PROJECT ANDEAN TECHNICAL REGULATION
GOOD MANUFACTURING PRACTICES IN COSMETIC PRODUCTS
(2019.01.10)

I. THE OBJECT, FIELD OF APPLICATION AND DEFINITIONS

1. The purpose of this Andean Technical Regulation is to establish the requirements for Good manufacturing practices that must be met by companies or establishments that manufacture, condition or manufacture cosmetic products that are marketed in the territories of the Member Countries in order to protect human health or safety.

Imported products that are marketed in the Andean subregion must comply with good manufacturing practices of cosmetic products according to the present Andean Technical Regulation or equivalent international standards.

2. This Andean Technical Regulation applies to the cosmetic products indicated in Decision 833, whose NANDINA sub-items are in the indicative list of Annex 1 of present document .

3. For the purposes of this Andean Technical Regulation, the following shall apply definitions, in addition to those established in Decision 833:

3.1 ı QUALITY ASSURANCE: Part of quality management aimed at
Provide confidence that the quality requirements will be met.

3.2 GOOD COSMETIC MANUFACTURING PRACTICES (BPM) **:** Set of standards, processes, human resources, infrastructure and technical procedures, whose application should be guarantee the quality and controlled production of each batch of cosmetic products, minimizing pollution factors within the productive chain in order to
obtain a safe product to be used by the human being.

3.3 QUALITY: Degree in which a set of inherent characteristics complies with the requirements.

3.4 POLLUTION: Presence of any undesirable material in the cosmetic product, either by chemical, physical or microbiological substances.

3.5 QUALITY MANAGEMENT: Coordinated activities to direct and control a organization in relation to quality.

II. OF THE REQUIREMENTS OF GOOD MANUFACTURING PRACTICE

Sub-Chapter II-I PERSONAL

4. PRINCIPLE

4.1 The people who participate in the execution of the activities described in this Andean Technical Regulations must have education (training), training, and / or experience that allow the good performance of the assigned tasks.

1 Definitions 3.1 and 3.3 were taken from ISO 9000: 2015

4.2 It is necessary that the main technical responsible personnel be in the company within your operating hours.

5. ORGANIZATION

5.1 The organizational structure must be clearly defined, in order to understand the organization and operation of the company. The staff must know your responsibility and its location in the organizational structure; this must be appropriate for the size of the company and the diversity of its products.

5.2 Each company must ensure that there are adequate levels of personnel in the different areas of activity, according to the diversity of its production.

5.3 The person responsible for quality control shall be independent in its competences of the responsible for production. National laws may define professions specific for the performance of these charges

5.4 Each company must have an adequate organizational structure, which must be demonstrated through general organization charts, where its structure is contemplated hierarchical

5.5 Every company engaged in the manufacture of cosmetic products must have the services of a technical director, who will be a pharmaceutical chemist professional or his equivalent established by national legislation.

5.6 The company must have a sufficient number of personnel duly trained in the regarding the activities to be carried out.

5.7 The organization of the company must have the support of senior management.

5.8 The implementation of Good Manufacturing Practices (GMP) should be responsibility of senior management and should require the participation and commitment of the personnel of all levels and areas of the company.

5.9 Managers should define and report on the areas to which they have access authorized personnel.

6. PERSONNEL RESPONSIBILITIES

6.1 All personnel must:

a) Know your position in the organizational structure;

b) Know their responsibilities and activities that have been defined;

c) Have access to and comply with the documentation pertinent to their particular field of responsibility;

d) Comply with the requirements of personal hygiene;

e) Be willing to report irregularities or other nonconformities that may be occur within the scope of their responsibilities; Y

f) Possess appropriate training and skills to fulfill the responsibilities and activities that have been assigned to them.

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7. TRAINING

7.1 Adequate training in GMP appropriate to the personnel must be provided to all personnel. activities carried out by the company and defined in this technical standard.

7.2 The training needs of all staff must be identified, independently level or seniority in the company, and the program must be developed and implemented of corresponding training.

7.3 The training courses can be carried out by the same company or by companies specialized external

7.4 Taking into account the technical knowledge and experience of a certain section of personnel, training courses should be programmed and implemented adapted to their

jobs and responsibilities. Consequently, it is essential that the key personnel and the of manufacturing receive complete training in terms of methods and level of competition required to carry out different operations (weighing, mixing, maintenance, industrial hygiene practices, manufacturing, verification, among others). He must have training records.

7.5 Training must be considered as a constant and continuous process that must be be subject to periodic reviews.

7.6 In addition to the basic training on the theory and practice of GMP, the new staff he must receive adequate training in the tasks assigned to him.

7.7 The level of knowledge acquired by staff should be assessed during or after of the training or both.

8. PERSONAL HYGIENE AND HEALTH.

8.1 Hygiene

8.1.1 Hygiene requirements adapted to the needs of the laboratory should be established, those that should be known and followed by any person whose activity is carried out in the areas of production, control and storage.

