Cosmetics Good Manufacturing Practice Regulations Draft

Announced Date:

Chapter 1 General Provisions

Article 1

These regulations are promulgated pursuant to the Paragraph 4, Article 8 of the Cosmetic Hygiene and Safety Act (hereafter referred to as the Act) and with reference to the ISO 22716: Cosmetics-Good manufacturing practices (GMP)-Guidelines on good manufacturing practices issued by the International Organization for Standardization.

Article 2

The terms used in this regulations are defined as follows:

1. Acceptance criteria: the acceptable numerical limits, ranges, or other suitable measurement regulations according to the test results.

2. Auditing: systematic and independent examination, the aim of which is to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable for achieving objectives.

3. Batch: defined quantity of raw material, packaging material or product issued from a single or series of manufacturing processes and identified as homogeneous.

4. Batch number: distinctive combination of numbers, letters and/or symbols, which specifically identifies a batch.

5. Bulk products: any products that are completed the manufacturing stages up to, but not

including, final packaging.

6. Calibration: under specified condition, to establish the operation methods and procedures to ensure the relationship between the values indicated by the measurement equipment or measurement system, or material measuring values and the known reference standard values.

7. Change control: any planned change of one or several activities related to Good Manufacturing Practice conducted by the internal organizations and responsible to ensure that all the manufacturing, packaging, controlling and storage of the products to meet the defined acceptance criteria.

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

9. Complaint: external information claiming a product does not meet the defined acceptance criteria.

10. Contamination: occurrence of any undesirable matter such as chemical, physical and/or microbiological matter in the product.

11. Consumables: materials such as cleaning agents and lubricants that are used up during cleaning, sanitization or maintenance operations.

12. Contract acceptor: person, company or external organization which enforce an operation outsourced by Cosmetics firms.

13. Control: verification that acceptance criteria are met.

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

15. Finished product: cosmetic product that has undergone all stages of production, including packaging in its final container, for shipment.

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

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

18. Major equipment: equipment specified in production and laboratory documents, which is considered essential to the process.

19. Maintenance: any periodic or unplanned support and verification operations designed to keep premises and equipment in proper working condition.

20. Manufacturing operation: set of operations from the weighing of raw materials to the making of the bulk product.

21. Out-of-specification: examination, measurement or test result that does not comply with the defined acceptance criteria.

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

23. Packaging material: any material employed in the packaging of a cosmetic product, excluding any outer packaging used for transportation. And according to direct contact with the product or not, defined as primary or secondary packaging material.

24. Plant: location for production of cosmetic products.

25. Premises: physical location, buildings or supporting structures used to conduct receipt, storage, manufacturing, packaging, control and shipment of product, raw materials and packaging materials.

26. Production: manufacturing and packaging operations.

27. Quality assurance: all those planned and systematic activities necessary to provide confidence that a product satisfies the defined acceptance criteria.

28. Raw material: any substance going into or involved in the manufacturing of a bulk product.

29. Recall: decision made by a cosmetics firm to call back a product batch that has been put on the market.

30. Reprocessing: re-treatment of all or part of a batch of finished product or bulk product of an unacceptable quality so that its quality may be rendered acceptable by one or more additional operations.

31. Return: sending finished cosmetic products which may or may not present quality

defect back to the cosmetics firm.

32. Sample: one or more representative elements selected from a set to obtain information about that set.

33. Sampling: set of operations relating to the taking and preparation of samples.

34. Sanitization: depending on the objectives set, operation used to reduce undesirable micro-organisms on inert contaminated surfaces, means as the operation of reducing invisible contaminants.

35. Shipment: set of operations relative to the preparation of an order and its putting in a transport vehicle.

36. Waste: any residue of a production operation, transformation or use, any substance, material, product that its holder intends for disposal.

Chapter 2 Personnel

Article 3

The personnel in the cosmetics manufacturing plants who participate the activities indicates in the acceptance criteria shall have an appropriate training to comply the quality of production, control and product storage operation.

