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TANZANIA FOOD AND DRUGS AUTHORITY

GOOD MANUFACTURING PRACTICE GUIDELINES FOR COSMETICS

Made under the Tanzania Food, Drugs and Cosmetics (Control of Cosmetics) Regulations, 2010

FIRST EDITION

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Foreword

The Tanzania Food and Drugs Authority (TFDA) was established under the Tanzania Food, Drugs and Cosmetics Act, Cap 219 with the mission of protecting and promoting public health by ensuring quality, safety and effectiveness of food, medicines, cosmetics and medical devices. The Authority has a legal responsibility of ensuring that all cosmetics manufactured and used in the country meet the prescribed standards for the intended use. The Authority has also been given mandate by section 86 of the Act to prescribe requirements for manufacturing cosmetics.

In order to streamline and effectively control cosmetics, this first edition of the Guidelines for *Good Manufacturing Practices for Cosmetics* has been prepared by TFDA. The guidelines have been made under the provisions of the Tanzania Food, Drugs and Cosmetics (Control of Cosmetics) Regulations, 2010.

The guidelines provide up to date technical guidance on minimal requirements for manufacturing cosmetics. Its aim is to improve cosmetics manufacturing practices in the country as well as outlining a framework of requirements that manufacturers should follow when manufacturing products intended to be marketed in the country. These guidelines can also be used as a training tool for cosmetics industry personnel, GMP auditors and training institutions.

These guidelines give the principles and requirements of Good Manufacturing Practices (GMP) for premises, equipment, personnel, quality and process controls, documentation, storage, manufacturing processes as well as packaging and labeling of cosmetics.

It is therefore anticipated that all those who are manufacturing cosmetics and those who will intend to manufacture cosmetics to be used in Tanzania will oblige with the aforementioned legal provisions and follow the procedures and requirements as set out in these Guidelines.

It is the expectation of TFDA that the guidelines will enable consistent and uniform procedures for the production and documentation of cosmetics manufacturing processes so

as products can consistently meet safety and quality standards. Nevertheless we welcome new ideas, opinions and suggestions in this context that will assist in improvement of the guidelines.

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Hiiti B. Sillo
Director General
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Abbreviations

BMR	Batch Manufacturing Record
GMP	Good Manufacturing Practices
ISO	International Organization for Standardization
MSDs	Material Safety Data sheet
SCCP	Scientific Committee on Consumer Products
SOP	Standard Operating Procedures
TFDA	Tanzania Food and Drugs Authority
US FDA	United States Food and Drugs Administration

Glossary of Terms
In the content of these guidelines, the following terms/phrases are defined as follows:-

Authority
Means Tanzania Food and Drugs Authority

Batch
Means a quantity of any cosmetic product produced in a given cycle of manufacture that is uniform in character and quality.

Batch Number
Means a designation in numbers and/or letters or combination of both that identifies the complete history of the batch, quality control and distribution.

Bulk Product
Means any processed product which will have to undergo the packaging operation in order to become a finished cosmetic product.

Calibration
Means a combination of checking an instrument and adjusting it to bring it within its limits for accuracy according to recognized standards.

Cosmetic
Means any article intended to be used by means of rubbing, pouring, steaming, sprinkling, spraying on or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance and includes any article intended for use as component of a cosmetic; such articles exclude articles intended besides the above purposes for use in the diagnosis, treatment or prevention of diseases and those intended to affect the structure or any function of the body.

Date of Manufacture

Means date of manufacturing of a batch of cosmetic product.

Documentation
Means all written procedures, instructions and records involved in the manufacture and quality control of cosmetic products.

Finished Product
Means a cosmetic product which has undergone all stages of manufacturing operations including packaging in its final container and labeling.

Good Manufacturing Practice
Means that part of quality assurance which ensures that cosmetic products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.

In-Process Control
Means checks performed during production in order to monitor and, if necessary, to adjust the process to ensure that the cosmetic product conforms to its specifications. The control of the environment or equipment may also be regarded as a part of in-process control.

Intermediate Product
Means any processed substance or mixture of substances which has to undergo one or more stages of processing to become a bulk product.