8.1.2 Personnel should be instructed in the cleaning of hands before entering the areas of production and especially after using health services.

8.1.3 Every person entering the production, control and storage areas must wear appropriate clothing and protection elements to avoid contamination of the cosmetic products.

8.1.4 Eating, drinking, chewing gum, smoking, storing food, beverages, tobacco or medicines for personal use, as well as the use of jewelry and makeup person who enters the production, control and storage areas.

8.2 Health

8.2.1 All personnel, before being hired and during the time of employment, must undergo medical examinations, to ensure an appropriate state of health that does not put products at risk of contamination at any stage of the process.

8.2.2 Any skin condition will be cause for temporary separation of the operator from the area of production.

8.2.3 Direct contact should be avoided during manufacturing or packaging operations

from the hands of the operator with raw materials and intermediate products or in bulk.

8.2.4 Any company or establishment engaged in the production of cosmetic products, must have the necessary elements to provide first aid to the staff that needs them.

8.2.5 Visits and untrained personnel should be prevented from accessing the areas of production, control and storage. If it is unavoidable, they should be informed previously about the precautions to be taken and in particular about personal hygiene and the right protective clothing. They must be supervised by a staff of the company.

Sub-Chapter II-II INSTALLATIONS, PRODUCTION AND QUALITY CONTROL

9. INSTALLATIONS

9.1 General conditions. The facilities must be located, designed, constructed and used Way that:

a) The protection of the product is guaranteed;

b) Efficient cleaning, sanitation and maintenance are allowed; Y

c) Minimize the risk of confusion and contamination of products, raw materials and packaging materials.

9.2 Design

9.2.1 The design of the facilities should be based on the type of cosmetic product elaborated, the existing conditions, the cleaning and, if necessary, the measures of sanitization required.

9.2.2 There must be specific areas and physically separated for the storage, production (weighing, manufacturing, packaging and packaging), quality control, auxiliary areas, washing, bathrooms and changing rooms.

9.2.3 Sufficient space must be provided to facilitate operations, such as reception, storage and production.

9.2.4 The flow of materials, products and personnel through the facilities should be defined and delimited in order to prevent confusion and cross-contamination.

9.2.5 The floors, walls, ceilings and windows of the production areas must be smooth, resistant and with sanitary or half-round angles, in a way that allows an easy cleaning and, if necessary, sanitization; these must be kept clean and in good state of conservation.

9.2.6 The windows of the production areas must have a non-opening design. The windows of different areas, if they are opened, must have protection mechanisms against the entry of external pollutants.

9.2.7 Both dressing rooms and restrooms must be physically separated from each other, but accessible to the production areas. They must be adequately ventilated and equipped with the necessary services.

9.3 Accessories The areas must have the protection elements and measures, such as showers and sinks wash eyes, when the production or control processes require it.

9.4 Identification of zones . Depending on the degree of contamination to which the production areas, are classified into two large groups:

Black areas: entrance and reception rooms, changing rooms and bathrooms, workshops maintenance, dining room, warehouses, offices and conditioning areas.

Gray Areas: Production areas (heavy, manufacturing and packaging.

Transition zones: Area located between a gray and black zone through which the personnel from one area to another.

In the case of quality control laboratories, they will be classified as gray or black areas according to the analysis made in them. In the case of microbiological control, will consider only in the gray area.

Such a qualification is established in order to take extreme precautions to avoid contamination of products, being the gray areas the most demanding in the application of measures to reduce health risk.

In the transition zone, the operating personnel will use the clothing designated for enter the production areas. The operating personnel that are directed or operate in gray areas, he will not be able to circulate with his production clothing through the black zones .

9.5 Lighting All areas must have adequate and sufficient lighting for the operations, designed and located in such a way as to facilitate cleaning. The lighting must be installed in a way that ensures the containment of any remainder of a potential break and take appropriate measures to ensure the protection of the product.

9.6 Ventilation . Ventilation should be sufficient for production operations planned and take appropriate measures to ensure the protection of the product. Depending on the type of product to be manufactured, an air treatment system must be guaranteed in the production areas.

9.7 Pipes, drains and ducts

9.7.1 Pipes, drains and ducts should be installed so that drips or condensations do not contaminate materials, products, surfaces and equipment.

9.7.2 Drains should be kept clean, protected with sanitary lids and not allowed

reflux

9.7.3 The design of the facilities must take into consideration the following:

a) Prevent beams, pipes and ducts from being exposed to products in areas of production and storage;

b) If there are exposed pipes, they should not be in contact with the walls but to be suspended by fixing brackets sufficiently separated as for allow cleaning;

c) Take specific measures to protect the product.

9.8 Cleaning and sanitization

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9.8.1 The facilities must be kept clean and orderly.

9.8.2 Cleaning should be carried out, and if necessary, sanitation to achieve the objective of protection of each product.

