed, identified and positioned in such a way so as to avoid being confused with other materials destined for other manufacturing processes?

### 3.5. Manufacture of bulk products

**Bulk Product:** any product which has passed through all phases of manufacturing except packaging.

Whatever the organisation of the production, the raw materials necessary for the formula of the product should be identified and quantified.

#### 3.5.1. Manufacture

**Manufacturing- Processing:** all those operations which allow the combination of raw materials prepared according to a defined procedure which results in a bulk product.

Before commencing any process of manufacture, the following should be checked:

- All the relevant instructions for the manufacture are available;
- All the raw materials are available;
- The necessary machinery is clean (and disinfected if it is necessary), for its smooth running and ready for use. It must be free from all the materials and information which belong to anterior processes;
- Any other condition previously specified is complied with.
- All manufacturing processes require clear and precise instructions, including:
  - The necessary machinery
  - The formula of the product
  - Detailed operational rules for each stage (e.g. the order of addition, velocities, temperatures, mixing times, etc., taking and testing of samples, either during or at the end of the manufacturing process, cleaning the machinery, requirements for the transfer of the product to bulk.
- A list of all the raw materials codified according to rules established by the company, stating the lot number and the quantities used.

Objective	Measures which should be taken	Examples
Ensure the manufacture of bulk products is realized in controlled conditions.	Establish the procedures of manufacture.	The order of introduction of the raw materials temperature, stirring times, etc.
	Determine the requirements which the machinery and the manufacturing equipment should comply with.	Type of mixing bowl, adequate volume for the quantity to be manufactured, etc.
	Check before the elaboration the condition and cleanness of the material.	Labels, stickers, posters, etc.

- Are the written manufacturing procedures available? Is the formula of the product included?
- Are the manufacturing processes carried out according to the written procedures?
- Is the cleanness of the equipment and machinery checked before its use?
- Are other methods available which guarantee that there is no confusion with other products?
- Is all the equipment clearly identified?

### 3.5.2. Storage of bulk products

Bulk products should be packaged as soon as possible. If the bulk products are kept awaiting packaging, the procedures should be established:

- The quality of equipment to be used;
- The storage conditions;
- The tests to be carried out in case of prolonged storage;
- These tests should be previously agreed upon and in writing
- The maximum storage period;
- The indications of deterioration;
- The procedures for collection of residues should be in writing

The packaging of bulk products should be carried out as soon as possible after manufacturing.

<b>Objective</b>	<b>Measures which should be taken</b>	<b>Examples</b>
Ensure that the bulk products are packaged as soon as possible.	Determine the maximum period of time of storage.	Ensure that the bulk products are packaged as soon as possible.
	Establish the procedures for re-control.	

- Is there a maximum period of storage for bulk products?
- Are there procedures for re-control?

# 4 PACKAGING OPERATIONS

**Packaging:** All the operations which include the filling and packaging of a bulk product before becoming a finished product.

When the packaging process is started, special attention should be paid to minimising the risk of cross contamination, for example the powder of the creams.

## 4.1. Packaging

Before commencing the packaging operations, all the machinery and materials/components, including the bulk products should be efficiently and correctly identified.

All the instructions referent to the packaging operations should be available before and during the operation.

Precautions should be taken to eliminate the presence or contact of any packaging material originating from another previous operation, to avoid any mixing of packaging material.

The products to be packaged should be clearly identified (for example the information dealing with the lot number and the minimum durability) on the line or in the place of work.

Objective	Measures which should be taken	Examples
Ensure that the packaging of the products is carried out in controlled conditions.	Establish precise packaging instructions...	
	Determine the requisites which the packaging machinery must comply with.	
	Verify before the packaging the condition and the cleanness of the machinery.	
	Verify the coherent between the product to be packaged and, its container and the labelling.	

- Is the product which is to be packaged clearly identified?
- Are the packaging lines and their state adequate?
- Is there a system for marking the lot numbers of the finished products?
- Are there clearing procedures which avoid contamination from other products?
- Are samples taken at the beginning of the packaging process for their control?

## 4.2. Distribution of the packaged products

This section will be dealt with in chapter 7.

# 5 QUALITY CONTROL

**Quality control:** part of the management of the quality is orientated to complying with the requisites of quality...

## 5.1. Introduction

The control of quality is related to the sampling, the specifications, the organisation and documentation of production to ensure that the necessary and relevant *issues are taken into account* and the materials which are not apt for their use, are not made available for sale or application until the specified requirements are correctly verified. Quality control is not only applied to the manufacture of bulk products, but must embrace all the activities of the organisation which can have an impact on the quality of the products.

The personnel responsible for the quality control related to production should have their responsibilities clearly defined. The production personnel should intervene in the reduction, elimination and prevention of defects in the quality.