Article 4

The personnel in the cosmetics manufacturing plants shall establish the organization according to the following:

1. Organization chart

(1) Regulate the organization to ensure the division of labor and competency according to the scale and diversity of its product of the manufacturing plants.

(2) To ensure there are adequate staffing levels in the different scope of activity according to its diversity of products.

(3) The quality assurance unit and quality control unit shall be independent to other departments. The responsibility of quality assurance and quality control can be undertaken by a separate quality assurance unit and quality control unit or a single unit.

2. Number of personnel: According to the activities defined in this regulation, the manufacturing plants shall have adequate personnel with appropriate training.

Article 5

The cosmetics manufacturing plants shall regulate the key responsibilities as follows:

1. Management responsibilities:

(1)The organization shall be supported by the top management of the company.

(2) The implementation of Good Manufacturing Practice shall be the responsibility of the top management and shall require the participation and commitment of the personnel at all level in the manufacturing premises for the achievement.

(3) Management shall categorize the areas in which the authorized personnel are allowed to access.

2. Personnel responsibilities:

(1) To ensure the position and department in the organizational structure.

(2) To ensure the scope of responsibilities.

(3) To obtain the related documents within the scope of responsibilities, and follow the regulations indicates in the documents.

(4) Comply with personal hygiene requirements.

(5) To report the irregularities and other non-conformities.

(6) To receive adequate educational training and skills to perform the activities and responsibilities.

Article 6

The personnel involved in production, control, storage and shipment of cosmetics manufacturer shall acquire the appropriate abilities of working experience and training according to the responsibilities.

plants shall enforce personnel training according to the following:

The training mentioned in the preceding paragraph shall be regulate as follows:

1. Appropriate training related to the activities in this regulation shall be provided to all personnel.

2. To ensure training needs of different levels and qualification of the personnel, and to conduct and enforce its related training program.

3. The training program shall be considered and developed according to the expertise, experience, and the scope of responsibilities of the personnel.

4. To evaluate training needs and manufacturing plants resources, or be carried out by outside company if necessary.

5. The personnel shall receive training normally and continually, and the training content and program shall be updated regularly.

6. Newly recruited personnel shall receive theory and practical training related to this regulation, and specific training according to the duties assigned to them.

7. The effectiveness of receiving the training shall be evaluated during the training process or afterwards.

Article 7

The cosmetics manufacturer shall control the hygiene and health of the personnel, and the following regulation shall apply:

1. To establish and to adapt the need of a hygiene program, these requirements shall be understood and followed by all personnel who entered in the production, control and storage area.

2. Personnel shall be instructed to the hand washing facility.

3. Ensure the personnel who enter production, control and storage area to wear appropriate clothing and protection outfit to avoid the contamination of cosmetic products.

4. Avoid the personnel from eating, drinking, chewing, smoking, or to store foods, drinks, smoking products or personal drugs in the production, control, and storage area.

5. Prohibit all the unhygienic practice in the production, control, storage area or in any

other area where the product may be adversely affected.

6. Any person affected by an apparent illness or having open wound, a measurement shall be taken to be excluded from direct contact to the products until the condition is corrected or determined by medical personnel that the quality of cosmetic products will not be compromised.

Article 8

Visitor or untrained personnel shall be prohibited to enter production, control and storage area. However, if there is any necessity to enter these areas, they should be given related precaution in advance, including rules about personal hygiene and the prescribed protective clothing, and closely supervised.

Chapter 3 Premises

Article 9

The location, design, construction, and use of the cosmetics manufacturing plants shall be regulated as follows:

1. To make sure the produces are protected.

2. Enforce effective cleaning. Sanitizing and maintenance shall be enforced when necessary.

3. To minimize the risk and control of mix-up of products, raw materials, and packaging materials.

The design of the premises shall consider the type of the cosmetic product produced, existing condition, cleaning, and necessary sanitizing measures.

Article 10

The storage, production, quality control, ancillary, washing and toilets of the cosmetics manufacturing plants shall be separated or identified clearly.

Article 11

There shall be sufficient space to enforce operations such as receiving department, storage and production in the cosmetics manufacturing plants.