9.8.3 Cleaning and sanitizing agents should be specified, which should be effective

9.8.4 Cleaning programs should be established and, if necessary, sanitation adequate to the specific needs of each area. It will be checked periodically compliance with this program and a record will be kept.

9.8.5 Risk of stagnant water, dust in the atmosphere, presence of insects or other animals.

9.8.6 Cleaning and sanitizing products must be clearly identified, in order to never come in contact with cosmetics.

9.9 Maintenance . The facilities used in the activities described in these Guidelines must be kept in a good state of preservation.

9.10 Inputs. The inputs used in the facilities should not affect the quality of the product.

9.11 Pest control . The facilities must be designed, constructed and maintained to prevent the access of insects, birds, rodents and other animals. The company must establish a pest control program appropriate to the facilities, carrying a record of its compliance.

10. TEAMS

10.1 General conditions

10.1.1 Production equipment must be designed, installed and maintained in accordance to its purposes, without jeopardizing the quality of the product. Also, you must be located taking into account the displacements, be cleaned and sanitized according to defined procedures.

10.1.2 Containers of both bulk and empty products must be protected from contaminants such as dust, moisture, among others.

10.1.3 Transfer hoses and accessories that are not in use should be cleaned and sanitized, keeping them dry and protected from dust, splashes or other pollution.

10.1.4 The material of the equipment, accessories and utensils must not be reactive, additive, or absorbent, with raw materials or with any other product used in the manufacturing that is put in your contact. This material must have characteristics sanitary such as being unalterable, smooth walls, without cracks or rugosities capable of housing remains that generate microbial contamination or of another type.

10.2 Installation

10.2.1 The design and installation of equipment should facilitate its drainage in order to allow the cleaning and sanitization.

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10.2.2 The equipment must be installed in environments large enough to allow the flow of personnel and materials, to minimize the potential for confusion and pollution.

10.2.3 The equipment must be easily identifiable.

10.3 Calibration

10.3.1 Laboratory and measuring instruments should be calibrated periodically.

10.3.2 If the results of the calibration are outside the acceptance criteria, the measuring instruments must be properly identified and removed from service, and an investigation must be conducted to determine any impact on the quality of the products or materials previously measured in said instruments and take the appropriate measures according to the result of said investigation.

10.4 Cleaning and sanitization

10.4.1 The cleaning and sanitizing of the equipment must be according to its design and use, and it must be done periodically according to established procedures, with special emphasis on the stopcocks, pumps, pipe elbows, splices and others, to avoid that they are foci of contamination.

10.4.2 Cleaning and sanitizing agents must be effective and have a schedule of rotation.

10.4.3 When the equipment is assigned for continuous production or batch production successive of the same product, it must be cleaned and sanitized at defined intervals, in such a way that the quality of the product is guaranteed.

10.4.4 Records of cleaning, maintenance and use of equipment, dated and signed by those responsible and will be part of the documentation of the batch produced.

10.5 Maintenance

10.5.1 All machinery and equipment must undergo maintenance programs and periodic verification.

10.5.2 All defective machinery and equipment must be properly identified, excluding them from their use and, if possible, isolating them.

10.5.3 The inputs used to carry out the maintenance activities of the equipment, not they must affect the quality of the product.

10.5.4 Only authorized personnel should have access to automatic equipment or systems used in the production and control.

10.5.5 Adequate alternative mechanisms should be available for systems that are need in case of failures or breakdowns.

11. RAW MATERIALS AND MATERIALS FOR PACKAGING AND PACKAGING

11.1 General conditions. Raw materials and materials for packaging that are acquired must meet the acceptance criteria defined with respect to the quality of finished products.

11.2 Shopping

11.2.1 Responsibilities for purchases of raw materials and packaging materials and Packaging should be based on:

a) The evaluation, selection and approval of the provider;

b) The determination of technical clauses, such as the type of selection that was carried out, acceptance criteria, actions in the case of defect or modifications and transportation conditions;
c) The determination of relationships and exchanges between the company and the supplier, as questionnaires, assistance and audits; Y
d) The determination of technical specifications, among others.

11.2.2 It is essential that quality specifications are established in close collaboration with the departments involved.

11.2.3 Purchasing documents must contain data clearly describing the product, keeping them in the form of physical records or magnetic media.

11.3 Reception. The reception of materials for production must follow procedures established; Each dispatch must be registered and its compliance verified. They must establish internal procedures on identification, transportation of materials raw materials, packaging material and packaging.

11.4 Identification and status

11.4.1 Containers of raw materials and packaging materials should be identified with the following information:

a) Commercial name;
b) Name or code given to the material by the establishment;
c) Date of receipt;
d) Name of the supplier and lot number;
e) Total amount and number of containers received; Y
f) Maturity date or re-analysis of raw materials as appropriate.

11.4.2 Raw materials and packaging materials that have defects that can affect the quality of the product should be withheld pending a decision.

11.4.3 Raw materials and packaging materials must be identified from appropriate form according to your status as approved, rejected or put into quarantine. Other systems may replace this physical identification system, if guarantee the same level of security.