All the inspections and tasks dealing with quality control should be carried out according to written procedures.

The personnel should have at their disposal the following information:

- Specifications
- Identification requisites
- sampling procedures
- Inspection procedures and testing methods
- Acceptance limits

## 5.2. Production control

**Production:** joint operations of a technical nature which are necessary to obtain a finished product. This also includes manufacturing and packaging activities.

Control in the production processes ensures quality, safety, and facilitates the optimization of the processes and assists in the analysis of manufacturing problems.

## 5.3. Equipment and machinery

To achieve optimum production conditions, the equipment and the machinery should be adequately inspected /and/or tested. Control procedures should be established.

Objective	Measures which should be taken	Examples
Ensure the equipment and the machinery which is used in the production processes. is in good working order the production processes.	Define the requirements of each piece of equipment	Environmental conditions, Location, Services
	Check the good working order of the equipment.	Validation of the processes, calibration of the equipment, etc.

- Are there specifications of the requirements for all the pieces of equipment available?

#### 5.4. Water processing systems

This has been dealt with in section 3.3.1.

#### 5.5. Testing of equipment

All the equipment should be checked regularly so it is kept in good working condition.

The results of the checks carried out should be inspected regularly. Those instruments which are found not to meet the level required should be clearly identified as not apt for use.

Objective	Measures which should be taken	Examples
Use equipment of an adequate size.	Determine the necessary measurements of the equipment.	Lists of equipment or classes of equipment.
	Determine the type of checks to carry out on measuring equipment.	Maintenance programmes, verification, calibration (for those pieces of equipment which measure critical parameters in the processes or products). Internal or external tests. Frequency of the tests.
Identification of equipment.	Determine the systems for identification. (code, control date, date of next control, availability)	Labels, signs, computer systems.

- Are there lists of measuring equipment available?
- Is the measuring equipment periodically checked, tested and adjusted?
- Are there written procedures for the realization of internal tests available?
- Have the limits of acceptance for the tests been established?
- Are the results obtained examined?
- Are actions established in the case of unsatisfactory results?
- Are the certificates issued examined by external centres?
- Is the equipment correctly identified?

### 5.6. Reactants

All the reactants should carry an identification which contains the following information:

- The name of the reactant;
- Its purity or concentration;
- The identity of the solvent;
- The date of preparation and its expiry date;
- Warning of any specific risk and restriction of its use;
- Name and signature of the name who prepared this reactant or at least that the reactant was purchased as a finished product.

Objective	Measures which should be taken	Examples
Reactants duly identified.	Establish the system for the identification of purchased reactants (name, purity, expiry date, risks of usage, date of opening)	Labels of origin, indelible signage of containers, signs or posters.
	Establish the system for the identification of prepared reactants (name, purity, date of preparation, expiry date, risks of usage, identification of person responsible for the preparation).	labels, posters, indelible signage on container.
Ensure the quality of the reactants used	Check the identification and expiry date of the reactants before using them.	Label, expiry date, indicate the date of aperture.
	Check the quality of the prepared solutions.	Standardization, Indication of date of preparation and expiry date

- Are the reactants identified with information relative to:
  - name
  - concentration
  - expiry date
  - precautions of use?
- Is the identity of the reactants checked before use?
- Are the procedures for the preparation of the solutions available?
- Are the procedures for the use of the reactants available?

### 5.7. Specifications of the merchandise

The specifications describe the requirements with which the raw materials, the packaging materials, bulk products, semi-finished and finished products; used and obtained during the production must comply with.

In accordance with the agreements previously made with the suppliers, each new reception of raw materials must be subject to an identification check or a complete inspection.

The quality of the raw materials, packaging materials and bulk products should be analysed at appropriate intervals to ensure that none of its characteristics have undergone alterations.

Objective	Measures which should be taken	Examples
Use accepted merchandise in the production	Establish the applicable specifications to each merchandise or group of merchandise. Define the technical documentation which should be demanded from the supplier of each piece of merchandise.	Carry out internal specifications, use of the specifications supplied by the supplier, use of technical data sheets, use of reference documents (pharmacopoeias, bibliography)
	Establish the checking system of compliance of specifications and their registration.	control Internal procedures of sampling, frequency of control, parameters to be controlled, criteria of acceptance, bulletins of control ...

- Are the specifications for raw materials, packaging material, semi-finished products, bulk products, finished products available in writing.
- Do the specifications contain information relative to
  - identification of the product
  - qualitative and quantitative requisites and their acceptable limits
  - references to methods of control?
- Is the compliance of specifications according to procedures documented?
- Is the result of the verifications registered?
- Are the opportune actions taken in the case of non-compliance of the aforementioned?