Manufacture or Manufacturing
Means the complete set of activities to produce a cosmetic product, comprising of production and quality control, from acquisition of all raw materials through processing and subsequent packaging and release for distribution of the finished product.

Master formula
Means a document or set of documents specifying the starting materials with their quantities and the packaging materials, together with a description of the procedures and precautions required to produce a specified quantity of a batch as well as the processing instructions, including the in-process controls.

Packaging
Means all operations, including filling and labelling, that a bulk product has to undergo in order to become a finished cosmetic product.

Packaging Material
Means any material, including printed material, employed in the packaging of a cosmetic product, but excluding any outer packaging used for transportation or shipment.

Processing
Means that part of production cycle starting from weighing of raw materials to obtaining a bulk product.

Product
Means cosmetic in relation to these guidelines

Production
All operations starting from processing to packaging to obtain a finished cosmetic product.

Quality Control
Means all measures taken during manufacturing which are designed to ensure the uniform output of cosmetic product that will conform to established specifications.

Quarantine
Means the status of materials or products set apart physically or by system, while awaiting a decision for their rejection or release for processing, packaging or distribution.

Raw Materials
Means any ingredient to be used in the formulation of a cosmetic product.

Rejected
Means the status of materials or products which are not permitted to be used for processing, packaging or distribution.

Released
Means the status of materials or products which are allowed to be used for processing, packaging or distribution.

Returned Products
Means finished cosmetic products sent back to the manufacturer.

Sanitation
Means hygienic control on manufacturing premises, personnel, equipment, apparatus and material handling.

Standard operating procedure (SOP):
An authorized written procedure giving instructions for performing operations not necessarily specific to a given product or material but of a more general nature (e.g.,equipment operation, maintenance and cleaning; validation; cleaning of premises and environmental control; sampling and inspection). Certain SOPs may be used to supplement

product-specific master and batch production documentation.

Specification of Materials

Means a list of detailed requirements with which the products or materials used or obtained during manufacture have to conform. A specification normally includes descriptive and numerical clauses stating standards and tolerated deviations. They serve as a basis for quality evaluation.

Starting Materials

Means any substance of a defined quality used in the production of a cosmetic product but excluding packaging materials

INTRODUCTION

Good Manufacturing Practices (GMP) is a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in production that cannot be eliminated through testing of the final product.

Tanzania Food, Drugs and Cosmetics (Control of Cosmetics) Regulations, 2010, provides for regulation of cosmetic products to ensure that they comply with safety and quality standards and are manufactured in a GMP compliant facility. The regulation of cosmetics include inspection of cosmetic manufacturing facilities to verify compliance to Good Manufacturing Practices (GMP). Furthermore, GMP is conducted as a pre-requisite for marketing authorization of cosmetic products as well as premises registration.

These guidelines have been developed with an objective of providing guidance to manufacturers with regards to minimum requirements for production and quality control of cosmetics to ensure that products manufactured consistently meet specified standards. The guidelines intends to assist industries and other stakeholders in identifying the standards and issues that can affect the quality and safety of cosmetic products.

In order to promote uniformity in inspection decisions and to ensure the maintainance of high standards of quality in the formulation, manufacture and control of cosmetics, the document provides detailed guidance on Good Manufacturing Practice requirements for the manufacturing of cosmetics.

The guidelines are divided into thirteen (13) chapters which outlines GMP requirements for Quality Management System, Personnel, Premises, Equipment, Sanitation and hygiene, Materials, Production, Quality Control, Documentation, Contract Manufacturing and Analysis, Complaints and Product Recall. Supplementary information on classification of GMP inspection non-conformance observations has been included so as to assist manufacturers to identify the non-conformances which have negative impact on the quality and safety of cosmetics products.

The requirements set forth in these guidelines are not meant to replace other legal controls, but rather to complement or supplement them. It is also recognised that there are acceptable methods, other than those described in these guidelines, which are capable of achieving the objectives of the guidelines.

These guidelines are therefore not intended to place any restraint upon the development of new concepts or new technologies, which have been validated and provide a level of quality assurance at least equivalent to those set out in these guidelines.