11.5 Release

11.5.1 Physical or alternative systems must be established to ensure that they are released only raw materials or approved packaging materials; this release should be done by authorized personnel.

11.5.2 Raw materials and packaging materials can be approved with based on the supplier's analysis certificate, only if requirements are established technicians, experience and knowledge of the supplier, audits and methods of tests agreed with the supplier.

11.6 Storage

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11.6.1 Each raw material, packaging material must be stored and handled in appropriate conditions and according to their characteristics, so that guarantee the validity and safety of them.

11.6.2 Specific storage conditions must be respected and monitored.

11.6.3 When raw materials are repacked, packaging materials should be carry the same labeling information of the original container. This activity should be executed in a gray area.

11.6.4 When raw materials, packaging materials and packaging are placed on quarantine or rejected, must be stored in their respective locations physical or by any other system that provides the same level of security.

11.6.5 Measures should be established to ensure the rotation of stocks. Such measures must ensure that raw materials, packaging materials and packaging oldest or that expire before they are released first.

11.6.6 A periodic inventory should be carried out to ensure the reliability of the stocks. Any discrepancy must be investigated and corrective actions taken corresponding.

11.7 Reevaluation. A system must be established to reanalyze raw materials, packaging materials, when appropriate, to determine their suitability after a defined period of storage. The system must prevent the use of raw materials, packaging materials that have been re-analyzed and that are not They have obtained a favorable quality control report that allows their use.

11.8 Water quality used for production

11.8.1 The water treatment system must guarantee water quality conditions, according to its use (deionized, softened, purified, sterile or others). The use is not allowed of drinking water in the production process.

11.8.2 The water production equipment must guarantee the quality of the same according to to the established specifications and allow sanitation according to defined procedures. The control parameters of the treatment process should be be monitored.

11.8.3 The material that makes up the water treatment pipes and equipment must not affect water quality Pipes and equipment must be designed and constructed of so as to avoid corrosion, contamination risks and stagnation. Should be identify the pipes (for hot, cold, demineralized water, steam) as well as the direction of flow.

11.8.4 The physicochemical and microbiological quality of the water must be monitored and recorded

with a defined frequency based on the treatment team. Any anomaly it must be followed by a corrective action.

12. PRODUCTION

12.1 General conditions. At each stage of production, measures must be taken relevant to obtain a finished product that meets the specifications defined.

12.2 Documentation

12.2.1 Documentation related to production must be available at the beginning of each one of the process stages.

12.2.2 Equipment, instruments, raw materials, packaging materials must be identified and packaging, semi-finished products and cleaning products, at each stage of production.

12.2.3 The batch / batch production starts with a production order that is a true copy of the current "master formula". In exceptional cases, if it requires any modification (quantities or techniques), it must be previously approved by the technical direction and must be recorded in the respective production order, with the corresponding justification and signature of those responsible.

12.2.4 Manufacturing operations must be carried out in accordance with the following documentation:

a) Equipment with the required technical conditions;
b) "Master formula" for each product;
c) Lot size of the product;
d) Production order containing the list of all the raw materials identified with codes or batch numbers and quantities by weight or volume; Y
e) Detailed manufacturing operations for each stage, such as the addition of materials raw materials, temperatures, speeds, mixing times, sampling, cleaning and, if it is necessary, sanitization of equipment, and subsequent handling of the product in bulk.

12.3 Initial checks . Before starting a new manufacture, you must ensure that the areas and equipment are clean and identified as such and in good Operating conditions. On the other hand, there should be no elements belonging to previous production processes.

12.4 Identification of operations in progress. The production line should be Identified according to the manufacturing stage and the product being prepared.

12.4.1 In case a code or batch number is assigned to the bulk product, it must be traceable to the code or batch number of the finished product.

12.4.2 All raw materials must be measured or weighed according to the formula in clean and adequate containers, and only in certain cases, directly on the equipment used for manufacturing; said containers must be marked with the proper identification. The scales must be according to the weight to be determined, must be calibrated and verified documentally.

12.4.3 Precautions must be taken in sampling, weighing or measuring to avoid cross contamination, defining specific areas that comply with the cleaning quality necessary to carry out these activities.

12.4.4 The identification of bulk product containers must indicate:

a) Name or identification code;
b) Code or lot number;
c) Storage conditions to ensure the quality of the product.
d) Date of preparation; Y
e) Product quality status (approved, rejected or quarantined).

12.5 Process control . Controls must be defined during the process and the criteria for acceptance; which must be done according to a defined procedure. Any

result outside the acceptance criteria must be informed and investigated to adopt the necessary corrective measures

12.6 On-line control equipment checks . If control equipment is used in line, these should be checked regularly according to a defined program.

12.7 Storage of bulk products

12.7.1 The bulk product should be stored in suitable containers, in defined areas and under appropriate conditions.

12.7.2 The maximum storage time for a bulk product must be defined. When this time is reached, the bulk product must be re-analyzed before its use.