**5.8. Control of the results**

The results should be registered and analysed. The registers should contain the results of the inspections, measurements or verifications and any observations by personnel who carried them out. Likewise, the registers should clearly show the state of the verification.

It should be clearly stated who has the competence to authorize the verification or not of the results of the inspections.

Objective	Measures which should be taken	Examples
Ensure that the cosmetic products put on the market conform to the controls.	Establish the controls to be carried out during all the processes and the personnel responsible for each activity.	Specifications of the control, bulletins of control.
	Establish the competence necessary for all the personnel who carry out the tasks of quality control.	Profile of the job, the person responsible for the release of the lot.
	Establish the measures to be taken in case of detection of non-conformity.	Reports of non-conformity, corrective actions

Objective	Measures which should be taken	Examples
Supply evidence that specified requisites have been complied with.	Determine the registries necessary in every activity and the responsibilities.	Inclusion in different documents of the registries to be used, lists of registries, etc.
	Determine the contents of the registries.	Inclusion in the documents of the contents of the registries, use of forms, use of computer systems...
	Determine the filing system and custody of the registries	Support paper (archives, folders. computer systems.

- Are registries of inspections carried out available?
- Do the inspection registries contain the following information:
  - denomination
  - quantity
  - date of production or reception
  - number of the production lot
  - origin
  - results of each of the controls
  - decision of use
  - date and signature of the personnel responsible for the release and the person who carried out the inspection?
- Are the registries kept safe during the specified period?
- Is any deviation which occurs documented?

## 5.9. Tests

Procedures for tests should be established in writing, these should include the personnel authorized to take samples, the methods and equipment to be used, the quantities to be taken and any other precautions which should be taken into account to avoid contamination of material or deterioration of its quality.

The reference sample of each lot of a finished product should be conserved (during an appropriate period to be determined by the organisation and at least the long as the date of minimum duration)-this applies to raw materials and finished products (the finished products should be kept in their complete packaging).The sample sizes should be large enough to permit at least two complete analysis to be carried out. All the samples should be kept in areas designated as restricted access.

Objective	Measures which should be taken	Examples
Ensure that the realization of adequate tests for the release of the product (raw materials, packaging materials, bulk products, semi-finished and finished products)	Establish procedures for sampling and control	Control methods, sampling instructions, etc.
Ensure the realization of re-controls in case of necessity	Determine the products of which samples will be kept.	Raw materials used in the manufacturing, finished product, etc.
	Determine the existence of special conditions for the conservation of samples and the period of conservation of same.	Expiry date and/or date of re-inspection of raw materials, expiry date of the finished product, sample-room, restricted access zone.
Identified samples.	Determine the system of identification of the samples	Labels, signs, indelible labelling of containers, etc.

- Are control and sampling procedures available?
- Are procedures for identification and archives for samples of raw materials and finished products available?
- Is there an archive of samples with controls of access to it available?

## 5.10. Control and analysis of data

**Corrective action:** action taken to eliminate the causes which are detected of nonconformities, defects or any other undesirable situations and avoid their repetition.

The use of the results of the tests is an important technique in the management of quality control.

It permits, on the one hand, to realise a follow-up of the quality in all the manufacturing processes and, on the other hand, control the results of the corrective actions which have been applied.

With the help of this information, it should help to identify the possible causes of the defects which have been found, with the object of deciding on the corrective actions which must be taken.

Objective	Measures which should be taken	Examples
Detect nonconformities	Register the parameters found of nonconformities in the inspections carried out.	reports of nonconformities data bases of incidents, control bulletins
prevent nonconformities	Establish a systemization for taking corrective actions.	Periodic check of the nonconformities, analysis of causes and measures. Posterior follow-up of the measures taken.
Improve processes	Establish a systemization for initiating preventive actions	Periodic check of the results of the registers of inspection, analysis of tendencies and measures to be taken, posterior follow-up of measures taken.

- Are the registries of detected nonconformities available?
- Are the results of the registries of inspections, as well as raw materials, packaging materials, bulk products and finished products analyzed?
- Have the corrective actions to be carried out based on deviations which have occurred been established? Are said actions carried out and are they documented?
- Are the causes analysed and are actions taken to avoid the repetition of the nonconformities?
- Is a follow-up of the effectiveness of the actions taken carried out?

# 6 SUBCONTRACTING

**Subcontracting:** the realization of an operation by an external person or organization (the subcontractor) in the name of a person, company or organisation (the title holder).

**Subcontractor:** the external person, company or organization that carries out an operation in the name of another person, company or organisation(the title holder).

## 6.1 Introduction

Whatever the type of subcontracting it is, all the subcontracting operations should be adequately defined and controlled so as to avoid the possibility of obtaining products or work of an unsatisfactory nature. With this objective in mind an agreement between the title holder and the subcontractor should be drawn up to establish the obligations of each party to obtain a product of the agreed quality.