Article 12

The flow of the materials, products, and personnel through the building or buildings shall be planned properly to avoid any mix-ups in the cosmetics manufacturing plants.

Article 13

The floors, walls, ceilings, and windows of the cosmetics manufacturing plants shall be regulated as follows:

1. The design and construction of floors, walls, ceilings and windows of the production area, shall be implemented with smooth surfaces to tolerate cleaning agents and sanitizers. They shall be easy to clean and sanitized to maintain in a good condition.

2. The windows shall be non-opening design, except if there is insufficient ventilation in the buildings. Those with opening design shall set up with screen windows.

Article 14

Sufficient and clean washing and toilet facilities shall be provided in the cosmetics manufacturing plants. The facilities shall be separated from production area, and convenient to use. Sufficient shower rooms and changing clothes area shall be provided when necessary.

Article 15

The lighting of the cosmetics manufacturing plants shall be regulated as follows:

1. Sufficient lighting facilities shall be installed to provide the needs for operation.

2. The lighting facilities shall be installed properly or other measures be taken to make sure there will not be any fragments from potential breakage to contaminate the products.

Article 16

There shall be sufficient ventilation, or other specific measures to be taken to protect the products in the cosmetics manufacturing plants alternatively.

Article 17

The pipework, drains and ducts in the cosmetics manufacturing plants shall be regulated as follows:

1. The pipework, drains and ducts shall be installed properly to avoid any drip and condensation to contaminate the raw materials, products, equipment, and premises.

2. Drains shall be kept flowing smoothly and without any back flow.

3. Exposed overhead rood beams, pipes and ducts shall be avoided. Exposed pipes shall be suspended by brackets or separated and not touch the walls for easy cleaning.

4. Specific measures to be taken to protect the products if necessary.

Article 18

The cleaning and sanitation of the premises of the cosmetics manufacturing plants shall be regulated as follows:

1. To conduct a specific cleaning and sanitation plan for each area, and to keep it in a clean

condition.

2. To enforce cleaning and necessary sanitation to ensure the products are not contaminated.

3. To identify the specific kinds of the cleaning agents and sanitizer, and to ensure the effectiveness when usage.

Article 19

The cosmetics manufacturing plants shall be repaired and maintained properly.

Article 20

The cleaning agents and lubricants cosmetics manufacturer used to clean, sanitize or maintain premises and facilities shall not affect the quality of the products.

Article 21

The pest control in the cosmetics manufacturing plants shall be regulated as follows:

1. The design, construction, and maintenance of the premises shall be effective to avoid any insects, birds, pests, rodents and other vermin.

2. A pest control plan shall be conducted.

3. Measures shall be taken to prevent attracting pests at the exterior of the premises.

Chapter 4 Equipment

Article 22

Equipment in the cosmetics manufacturing plants shall meets the intended uses, and easy to clean, sanitize, and maintain if necessary.

All equipment related to this regulation in the cosmetics manufacturing plants shall be governed by provision in this chapter. For those with automated system integration technology shall require the same consent.

Article 23

The design of the equipment in the cosmetics manufacturing plants shall meet the requirements as follows:

1. The production equipment shall be designed to prevent the products from being contaminated.

2. The container for bulk products shall come with the protection to avoid dusts, moisture and air contaminants.

3. Used transfer hoses and accessories shall be cleaned and sanitized if necessary, kept dry and protected from dusts, splash or other contamination.

4. The material of the equipment shall be compatible with the products, cleaning agents, and sanitizer.

Article 24

The installation of the equipment in the cosmetics manufacturing plants shall be regulated as follows:

1. The design and installation of the equipment shall be easy to drain in order to clean and sanitize.

2. The placement for the equipment shall consider the movement of materials, mobile equipment and personnel flow which do not pose a risk to the quality.

3. Appropriate access space under, inside and around the equipment shall be provided for cleaning and sanitizing.

4. The major equipment shall be easy to identify.

Article 25

The calibration of the equipment in the cosmetics manufacturing plants shall be regulated as follows:

1. Laboratory and production measuring instruments related to production quality shall be calibrated regularly.

2. If calibration results of measuring instruments do not meet the acceptance criteria, those shall be identified specifically and removed from service.