12.7.3 If there are raw materials that have not been used after being weighed or measured and It is considered acceptable for them to be returned to the warehouse, their containers must be Closed and clearly identified.

12.8 Packaging operations

12.8.1 Packing and packing operations must be carried out in accordance with the specific documents and the verification of:

a) equipment with the required technical conditions;
b) the identified packaging, packaging and bulk product materials, indicating the codes or lot number and quantities, defined for the intended final product;
c) the detailed operations that contemplate the sampling and the respective controls in process
d) the cleaning of equipment and areas, as well as the absence of materials, products bulk and documents corresponding to the previous filling and packing;

12.8.2 Packing and packing lines must be clearly identified according to the product in process (name or identification code, the name or code of identification of the finished product and the code or lot number).

12.8.3 Container and packing controls and their acceptance criteria should be defined. These they must follow a defined program, so that any result that is outside The acceptance criteria must be informed and investigated.

12.8.4 If the packaging materials are not used after the operations of packaging and are considered compliant to return to the warehouse, their containers must be closed and properly identified.

12.8.5 When the packaging and packaging is not carried out continuously, it must be adopted special measures, including the separation and identification of areas, in a that there is no confusion in the labeling.

12.9 Production areas

12.9.1 Manufactured cosmetics of different nature (solids, semi-solids, liquids) in common areas; however, for the case of products liquids and semisolids can be manufactured in the same area per campaign; this practice must be authorized by the competent National Authority (ANC).

The nature of the operations to be carried out in the plant depends on the types of cosmetics that are made, some of which present requirements

specific, so they should be prepared in areas with special conditions and specific equipment.

12.9.2 Access to production areas should be restricted to unauthorized personnel.

12.9.3 The areas destined to the elaboration of cosmetics will be exclusively dedicated to said end

12.9.4 Any modification to the conditions of good manufacturing practices with the which the authorization of the establishment was granted, must be informed to the Competent National Authority, carrying out the corresponding procedure.

13. FINISHED PRODUCTS

13.1 Release

13.1.1 Prior to marketing, all finished products must be controlled according to the established test methods and must meet the criteria acceptance.

13.1.2 The release of the product must be carried out by the responsible technical personnel.

13.2 Storage and dispatch

13.2.1 Finished products must be stored in defined areas under conditions appropriate according to their nature, for an appropriate period of time. Should ensure an efficient identification of the lot, as well as the correct rotation of this. The environmental conditions must be monitored during the period of storage.

13.2.2 Finished products approved, quarantined or rejected must be stored in their defined physical locations or by any other system storage that provides the same level of security.

13.2.3 The identification of finished product containers should indicate:

a) Name or identification code;
b) Code or lot number;
c) Storage conditions when such information is critical to ensure the product quality;
d) Quantity;
e) Date of preparation; Y
f) Quality status (approved, quarantined or rejected) or a system that allows define this state.

13.2.4 Measures should be established to ensure the rotation of stocks. Such measures must ensure that the oldest product or the one that expires before is released first.

13.2.5 The control of periodic inventory must be carried out for the purposes of:

a) Guarantee the accuracy of the inventory; Y
b) Ensure that the acceptance criteria are met.

13.2.6 In inventory control, any discrepancy must be investigated and actions taken corresponding corrective

13.2.7 Measures must be established to ensure that the quality of the product is maintained completed during the dispatch of the same, such measures must allow its traceability

13.3 Returns

13.3.1 Returns must be properly identified and stored in defined areas.

13.3.2 Returns must be verified according to the criteria established for Determine your disposition.

13.3.3 Returns must have approval by quality control before of being put back on the market and measures must be established to differentiate any return that has been conditioned to comply with the criteria of acceptance.

Measures must also be taken to avoid redistribution of the finished product that does not has been released.

14. QUALITY CONTROL LABORATORY

14.1 General conditions

14.1.1 The procedures described for personnel, facilities, equipment, subcontracting and documentation must be applied to the quality control laboratory.

14.1.2 The quality control laboratory is responsible for ensuring the execution of all the necessary and pertinent controls within its activity, for sampling and trial, so that raw materials, packaging materials and materials are approved. packing, bulk product and finished products, only if its quality meets the required acceptance criteria.

14.2 Test methods

14.2.1 The quality control laboratory shall use the necessary testing methods to Confirm that the raw materials, packaging material, bulk product and Finished product meets the required specifications.

14.2.2 Controls must be performed based on defined test methods or standardized and should be available.

14.2.3 The specifications that must be fulfilled by raw materials must be established, packaging and packaging material, bulk products and finished products.

14.3 Results. The results obtained must be recorded and verified; these records must have at least the following information:

a) Result of measurements and verifications, as well as observations by the

staff that carries out the operations; Y
b) The situation of rejected or approved or pending analysis.

14.4 Out-of-specification results

14.4.1 Authorized personnel should review and investigate the results that are outside of specification.

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14.4.2 There must be sufficient justification to perform the reanalysis of the materials raw materials, packaging material, bulk products and finished products.