## 6.2. The title holder

The title holder is responsible for evaluating the capacity of the subcontractor to carry out the subcontracted activities.

## 6.3. The subcontractor

The subcontractor is under the same requirements as the title holder. The subcontractor should not subcontract a third organization, for part of the work which was subcontracted to them without the approval and consent of the title holder.

The subcontractor should facilitate any inspections and audits which the title holder established in the contract.

## 6.4. The contract

It should be designed between the title holder and the subcontractor, procedures and specifications, with the objective of defining the respective responsibilities for the manufacture of the product.

Objective	Measures which should be taken	Examples
Ensure the reception of a product of the quality adjusted to the specifications in any type of subcontracted operations. The operations to be carried out by the subcontractor.	clearly define all the subcontracted operations	Contract where all the details of the operations to be carried out by the subcontractor are set out.

Objective	Measures which should be taken	Examples
	Clearly define the obligations/rights of each party	
Ensure that the subcontractor complies with the rules described in the GMP's	Establish the possibility of carrying out an initial audit, and posterior periodical audits, which permit the continuous evaluation of the subcontractor.	Evaluation of the means/capacities of the subcontractor, checking that they are adequate for the products/quantities which is the object of the subcontracting
	Design/agree on the procedures/specifications adequate for the manufacture/packaging and control of the subcontracted products.	Procedures in writing for each operation
Ensure that the product complies with all of their specifications before putting it on the market.	Establish defined procedures for the release of finished products	Procedures for checking the compliance with the specifications (methods of analysis, regularity, sampling systems, analysis of the deviations etc.)

- Is each and every one of the operations to be realised by the subcontractor defined?
- Does a written agreement between the title holder and the subcontractor which establishes the obligations and responsibilities of each party exist?
- Is there an evaluation on the part of the title holder of the capacity of the subcontractor to carry out each and every one of the operations for which they have been contracted?
- Is it ensured that the subcontractor possesses adequate means with regards to personnel, premises, machinery and, systems to guarantee the agreed quality?
- Does the title holder supply all the required information, detailing the products, processes, specifications, control methods, etc.?
- Is it confirmed that the subcontractor respects all the pre-established terms and conditions?
- Does the subcontractor facilitate any checks or audits which the title holder requires?
- Do the personnel who are competent and well trained in GMP's agree with all the technical aspects in relation with the operations to be carried out by the subcontractor?
- Are measures included in the contract which authorise the title holder to realise audits which ensure that the corresponding GMP's are carried out?
- Are there defined procedures for the release of the finished products?
- Is the person who has the authority to release the finished products defined?
- In the case of a slight deviation from the specifications, who has the authority to decide if the product can be approved?
- Is this type of situation documented? How?
- Is there a procedure established to determine the actions to be taken with the rejected product?

## 7. THE STORAGE OF FINISHED PRODUCTS, ISSUE AND TRANSPORT

**Finished product:** product obtained after finalizing the manufacturing process, exactly as it will be put on the market.

### 7.1. Storage and issue

Written procedures should be established for the storage of finished products, with special attention on maintaining the quality of the product.

The conformity of all the finished products in accord with the established procedures should be verified before being put on the market.

Objective	Measures which should be taken	Examples
Storage of approved finished cosmetic products.	Have at one's disposal instructions to verify the conformity of the finished products on their reception and their posterior storage.	Registers of approval Quality control (Computers or paper) Temperatures Storage Maximum storage period Storage heights Determinate storage zones, etc. Indication of dangers
Identified finished Cosmetic products	Establish systems of identification and their availability	Labels, signs, colour codes, computer alert systems

Objective	Measures which should be taken	Examples
Release / distribution of approved cosmetic products.	Establish systems which ensure the release exclusively of approved products. Check the status of the products before their release.	Final registers quality control  Computer systems, labels. re-inspection dates, expiry date.
Avoid becoming obsolete	Establish rotation systems for outgoing products	computer alert systems FIFO systems maximum periods of Storage.
Ensure the conformity of the finished cosmetic products during their transportation.	Establish instructions to avoid the deterioration of the quality of the finished product. Instructions relative to hazards	Fragile labels, Transport temperatures, Storage height etc. transport ADR delivery notes indicating conformity

- Are there instructions available for the reception of finished products?
- Are there instructions available for the verification of their conformity?
- Are there instructions available for storage and transportation?
- Are there safety instructions available for storage and transport?
- Are there instructions available for the identification and availability of finished products?
- Are there instructions available to avoid products becoming obsolete?
- Are there instructions procedures for the preparation of releases and the delivery of products?
- Are the conditions for transportation identified?
- Is there a list of authorized transport companies?
- Is there a periodic follow-up of them?
- Are the known transport incidents filed?