3. The condition set forth in the preceding subparagraph shall be investigated to confirm the impact to the production quality and to take appropriate measures afterwards according to the investigation result.

Article 26

The cleaning and sanitation of the equipment in the cosmetics manufacturing plants shall be regulated as follows:

1. All equipment shall be cleaned adequately. A Sanitation plan shall be established if necessary.

2. Cleaning agents and sanitizers shall be identified and effective.

3. Where equipment is assigned for continuous production or production of successive

batches of the same products, that equipment shall be cleaned and if necessary, a sanitizing period can be established to carry out.

Article 27

The maintenance of the equipment in the cosmetics manufacturing plants shall be regulated as follows:

1. To be maintained regularly.

2. Maintenance operation shall not affect the quality of the products.

3. The defective equipment shall be identified accordingly and excluded from use and isolated, except for any unavoidable condition.

Article 28

The consumable uses for equipment in the cosmetics manufacturing plants shall not affect the quality of the products.

Article 29

The equipment or automated system in the cosmetics manufacturing plants used in production and control shall be access and used by authorized personnel.

Article 27

The cosmetics manufacturer shall prepare an adequate alternative back-up plan for operation system breakdown or failure.

Chapter 5 Raw Materials and Packaging Materials

Article 31

Raw materials and packaging materials are purchased from the cosmetics manufacturer shall meet the acceptance criteria.

The acceptance criteria mentioned in the preceding paragraph shall be established according to the quality requirements of finished products.

Article 32

Raw materials and packaging materials are purchased from the cosmetics manufacturer shall consider the following requirements:

1. The supplier qualification.

2. The establishments of technical clauses such as type of selection to be conducted, acceptance criteria, measures to take in the case of defect or modification, transport conditions.

3. Setting of the relations and interactions between the company and supplier such as questionnaire, assistance, and audit.

Article 33

The receipt of the raw materials and packaging materials of the cosmetics manufacturer shall be regulated as follows:

1. The records of the purchase order, the deliver notes and the receiving materials shall all match.

2. The integrity of the raw materials and packaging materials shall be checked visually. Transportation data shall be inspected if necessary.

Article 34

The raw materials and packaging materials identification and status in the cosmetics manufacturing plants shall be regulated as follow:

1. The containers of raw materials and packaging materials shall be labelled in order to identify the material and batch information.

2. The raw materials and packaging materials shows defects that may affect the product quality shall be suspended hold for further decision.

3. The raw materials and packaging materials shall be identified and separated according to its status, such as accepted, rejected or quarantined. Those can be identified by using physical system of identification or others that can make sure the same level identification.

The identification mentioned in the preceding paragraph shall include the following:

1. Name of the product indicated on the delivery note.

2. Name or code of the materials given by the company. If different from the name or code number given by the supplier, shall be indicated clearly.

3. Batch reference provided by the supplier and the one given at the receipt shall all be presented if there is any difference.

4. Name of the supplier.

5. Date and number of the receipt, if necessary.

Article 35

The release of the raw materials and packaging materials in the cosmetics manufacturing plants shall be regulate as follows:

1. To establish physical or other alternative system to ensure only released raw materials and packaging materials are used.

2. The release of the raw materials shall be enforced by authorized personnel who are responsible for the quality.

3. The certificates of analysis provided by the supplier can be accepted as the basis of release, only if the supplier possess the sufficient technology, experience and knowledge, adopt the test methods agreed by the cosmetics firm, and completed appropriate audit.

The raw materials released under the requirements mentioned in the preceding paragraph, those weighted and unused raw materials after process operation shall be placed in a sealed container and labelled properly. Then it can be restored to the storage.

Article 36

The storage of the raw materials and packaging materials in the cosmetics manufacturing plants shall be regulated as follows:

1. Storage condition shall be set up properly to fit each batch of raw materials and packaging materials. The company shall monitor and control to maintain the specific storage condition, if necessary.