14.4.3 Authorized personnel must make a decision after having investigated the causes that caused the deviation, in relation to its acceptance or rejection or leave pending result.

14.5 Reagents and other requirements. Reagents, solutions, culture media, etc. They must be identified with the following information:

A name;
b) Nominal concentration, as the case may be;
c) Actual concentration, as the case may be;
d) Expiration date;
e) Name and signature of the person who prepared it,
f) Date of preparation, as appropriate;
g) Opening date, as applicable;
h) Storage conditions, as applicable; Y
i) Re-normalization date, when applicable.

14.6 Sampling

14.6.1 Sampling must be carried out by authorized personnel, according to a procedure settled down.

14.6.2 Sampling should be defined in the following terms:

a) Sampling method; based on nationally recognized statistical standards or international;
b) Materials, instruments and utensils to be used,
c) Sample quantities to be taken,
d) Precautions that must be taken to avoid contamination or deterioration;
e) Identification of the sample;
f) Sampling frequency for reanalysis.

14.6.3 Samples must be identified through:

a) Name or identification code;
b) Code or lot number;
c) Date of sampling;
d) Container from which the sample was taken;
e) Sampling point, when applicable.

14.7 Sample retention

14.7.1 The retention samples of the finished product and the raw material must be kept in defined areas and with restricted access.

14.7.2 The retention samples of the finished product must:
a) Store in the packaging material corresponding to the commercial presentation such as it was released, in sufficient quantity to allow at least two (02) analyzes complete;
b) Preserved for one (1) year after its expiration date; Y
c) Be stored according to the manufacturer's recommendations.

If the size of the commercial presentation of the batch of product released is large, The retention sample may be less than this volume as long as the container that

it contains the same characteristics of the presentation to be marketed, must be taken from the packaging process and identified with the same information of the batch released.

14.7.3 The retention samples of raw material must:
a) Store in sufficient quantity of each batch used, to allow at least two (02) complete analyzes;
b) To be kept until the stocks are exhausted, without exceeding its date of expiration; Y
c) Store in the conditions established by the manufacturer.

15. PRODUCTS OUT OF SPECIFICATION

15.1 Finished products, bulk products, raw materials and packaging materials and packaging rejected

15.1.1 Investigations of raw materials, packaging material, product a Bulk and finished product rejected, must be made by authorized personnel for the effect.

15.1.2 Decisions to destroy or reprocess must be approved by the staff Quality manager.

15.2 Reprocessed finished products and bulk products

15.2.1 If all or part of a batch of finished or bulk product does not comply with required specifications, the personnel responsible for quality must decide whether to reprocess or not the product.

15.2.2 The reprocessing procedure must be defined and approved.

15.2.3 Controls must be carried out on the finished or reprocessed bulk products. The Authorized quality control personnel should review the results to verify the conformity of the finished or bulk product with the required specifications.

16. WASTE

16.1 Wastes should be disposed of in a timely and sanitary manner, in accordance with the current legislation of each country.

16.2 The company must define the different types of waste from production and control of quality that could affect the quality of the product.

16.3 The waste stream should not affect the production and control operations of quality.

16.4 Appropriate measures must be taken in relation to the collection, transport, storage and disposal of waste.

16.5 Waste containers must be correctly identified according to their content and safety information, as appropriate.

17. CONTRACTS

17.1 A written contract, controlled and signed by the Parties, must be established between the contractor and the contractor, which covers the subcontracted activities. The objective of this

measure is to obtain a product or service that meets the requirements defined by the contractor.

Outsourcing can occur under the following services:

a) Manufacturing;
b) The container and packaging;
c) Analysis of quality control;
d) Cleaning, sanitation of the premises;
e) Pest control;
f) Maintenance of equipment and facilities;

g) Disposal of waste; Y
h) Others.

17.2 The contractor must evaluate the competence and capacity of the contractor to carry out the contracted operations. You must also evaluate if the contractor complies with the requirements established in the current sanitary regulations when appropriate. The contractor must provide the contractor with all the information required to carry out the all operations correctly.

17.3 The conditions and formal terms of the contract must be respected. The contractor must ensure that you have all the means, experience and competent personnel to satisfy the requirements of the contract. In addition, the contractor must provide all verifications and audits that the contracting party has defined.

17.4 The contractor must inform the contractor of any change that may affect the quality of the services or products supplied before their implementation, to unless otherwise specified in the contract.

17.5 The contractor and the contractor must establish an agreement specifying their duties and responsibilities. All data must remain available to the contractor.

18. DEVIATIONS

18.1 Deviations from the specified requirements must be authorized by the responsible staff with the necessary information that supports the decision.

18.2 Corrective and preventive actions must be implemented to avoid the recurrence of the deviations.

19. COMPLAINTS AND WITHDRAWALS

19.1 General conditions. All complaints received must be reviewed, investigated and follow up, as appropriate.

When it is decided to remove products from the market, the necessary measures must be taken to complete the withdrawal, and implement corrective actions.