## 7.2. Nonconforming Products

**Corrective action:** action taken to eliminate the causes of a detected nonconformity, defective or other undesired situation to prevent its repetition.

Written systemized procedures which should establish what to do with the nonconforming products as well as how to install corrective actions. The nonconformities which occur during manufacturing should be registered; likewise those which have been detected by clients. The system should ensure that the nonconformities are analysed and corrected to prevent their repetition.

Objective	Measures which should be taken	Examples
Use exclusively conforming products.	Establish a system for the treatment of nonconforming products.	Registers of nonconforming products and possible actions to be taken (rejection, reprocessing, reparation, approve with concessions)
Prevent nonconformities	Establish the personnel responsible for deciding the treatment to be given to nonconforming products.	

- Is a register available for nonconforming products?
- Is there a written procedure for the treatment of nonconforming products?
- Are the personnel responsible for deciding the treatment to be given to nonconforming products defined?
- Do the personnel know who the people responsible for the decisions are?
- Are the reprocessed products analysed again according to written procedures to test their conformity?

### 7.3. Lot traceability

**Lot:** defined quantity. Considered authorized, of a raw material, packaging material or a product obtained by an operation or a series of operations.

The compilation and analysis of the filed registers of each manufactured lot should ensure the traceability of each lot in the event of any incident related to the quality of the product.

The registration and supervision of all the operations should be made in each industrial phase.

These documents should be easily accessible.

Objective	Measures which should be taken	Examples
Being able to reconstruct the history of any lot of cosmetic products.	Establish a coding system of raw materials, packaging material, bulk products and arrivals lots. Establish a coding system of finished products lots.	Day, month, year, shift, machines, etc.
	Establish the registers which should be kept relative to the manufacture of a cosmetic product lot and what is necessary and useful to achieving its traceability.	Lists of registers relative to the manufacture in each phase, by means of paper or computer.
	Establish a system of archives of the registers relative to each finished product lot.	Archives for activities realized, production processes, quality control, packaging, storage, release.

Objective	Measures which should be taken	Examples
	Define the period of custody of all the archives and systems of elimination and inform the personnel.	Custody alerts of the documentation.

- Is there a coding system for raw materials, packaging materials and bulk materials available?
- Is there a coding system for finished products available?
- Is there a system which informs the personnel of the results of all the activities relating to manufacturing and control of each finished product lot?  
(dates, storage, volumes or units, containers, etc.)
- Are the relevant commentaries and observations registered?
- Does this system ensure that it is possible to analyse the information related to
  - raw materials, bulk products and packaging materials which have been used results of controls carried out in different phases of manufacturing
  - results of automated processes
  - machinery, equipment and personnel who intervene in the different phases of manufacturing.
  - adjustments or corrections during the process
  - incidents found and their resolution
  - Are there instructions to find out and determine the period of custody of information?
  - Do the personnel know of these instructions?

# 8 COMPLAINTS AND WITHDRAWAL OF PRODUCTS

**Complaint:** internal communication manifesting a defect in the quality of a product.

**Withdrawal:** decision taken by a company to recover product lot which it has put on the market.

All the complaints, as well as any other information which involves products potentially defect must be carefully analysed according to written procedures.

## 8.1. Complaints

Any complaint about a defective product should be registered with all the original details and analysed exhaustively.

If a defect is discovered or suspected in a lot, bear it in mind and verify other lots to determine if they are also affected. All the decisions and measures taken as a result of a complaint due to a defect in a product or the appearance of adverse reactions should be registered and associated with the archives of the corresponding lot.

## 8.2. Withdrawal of products

Before the withdrawal of products it is necessary to act immediately. The products which are the object of the withdrawal should be identified and segregated from the rest until a decision is adopted about said product. It is necessary to contact the competent authorities about those incidents which can have an affect on the safety of the consumers. The process of withdrawing products should be evaluated periodically.

Objective	Measures which should be taken	Examples
Ensure a correct follow-up of incidents (complaints and withdrawals of products) on the market and the application of corrective measures.	Establish the procedure for the follow-up and treatment of incidents in the market.	Register of complaints, analysis of the causes of the complaint, establishment of the actions to be taken, response to the client, etc.

Objective	Measures which should be taken	Examples
	Define the responsibilities for the treatment of incidents	
	Establish the procedures to follow for the withdrawal of products from the market.	
	Establish a system of follow-up of the undesired effects	Follow-up files of undesired effects and periodic reports

- Is there a written procedure for the treatment of complaints available?
- Are the results of the treatment of complaints registered or filed?
- Are the incidents of products on the market which may have negative effects on the safety of the consumer communicated to the health authorities?
- Is there a system to ensure that, when faced with a complaint that there are not other products/lots which are affected?
- Is the process of the treatment of complaints periodically evaluated? And the process for the withdrawal of products from the market?
- Are the registers dealing with complaints or the withdrawal of products associated with information relative to corresponding lots which have been affected?