2. The raw materials and packaging materials shall be stored and handled properly according to its characteristics.

3. The container of the raw materials and packaging materials shall be sealed and stored

off the floor.

4. When repacking the raw materials and packaging materials, the content on the labels shall be identical to the original labels.

5. When raw materials and packaging materials are rejected or quarantined, they shall be stored at a certain location, or other ways to ensure they can be identified.

6. To establish measures to ensure stock turnover, and stock rotation shall follow the principle of first in, first out.

7. Periodic inventory shall be performed to ensure the inventory information is correct. Any significant discrepancy shall be inspected and corrected.

Article 37

In order to prevent the misuse of the materials which are reached the defined period of storage of the materials, the cosmetics manufacturer shall establish a re-evaluation system to determine the suitability for use.

Article 38

The quality of water used in production shall be regulated as follows:

1. The water treatment system shall supply a defined quality of water.

2. The water quality shall be monitored or verified through water quality testing or process parameters.

3. The water treatment system shall permit sanitation.

4. The material used for the water treatment equipment shall be selected to ensure the

water quality is not affected and the settlement of the water treatment equipment shall avoid any water stagnation and the risk of contamination.

Chapter 6 Production

Article 39

At each stage of manufacturing operation and packaging operation, measures shall be taken to ensure the finished products meet the defined specification.

Article 40

The manufacturing operations of the cosmetics, the relevant documents according to the need of every stage shall be prepared and available at any time. The documents are:

1. Equipment documents.

2. Formula for the products.

3. List of all raw material with the quantities and identified batch numbers.

4. Detailed manufacturing for each stage, including the addition of the raw materials, temperature, speeds, mixing time, sampling, cleaning, necessary sanitizing and transfer of bulk products.

Before starting any manufacturing operations mentioned in the preceding paragraph, these items have to be ensure:

1. Prepare all the relevant documents and raw materials, available and released, related to manufacturing.

2. Equipment has been through appropriate cleaning and sanitizing, and is able to use

properly.

3. Operation area is cleaned to prevent from mixing any materials from the previous manufacturing operations.

The manufacturing operations mentioned in Paragraph 1, the identification of in-process operation shall be regulated as follows:

1. All raw materials measured and weighted according to the formula, and placed in a labelled, cleaned and suitable container, or directly put into the manufacturing equipment.

2. Major equipment, raw material containers, and bulk product containers shall be identified easily at any time.

3. The identification on the bulk product container shall include: Name or identification code, batch number and storage condition when such information is critical to assure the quality of the products.

The manufacturing operation mentioned in the preceding paragraph, the in-process control shall be regulated as follows:

1. To establish and enforce an in-process control plan including acceptance criteria.

2. Any result does not meet the acceptance criteria during the enforcement of in-process control plan mentioned in the preceding subparagraph shall be reported and investigated according to the procedure.

Article 41

Every batch of manufactured bulk products shall be assigned a batch number. When the batch number is different from the numbers on the finished products, it shall be easy to identified and related to each other.

The storage of bulk products mentioned in the preceding paragraph shall be regulated as follows:

1. Bulk products shall be stored in a proper container, and placed in a specific area under the appropriate condition.

2. The storage duration of the bulk products shall be defined.

3. When this duration is reached, the bulk products shall not be used without re-evaluation.

Article 42

The packaging operations of the cosmetics, the relevant documents according to the need of every stage shall be prepared and available at any time. The documents are:

1. Equipment documents.

2. Lists of packaging materials.

3. Operation details in every stages including filling, sealing, labelling and coding.

Before starting any packaging operations mentioned in the preceding paragraph, these items have to be ensure:

1. Prepare all packaging materials and the relevant documents listed in the preceding paragraph.

2. Equipment has been through appropriate cleaning and sanitizing and is able to use

properly.

3. Operation area is cleaned to prevent from mixing any content and packaging materials from the previous manufacturing operations.

4. Coding to permit identification of the defined product.

Every batch of finished products after packaging shall be assigned a batch number. When the batch number is different from the numbers on the bulk products, it shall be easy to identified and related to each other.