19.2 Complaints or product claims

19.2.1 All complaints or claims of the product must be handled by the staff responsible for this activity.

19.2.2 Any complaint or claim concerning a product defect must be kept together to the grievance supports and tracking information.

19.2.3 A complete and adequate follow-up of the affected lot with a investigation.

19.2.4 In investigations of complaints or claims and their follow-up should include:

a) Preventive actions to avoid the recurrence of the defect;
b) Verification, if applicable, of other lots, to determine if they are also affected.

19.3 Review. Complaints or complaints should be reviewed periodically to verify the trends or recurrence of a defect.

19.4 Withdrawal of products

19.4.1 Authorized personnel must coordinate the product recall process of the market and You must write a report of it.

19.4.2 Market product recall operations should start immediately and timely.

19.4.3 The relevant authorities should be informed about withdrawals of the product from the market.

19.4.4 The recalled products must be identified and stored separately in a Safe area waiting for a decision.

19.4.5 The process of withdrawing the product from the market must be periodically evaluated.

20. CHANGE CONTROL

Changes that may affect the quality of the product must be approved and made by authorized personnel, based on sufficient data.

21. INTERNAL AUDIT

21.1 Internal audits must be carried out in detail, either periodically or by specific request, and must be carried out by qualified personnel, impartial and independent of the area to be audited.

21.2 All observations made during the internal audit should be evaluated and communicated to the audited area to implement the corrective actions and relevant preventive

21.3 The follow-up of the internal audit must confirm the satisfactory execution of the corrective action.

22. DOCUMENTATION

22.1 General conditions

22.1.1 All requirements specified in this regulation must be documented and registered.

22.1.2 A documentation system must be established, designed, implemented and maintained that is appropriate to the organizational structure of the company and the products that factory. An electronic system can be used to generate and manage documents, provided that the reliability, veracity and security of the information.

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22.1.3 The documents must be composed of procedures, instructions, appropriate specifications, protocols, reports, methods, formats and records for the activities covered by this regulation.

22.2 Drafting, approval and distribution

22.2.1 The methodology for preparing the documents, the responsible for its preparation, review and approval, as well as the content, management, distribution and control of them.

22.2.2 The documents must be:

a) Written in legible and understandable form;
b) Approved, signed and dated by authorized personnel before use,
c) Prepared, updated, withdrawn, distributed, classified;
d) Referenced to ensure that obsolete documents are not used;
e) Accessible to the appropriate personnel; Y
f) Withdrawn from the work area and destroyed if they are not in force.

22.2.3 The records that are carried out in manuscript form must:

a) Indicate the data that must be entered;
b) Be legibly written with indelible ink;
c) Be signed and dated by the responsible personnel;
d) In case of corrections, the original information must be legible and have the date and signature of the person responsible for the correction; Y
e) Be written immediately after the activity.

22.3 Review . The documents must be updated and record the revision number.

22.4 File

22.4.1 Original documents must be archived and controlled copies must be used.

22.4.2 The duration of the file of all the documentation must be defined.

22.4.3 Documents can be filed either electronically or in print, and it must guarantee its readability.

22.4.4 Backup copies should be archived in a separate and secure place at intervals

regular

III. OF THE ADMINISTRATIVE AND EVALUATION PROCEDURE OF THE ACCORDANCE

23. The competent National Authorities (NCAs) of the Member Countries will require the compliance with the present Andean Technical Regulation of Good Practices Manufacturing, when granting the sanitary authorization of operation or certificate of capacity or permission of operation of the companies or establishments that manufacture, condition or cosmetic products; this document will be necessary for Access the Compulsory Sanitary Notification (NSO) required by Decision 833 and its amendments or the regulations that replace it.

24. The sanitary authorization of operation or certificate of capacity or permission of operation that demonstrates compliance with this Andean Technical Regulation, will be granted through the application of the inspection guide and evaluation criteria

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harmonized, issued by the corresponding Community body as established in Decision 827; which will have indefinite validity.

The company or establishment must maintain the conditions under which it was granted the sanitary authorization of operation or certificate of capacity or permission of functioning. If for control and surveillance purposes, the ANC detects non-compliance of any of the aforementioned conditions, or when the ANC is not allowed the entrance to the establishment to verify such conditions up to two (2) On occasions, it may apply the sanctions or measures that may be established in Chapter IV of this Andean Technical Regulation.

25. The company or establishment that manufactures, conditions or assembles cosmetic products inform the Competent National Authority of the modifications to the conditions initially authorized to grant the certificate of capacity or sanitary authorization of operation or operating permit, and when the company or establishment Stop working.

26. In the case of products imported into the subregion that require access to the NSO, it must be evidence compliance with good manufacturing practices as established in this Andean Technical Regulation or in equivalent international standards, by a statement of first or third party issued by a body of conformity assessment accredited by the National Accreditation Body or recognized by the competent National Authority of the country of origin.