## 9. INDUSTRIAL HYGIENE

**Disinfection:** all the hygienic procedures which contribute to the reduction of contaminating microbial flora to their lowest levels, in accord with the type of process involved. Disinfection does not include sterilization.

**Sterilization:** process by means of which all types of micro-organisms, including the bacterial spores are destroyed.

**Sanitation:** process which involves cleaning followed by a posterior disinfection.

### 9.1. Introduction

A cosmetic product should not adversely affect the health of the consumer, nor undergo any deterioration of its quality, due to the presence or multiplication of micro-organisms in itself. To achieve this, it is essential to comply with the practices of good hygiene.

### 9.2. Hygiene of the installations and equipment

To minimize the sources of contamination the premises, equipment, machinery and instruments, as well as the raw materials, packaging material, bulk materials and finished products should be kept in good hygienic conditions.

Objective	Measures which should be taken	Examples
Ensure that all the installations are kept in a hygienic and suitably orderly state.	Set out specific procedures for cleaning all the installations.	toilet facilities, storerooms, weighing, manufacturing, packaging and locker areas as well as the exteriors
	Have programmes for the hygiene of all the installations	
	Have registers of hygiene relevant to each of the areas	
	Have plans for pest (insects/rodents) control.	

<b>Objective</b>	<b>Measures which should be taken</b>	<b>Examples</b>
Ensure that the equipment used in the production is clean and adequately protected	Elaborate specific procedures of hygiene for each piece of equipment	Pumps, motors, packaging belts, utensils, storage tanks, intermediate benches
	Have programmes of hygiene for all the equipment.	hoses, motors, tanks
	Avoid accumulations of residual liquids in the equipment	
	Protect the clean equipment to avoid contamination	
	Inspect the state of the equipment before being used and verify its "cleanness"	
	Identify if the equipment is clean or dirty	

- Are there continuous training programmes for the personnel dedicated to hygiene of installations and equipment?
- Are there written procedures for the hygiene of the installations and the equipment?
- Are there periodic inspections to check the satisfactory functioning of the established cleaning programmes
- Are spilt products immediately cleaned up?
- Are the residues correctly eliminated?
- Are the utensils and products for hygiene stored in zones separately from those used in the manufacturing processes?
- Are doors and windows kept closed to avoid the entrance of external contaminants?
- Are the premises and storerooms free from insects, rodents and other pests?
- Are internal audits which permit evaluations of the general hygienic conditions of the installations and equipment carried out periodically?

### 9.3. Hygiene of the personnel

Programmes of hygiene should be established which are adapted to the necessities of the company, included in the procedures are mentions of the health, obligations of the workers, hygienic practices and clothing.

These requirements should be understood and adopted by each one of the individuals in the areas of production or control. Every person who enters into the manufacturing areas should wear clothing with adequate protection.

Eating, drinking, smoking and chewing as well as medication belonging to the personnel should be strictly forbidden from the areas of production and storage areas. In general, any anti-hygienic practice should be forbidden within the manufacturing areas or in any other area where the product could be adversely affected.

Measures should be taken to ensure as far as feasible that nobody affected by an infectious illness or with an open wound on their body carries out production tasks.

Objective	Measures which should be taken	Examples
Ensure that the personnel follow the programmes of adequate hygiene.	Use clothing exclusively for the place of work	Clean clothing, cap or head covering which completely covers the hair, gloves when the manipulator has direct contact with the product, etc.
	Instruct the worker as to all the habits regarding personal hygiene in the work place	washing and hand care (on beginning the working day, after using the washroom, when getting dirty, or changing the activity in the work area) Not wearing any type of jewellery (bracelets, wrist watches...) Forbid food, drink or smoking except in the authorised areas

Objective	Measures which should be taken	Examples
	The person responsible should be vigilant that the personnel under them are not suffering from any health problem that could affect the product,	Protection of wounds, masks

- Are there any continuous training programmes for the personnel about habits of hygiene?
- Do the personnel know the basic rules of hygiene?
- Do the personnel wear different clothing and footwear from their street-wear and is it adequate for the place of work?
- Are all their personal objects kept outside the manufacturing areas?
- Are there signs reminding workers of prohibitions (eating, drinking, and smoking outside the authorised area)

# 10. DOCUMENTATION

## 10.1. Introduction

A good documentation constitutes an essential part of the system for ensuring the quality. Clearly written communication prevents the errors of oral communication and facilitates tracing the history of the lot. The specifications, formulas, instructions, procedures and registration must be free from errors and available in writing. The legibility of the documents is of great importance.