During packaging operations, the identification information shall be placed on each operation line at that time. The information are: name and identification code of the packaging operation line, Name and identification code of the finished products and the batch numbers.

The unused packaging materials shall be placed in a sealed container and labelled properly. Then it can be restored to the storage.

When filling and labelling operation does not complete at once, measures such as quarantine and identification shall be taken to avoid mix-up or mislabeling.

Article 43

The packaging operations mentioned in the preceding paragraph, the in-process control shall be regulated as follows:

1. To establish and enforce an in-process control plan including acceptance criteria.

2. Any result does not meet the acceptance criteria shall be and reported and investigated according to the procedure.

The in-process control mentioned in the preceding paragraph, for those who use on-line control equipment shall be checked regularly according to the established period, items and content.

Chapter 7 Finished Products

Article 44

The finished products of the cosmetics shall meet the acceptance criteria.

The cosmetics manufacturer shall use proper storage, shipment and return methods to ensure the quality of the finished products.

Article 45

The release of finished products shall be regulated as follows:

1. Before releasing to the market, all finished products shall be controlled to make sure to meet to acceptance criteria according to the established test methods.

2. The release of the finished products shall be enforced by authorized personnel who are responsible for the quality.

Article 46

The storage of the finished products shall be regulated as follows:

1. The finished products shall be stored in a specific area in a systematic method according to the storage condition and duration. They shall be monitored and controlled, if necessary.

2. The finished products shall be categorized into release, quarantine or reject and they shall be stored at a certain location, or other ways to ensure they can be identified.

3. The identification of the finished products shall include:

(1) Name or identification code, batch number and Quantity of the finished products.

(2) The critical storage condition to assure the quality of the finished products.

4. To establish measures to ensure stock turnover, and stock rotation shall follow the principle of first in, first out.

5. Periodic inventory shall be performed to ensure the inventory information is correct. Any significant discrepancy shall be investigated.

Article 47

Cosmetics manufacturer shall adopt the proper protective measures of shipping methods in order to maintain the quality of the finished products during the shipping process.

Article 48

The returns of the finished products shall be regulated as follows:

1. The returns shall be identified and be stored in a specific area.

2. The returns shall be evaluated according to the established standard to determine their disposition.

3. Any re-marketing products shall be released according to the procedure.

4. To establish measures to identified any reprocessed return and to avoid redistribution of unreleased returns.

Chapter 8 Quality Control Laboratory

Article 49

Regulations described for personnel, premises, equipment, subcontracting and documentations shall apply to the quality control laboratory.

The responsible activities of the quality control laboratory mentioned in the preceding paragraph are: to enforce necessary sampling and testing and its related control in order to ensure the release of the materials for use and the release of the product for packaging shipping comply to the acceptance criteria.

Article 50

The quality control laboratory shall define and establish the acceptance criteria of raw materials, packaging materials, bulk products and finished products.

The compliance with the acceptance criteria mentioned in the preceding paragraph shall use necessary test methods to ensure.

The test methods mentioned in the preceding paragraph shall be clear, appropriate and workable.

All results shall be reviewed by the quality control laboratory mentioned in Paragraph 1, and decisions of approval, rejection or pending shall be made after the review.

Article 51

The result mentioned in the preceding paragraph is out-of-specification shall be regulated as follows:

1. Out-of-specification results shall be reviewed and investigated properly by the responsible personnel. After the review, the decisions shall be made as deviation, rejection or pending.

2. Re-testing shall not be performed except with a sufficient and legitimate reason.

Article 52

Reagents, solutions, reference standards and culture media, etc. shall be labelled identification information such as name and opening date. If necessary, shall include strength or concentration, storage condition, expiration date, and the name or signature of the person who prepared.

Article 53

The cosmetics manufacturing plants shall perform sampling operation by authorized personnel according to the established sampling operation plan.