IV. OF CONTROL AND SURVEILLANCE

27. The competent National Authority of the Member Country, in the exercise of the functions of control and surveillance in the market established in Decision 833 and its amendments or the regulation that replaces it, will be in charge of the supervision and verification of compliance with the provisions of this Andean Technical Regulation.

28. The competent National Authority may require the company or establishment, when it considers it, the presentation of the documentation required in the present Andean Technical Regulation.

29. The competent National Authority of the Member Country will proceed to apply the sanitary measures of security and the sanctions that are due to non-compliance of this Andean Technical Regulation as established in Decision 833 and its amendments or the regulations that replace it.

V. COMPLEMENTARY PROVISIONS

FIRST Entry into force. The present Andean Technical Regulations shall enter into force from twenty-four (24) months after the date of its publication in the Official Gazette of the Agreement of Cartagena.

SECOND. As of the date of entry into force of this Andean Technical Regulation, Repeat the provisions that are contrary.

THIRD. Review and update. The present Andean Technical Regulation will be reviewed less once every five (5) years, in order to update or repeal it, or when the conditions that gave rise to it change or disappear.

APPENDIX 1

Indicative list of NANDINA sub-items of cosmetic products included in this Andean Technical Regulation (According to the NANDINA Nomenclature of Decision 812)

Code	Merchandise description	Observations
3303.00.00	Perfumes and toilet waters	
33.04	**Beauty preparations, makeup and for Skin care, except medications, including sunscreen preparations and tanning machines; preparations for manicures and pedicures**	
3304.10.00	- Preparations for the make-up of lips	Only for

3304.20.00	- Preparations for eye makeup	cosmetic product Only for cosmetic product
3304.30.00	- Preparations for manicure or pedicure	
	- The others:	
3304.91.00	- - Powders, including compacts	
3304.99.00	- - The others	Only for cosmetic product
33.05	**Hair preparations.**	
3305.10.00	- Shampoos	Only for cosmetic product
3305.20.00	- Preparations for corrugation or straightening permanent	
3305.30.00	- Hair spray	
3305.90.00	- The others	Only for cosmetic product
33.06	**Preparations for oral or dental hygiene, including powders and creams for the adherence of dentures; thread used for cleaning the interdental spaces (dental floss), in containers Individuals for retail sale.**	
3306.10.00	- Dentifrices	Only for cosmetic product
3306.90.00	- Other	Only for cosmetic product
33.07	**Preparations for shaving or for before or after shaving, body deodorants, preparations for bathing, depilatories and others perfumery, toilet or shower preparations cosmetic, not expressed or understood in other part; Deodorant preparations premises, even without perfuming, even if disinfectant properties.**	
3307.10.00	- Preparations for shaving or for before or after of shaving	
3307.20.00	- Body deodorants and antiperspirants	Only for products cosmetics
3307.30.00	- Scented salts and other preparations for bathroom	Only for cosmetic product

Code	Merchandise description	Observations

3307.90	- Others:	
3307.90.90	Other	Only for cosmetic product
34.01	**Soap; organic products and preparations tense assets used as soap, in bars, breads, pieces or pieces cut or molded, even if they contain soap; products and organic surfactant preparations for washing the skin, liquid or cream, put up for retail sale, even if they contain soap; paper, wadding, felt and non-woven fabric, impregnated, coated or coated with soap or detergents**	
	- Soap, organic products and preparations surfactants, in bars, loaves, pieces or pieces stamped or molded, and paper, wadding, felt and non-woven fabric, impregnated, coated or coated with soap or detergents:	
3401.11.00	- - Of toilet (not including medicinal)	
3401.20.00	- Soap in other forms	Only for cosmetic product
3401.30.00	- Organic surfactant products and preparations for washing the skin, liquid or cream, put up for retail sale, although contain soap	Only for cosmetic product
38.08	**Insecticides, rodenticides and other anti-rodents, fungicides, herbicides, inhibitors of germination and growth regulators of plants, disinfectants and similar products, presented in forms or in containers for sale retail, or as preparations or articles such as ribbons, wicks and candles, sulfur, and flypaper.**	
	- Others:	
3808.91	- - Insecticides:	
3808.91.14	- - - - Containing permethrin or cypermethrin or other synthetic substitutes for pyrethrum (pyrethroid), except those mentioned in Note 2 of subheading of this Chapter	Only for cosmetic product
3808.91.19	- - - - Other	Only for cosmetic product
	- - - Others:	
3808.91.91	- - - - Containing natural pyrethrum (pyrethrin)	Only for cosmetic product
3808.91.97	- - - - Containing permethrin or cypermethrin or other synthetic substitutes for pyrethrum (pyrethroid), except those mentioned in Note 2 of subheading of this Chapter	Only for cosmetic product
3808.91.99	- - - - Other	Only for cosmetic product

Note: Cosmetic products must comply with the definition of community regulations.