When electronic data, photographs or of any another type is used in place of written documents, the systems used will serve to demonstrate that the data is appropriately kept during the anticipated period of the archive. The data kept with this system will be easily available and in a legible format. The data electronically kept should be protected against loss or damage (for example by duplication or by transferring it to another system of archives).

Objective	Measures which should be taken	Examples
Ensure that a documental archive of all the activities of the company relative to the quality of the products	Elaborate procedures and instructions which describe, in an understandable way for those who are going to use it, all those tasks, functions and structures related to the manufacture.	Standard formula and standard method , packaging instructions, sampling, specifications of materials, materials and finished product. see sections 2.4 and 2.5

- Is the safety of how the documentation is kept so as to facilitate its recovery at a given moment contemplated?
- Is the documentation understandable enough for those who are going to use it?
- Is the possible localization and interpretation of the documentation simple, whatever the medium?

## 10.2. Clarity of the documentation

The documentation should be designed (specifications of the organization and company resources), elaborated, revised and distributed carefully  
The documents should be regularly revised and kept updated.

Objective	Measures which should be taken	Examples
Ensure that a documental archive of all of the activities of the company relative to the quality of the products is maintained.	Elaborate normalised procedures which clearly establish the processes to be carried out and the personnel responsible for its realisation.	
Ensure that all the documents and data related to the system of quality are controlled.	Elaborate a procedure which clearly establishes the way to elaborate, control, distribute, file and revise all the documentation of the company.	Designate a person to be responsible for the coordination of the documentation, who will procure its adequate elaboration, distribution, filing and revision when necessary.
	Check that there is no obsolete documentation is in circulation.	When a revision of a document is emitted, during its distribution withdraw the anterior version at the same time.
	Carry out a periodic revision of all the documentation.	Implicate the department affected so that they periodically revise their procedures.
	Identify unequivocally and file a copy of the obsolete document.	Destroy immediately the left over copies whether they are controlled or not, of the obsolete document.

- Are the procedures adequate for the structure of the company and the products of the company?
- Is there a filed copy of each and every one of the procedures in force?
- Are they periodically revised by the personnel implicated in the procedure?
- Is the documentation in circulation all in force?
- Are the changes, the motives for the changes and the personnel responsible for the changes, registered, dated and signed?

### 10.3. Audits

**Audits:** systematic process, independent and documented which permits a determination of if the activities of quality and the results comply with the planned requirements and if said requirements have been put into practice effectively and adequately to achieve the objectives previously set out.

The audits should be carried out in a detailed and independent manner, regularly or by petition, by competent persons specially designated to put it into effect.

These audits can take place at the selfsame company, at the suppliers', or at the subcontractors'.

They should implicate the system of quality in general. The object of the audits is to ensure conformity with the Good Manufacturing Practices of Cosmetics, and if necessary, to propose corrective actions

The follow-up audits should verify the efficiency of the corrective actions.

<b>Objective</b>	<b>Measures which should be taken</b>	<b>Examples</b>
Ensure the maintenance of the Good Manufacturing Practices and the good functioning of the quality system of the company.	Establish a system for periodically checking the maintenance of the Good Practices.	Plans of periodic internal audits, Audit plans to suppliers, check lists. Revision of the quality documentation..

Objective	Measures which should be taken	Examples
	Audits to be carried out by competent and independent personnel.	Internal personnel who are independent from the productive processes. Subcontracted personnel.
	Register the results of the audit and establish the opportune corrective actions.	Certificate or report of the audit with proposals for specific corrective actions and the periods for their realisation.

- Are audits periodically carried out to check the maintenance of the Good Manufacturing Practices and the correct functioning of the quality system of the company?
- Is the result registered?
- Are the audits carried out by competent personnel?
- Are actions established as a consequence of the results of the audits?
- Are follow-up audits of the proposals for corrective actions carried out?

## 11 GLOSSARY

The definitions given below apply to the words used in this guide. They may have different meanings in other contexts.

**AUDIT:** systematic process, independent and documented which permits determining if the activities of quality and their results fulfil the planned requisites and if said requisites have been put into practice in an effective and adequate way to achieve the previously intended objective. Note: the internal audits, in some cases are referred to as first party audits, these are carried out by, or in the name of, the selfsame company for internal purposes. The external audits include what are generally referred to as “second or third party audits”.

The second party audits are carried out by parties who have an interest in the organisation, such as the clients, or other persons in their name. The third party audits are carried out by independent external organizations.

**BULK PRODUCT:** any product which has passed through all the phases of manufacture except packaging.

**CALIBRACIÓN:** group of operations which establish under specific conditions, the relation between indicated values by measuring instruments or measuring systems, or values represented by measuring materials, and the known values corresponding to the norm of reference.