The operation plan mentioned in the preceding paragraph shall include the following:

1. Sampling methods

2. Equipment to be used

3. Number of the samples

4. Any precautions to be observed to avoid samples from contamination and deterioration.

5. Identification information of sample

6. Sampling frequency

Article 54

The identification information of sample mentioned in Paragraph 2 of the preceding Article shall include the following:

1. Name or identification code

2. Batch number

3. Sampling date

4. The container from which the sample was taken

5. The sampling point, if necessary

Article 55

The retention sample shall be regulated as follows:

1. The sample of the finished products shall be retained properly in a specific area.

2. The amount of the retain samples of the finished products shall be sufficient enough to enforce analysis.

3. The samples of the finished products shall be retained with the complete packaging, and retain for an appropriate period according to the storage condition.

4. The samples of the raw materials shall be retained according to the regulations of the manufacturing plants or other relevant regulations.

Chapter 9 Treatment of Product that is Out of Specification

Article 56

The treatment of rejected finished products, bulk products, raw materials and packaging materials of the cosmetics manufacturer shall be regulated as follows:

1. Investigation of rejected products or materials shall be conducted by authorized

personnel.

2. Decisions from quality control related authorized personnel to be made to determine any further action of the rejected items.

Article 57

The reprocessing of the finished products and bulk products shall be regulated as follows:

1. The performance of reprocessing shall be approved by the quality control related authorized personnel.

2. The methods of repeocessing shall be specified and approved.

3. To enforce control of finished products and bulk products after re-processing and to be reviewed by the authorized personnel in order to ensure to comply with the defined acceptance criteria.

Chapter 10 Waste

Article 58

The cosmetics manufacturer shall dispose the wastes in a proper and sanitary manner.

Article 59

The cosmetics manufacturer shall identify the type of waste that may affect the product quality clearly according to the information of production and quality control laboratory.

Article 60

The waste disposal shall be regulated as follows:

1. The flow of the waste disposal shall not affect the operation of production and laboratory.

2. Appropriate measures shall be taken concerning collection, transportation, storage and disposal of the wastes.

Article 61

The containers for waste shall be properly identified as to the contents and other information.

Article 62

The cosmetics manufacturer shall dispose the wastes in a proper way with adequate level of control.

Chapter 11 Subtracting

Article 63

The cosmetics manufacturer shall establish a written contract or an agreement with the subcontractor according to the subcontract items, and to indicate the objectives, obligations, responsibilities and contract performance management in the written documents, in order to ensure the products being made or the service being provided can meet the requirements from the cosmetics manufacturer.

The subcontractor shall retain or provide all the information related the contract of the preceding paragraph to the cosmetics manufacturer.

The subcontracting items mentioned in Paragraph 1 includes: manufacture, packaging, analysis, pest control, cleaning and sanitizing of the premises, and maintenance of the equipment and premises.

Article 64

When the cosmetics manufacturer conduct the subcontracting in the preceding article, the subcontracting should be regulated as follows:

1. To evaluate the performance ability, legal compliance and productivity of the subcontractor, to ensure they have all the abilities to enforce the contract and to assure all the subcontracting items can be carried out according to the contract

2. To provide the subcontractor with all the necessary information.

Article 65

The subcontractor shall be regulated as follows:

1. To ensure the performance ability, experience and the personnel ability meet the requirements indicated in the contract.

2. The subcontractor shall not out-source the items listed in the contract to the third party, except with the approval from the cosmetics manufacturer; with the approval, the subcontractor and the third party shall conduct another agreement to ensure the cosmetics manufacturer obtain all the operation information according to the original contract or agreement.

3. To cooperate with the cosmetics manufacturer to conduct investigation and to audit according to the contract or agreement.

4. Except with another agreement in addition to the contract or agreement, without the approval from the cosmetics manufacturer, the subcontractor cannot make any change to the contract items which may affect the products or service quality.

Chapter 12 Deviations

Article 66

When the cosmetics manufacturer discovers any deviations, the decisions shall be made according to the support of sufficient data.

Article 67

The cosmetics manufacturer shall take corrective action to prevent recurrence of the deviation.

Chapter 13 Complaints and Recalls

Article 68

The complaints shall be reviewed, investigated and follow-up on, as appropriate.