**COMPLAINT:** External communication manifesting a defect in the quality of a product.

**CORRECTIVE ACTION:** Action taken to eliminate the causes of a detected nonconformity, defect or another undesired situation to prevent its repetition.

**DESINFECTIÓN:** All the hygienic procedures which contribute to the reduction of the microbial flora to its lowest levels, in accordance with the type of process involved. Disinfection does not include sterilization.

**FILLING AND PACKAGING:** Conjunction of operations starting off with a bulk product and packaging materials leading to a finished product.

**FINISHED PRODUCT:** product obtained after finalising the manufacturing process, and which will be put on the market exactly as it is.

**FORMULA:** a qualitative and quantitative list of ingredients (raw materials)

**IDENTIFICATION:** the simple action or group of simple actions (as well as their results) which ensure that during the manufacture the appropriate raw materials and/or packaging materials are used; the identification is not however a guarantee of conforming to the quality.

**INSPECTION:** activities such as the measurement, the examination, the realization of tests and calibration of one or more characteristics of a product or service, and comparison of these with the specific requisites to determine its conformity.

**INSTRUCCIONES:** Documents which describe in detail any manufacturing operations.

**LOT:** defined quantity, considered homogeneous, of a raw material, or packaging material or a product obtained by an operation or a series of operations.  
In the case of continuous processes, a lot can be the quantity produced in given period of time.

**LOT NUMBER:** a numeric, alphabetic or a alphanumeric or marking reference which specifically identifies a lot.

**MAINTENANCE:** All the periodic support and checking operations designed to maintain the equipment and installations in good working order.

**MANUFACTURING:** conjunction of operations of a technical nature (transformation of the products, processed, filled and packaged, stored, maintenance, controls, inspections, etc.), necessary to obtain the finished product, likewise any administrative and economic related operation.

**NOMENCLATURE:** The exhaustive list of constituents (raw materials and packaging material) of the cosmetic product which is manufactured.

**PACKAGING:** All the operations which include the filling and packaging of a bulk product before becoming a finished product.

**PACKAGING MATERIAL:** each element or article necessary to contain the finished product, and principally to ensure its physical protection, excluding any exterior packaging for transportation or shipping. The packaging materials are classified as primary or secondary depending on if they come into direct contact with the product or not.

**PREPARATION:** All the operations of a qualitative nature (identification) or of a quantitative nature (measurement) regarding the components (raw materials, packaging materials) to be produced in conformity with a formula or nomenclature of the product. The measurement here is defined as any continuous or discontinuous system of measurement.

**PROCEDURE:** specific way to carry out an activity or documentation.

**PROCESS:** any operation involved in the manufacture of a determinate product.

**PROCESSED-MANUFACTURING:** all those operations which permit the combination of raw materials prepared in accord with a defined procedure and which result in a bulk product.

**PRODUCCIÓN:** collection of operations of a technical nature necessary to obtain the finished product. It therefore includes the manufacturing and packaging activities.

**QUALITY ASSURANCE:** all those planned and systematic actions necessary to provide adequate confidence that the product or service will satisfy the requisites of pre-established quality.

**QUALITY CONTROL:** part of the management of quality orientated to complying with the requirements of quality.

**QUALITY MANAGEMENT:** management activities which determine the quality policy, objectives and responsibilities, these are introduced by means of quality plans, quality control, quality assurance and quality improvement inside the system of quality.

**RAW MATERIAL:** any substance which participates or is involved in the manufacture/processing of a bulk product.

**REGISTRIES OF A LOT:** all the documentation relative to a defined quantity of a manufactured product.

**SAMPLE:** One or more representative elements which have been selected from a whole to obtain information about the whole.

**SAMPLING:** collection of related operations with the taking and preparation of samples.

**SANITATION:** process which entails cleaning followed by posterior disinfection.

**SEMI-FINISHED PRODUCT:** Product obtained after primary packaging, which requires at least one addition before it can be considered a finished product.

**SPECIFICATION:** document which describes the requirements to which the product or the service has to be adjusted.

**STERILIZATION:** process by means of which all types of micro-organisms, including bacterial spores are destroyed.

**SUBCONTRACTING:** the realization of an operation by an external person or organization (the subcontractor) in the name of a person, company or organization (the title holder).

**SUBCONTRACTOR:** The external person, company or organization which carries out an operation in the name of another person, company or organization (the title holder).

**TRAINING:** continuous education with a view to maintaining and/or the acquisition by the employees of the abilities required for them to fulfil their role in the company.

**QUALITY SYSTEM:** organizational structure, procedures, processes and resources necessary to manage the quality.

**VERIFICATION:** The confirmation by means of the presentation of objective evidence that the specific requisites have been fulfilled.

**WITHDRAWAL:** Decision taken by the company to recover a product lot which it has put on the market.