Article 69

Product complaints shall be regulated as follows:

1. To assign authorized personnel to handle complaints.

2. The handling of complaints shall be follow-up and all the detailed shall be recorded and preserved.

3. Appropriate follow-up on the concerning batch shall be completed.

4. The investigation and follow-up of the complaints shall include:

   (1) Measures to be taken to prevent any recurrence of defect.

   (2) To check other batch of the products to ensure whether if they are affected.

5. The amount and content of complaints shall be reviewed periodically, to ensure for trends or recurrence of defect.

Article 70

In the case of subcontracting, the cosmetics manufacturer and the subcontractor shall establish a written contract or an agreement on the process of managing complaints.

Article 71

Recall of the products shall be regulated as follows:

1. When products are recalled, appropriate measures and steps shall be taken to complete according to the rules in these regulations.

2. The responsible personnel shall negotiate the recall process.

3. The operation of the product recall shall be initiated promptly and in a timely manner.

4. The related authorities shall be notified of recalls which might cause the impact of consumer safety.

5. The recalled products shall be identified, isolated and stored in a safe area.

6. The product recall process shall be reviewed and evaluated periodically.

Chapter 14 Change Control

Article 72

When there is any change to be done which might affect the product quality, the cosmetics manufacturer shall assign authorized personnel to check and approve with sufficient data support.

Chapter 15 Internal Audit

Chapter 73

The Cosmetics manufacture plants shall enforce internal audit in order to comply with these regulations, and, if necessary, take corrective measures according to the results of internal audit.

Article 74

The enforcement of internal audit shall be regulated as follows:

1. To assign a responsible competent personnel to conduct internal audit independent and detailed manner, periodically or on demand.

2. The observations made from internal audit shall be evaluated and notified the appropriate management.

Article 75

The cosmetics manufacturer shall ensure the corrective measures mentioned in Article 73 are achieved or implemented.

Chapter 16 Documentation

Article 76

The cosmetics manufacturer shall design, establish, install and maintain its own documentation systems according to its organization structure and the type of the products.

The documentation systems mentioned in the preceding paragraph is an internal part of Good Manufacturer Practices. The documentation shall record all the operation activities according to these regulations to prevent risks of misinterpretation, loss of information, confusions or error.

The systems mentioned in Paragraph 1 can be established and managed in electronic.

Article 77

The content of documentation systems mentioned in the preceding article shall include: procedures, instructions, specifications, protocols, reports, methods, and records.

The content of the documentation mentioned in the preceding paragraph shall be kept in hard-copy papers or electronic data processing records.

Article 78

All activities in these regulations such as operation details, measures to be taken, and precautions to be taken shall be detailed documented. The title, nature and purpose shall be stated in every document.

The content of the documents mentioned in the preceding paragraph shall be written legibly and comprehensively. The authorized responsible personnel shall sign and indicate the date as approval before the announcement, and update appropriately, annul, distribute, and archive accordingly.

The documents mentioned in Paragraph 1 shall be obtained from the appropriate personnel in the manufacturing plants, and the annulled documents shall be ensured were deleted, destroyed and not being used again.

Article 79

The required hand written records in the document mentioned in the preceding article shall be regulated to write legibly with permanent ink. The recorder shall sign and indicated the date of the record. For those correction of the written records shall require the same consent.

The correction of the written records mentioned in the preceding paragraph shall leave the original entry readable, if necessary, the reason of the correction shall be recorded.

Article 80

The documents shall be updated if necessary. For those are updated, shall indicate the revision number and the reasons for each revision shall be retained.

Article 81

Archiving of the documentation shall be regulated as follows:

1. The controlled copies each revision of the documents shall be used, and the original records shall be archived.

2. The duration of archiving original documents shall be defined according to the related regulations.

3. The storage of original documents shall be properly secured.

4. The documents shall be stored electronically or as hard-copy papers, and to ensure their legibility.

5. The documents shall be back-upped regularly and stored in a separated safe location.

Article 82

These regulations shall be effective as of the date of promulgation.