CHAPTER 1: QUALITY MANAGEMENT SYSTEM

Principle:

A quality system should be developed and implemented as a means by which stated policies and objectives will be achieved. It should define the organisational structure, functions, responsibilities, procedures, instructions, processes and resources for implementing the quality management system.

General:

1.1 Manufacturers shall have a documented quality policy describing the overall intentions regarding quality, as formally expressed and authorized by management.

1.2 Manufacturers shall institute and implement quality management system which includes:

(a) An appropriate infrastructure or "quality system", encompassing the organizational structure, procedures, processes and resources; and

(b) Systematic actions necessary to ensure adequate confidence that a product and documentation will satisfy given requirements for quality. The totality of these actions is termed as "quality assurance".

1.3 The quality system operation should ensure that, samples of starting materials, intermediate or bulk and finished products are taken, tested to determine their release or rejection on the basis of test results and other available evidence related to quality.

1.4 Authorized SOPs for all administrative and technical operations performed should be in place.

1.5 Manufacturers should establish a system of conducting periodic internal self inspections which should be led by knowledgeable and experienced person in the field of cosmetics manufacturing.

1.6 A report should be made at the completion of each self inspection. Corrective and preventive action plan should be established and implemented.

CHAPTER 2: PERSONNEL

Principle:

There should be an adequate number of personnel having knowledge, experience, skills and capabilities relevant to their assigned functions. They should be in good health and capable of handling the duties assigned to them.

General:

2.1 Organization, Qualification and Responsibilities

2.1.1 The organizational structure should be defined such that the organization and functioning of the staff of the company be understood. It should be appropriate for the size of the company and the diversity of its products.

2.1.2 Each company should ensure that there are adequate staffing levels in the different scope of activity, according to the diversity of its production.

2.1.3 The organisational structure of the company shall be such that the production and the quality control sections are headed by different persons, neither of whom shall be responsible to the other.

2.1.4 The quality assurance and quality control responsibilities can be undertaken by a separate quality assurance unit and a quality control unit, or they can be undertaken by a single unit i.e. quality unit.

2.1.5 The head of production should be adequately trained and experienced in cosmetic manufacturing.

2.1.6 The head of quality control should be adequately trained and experienced in the field of quality control.

2.1.7 The responsibilities and authority of key personnel should be clearly defined and they should be employed on full time basis.

2.1.8 An adequate number of trained personnel should be appointed to execute direct supervision in each section of the production and the quality control unit.

2.1.9 The head of the production department should have authority and responsibilities to manage production of products covering operations, equipment, production personnel, production areas and records. Generally, he/she should have the following responsibilities:

(a) To ensure that products are produced and stored according to the appropriate documentation in order to obtain the required quality;

(b) To approve the instructions relating to production operations, including the in-process controls, and to ensure their strict implementation;
(c) To ensure that the production records are handled and signed by a designated person.
(d) To check the maintenance of the department, premises, and equipment
(e) To ensure that the appropriate calibrations of control equipment are performed and recorded and the reports made available.
(f) To ensure that the required initial and continuing training of production personnel is carried out and adapted according to needs.

2.1.10 The head of the quality unit including quality assurance and quality control department should generally have the following responsibilities:

(a) To approve or reject starting materials, packaging materials, intermediate, bulk, and finished products;

(b) To evaluate batch records;

(c) To ensure that all necessary testing is carried out;

(d) to approve sampling instructions, specifications, test methods, and other quality control procedures;

(e) To approve and monitor analyses carried out under contract;

(f) To check the maintenance of the department, premises and equipment

(g) To ensure that the appropriate analytical procedures are used and calibrations of control equipment are done;

(h) To ensure that the required initial and continuing training of quality control personnel is carried out and adapted according to need establishment,

implementation and maintenance of the quality system; supervision of regular internal audits or self-inspections.

2.2 Training

2.2.1 All personnel directly involved in the manufacturing activities should be trained on the chapters of these guidelines and any other relevant material which may be useful for personnel engaging in the cosmetics manufacturing. Special attention should be given during training of personnel working with hazardous materials.

2.2.2 Training in GMP should be conducted on a continuous basis.

2.2.3 Records of training should be maintained and its effectiveness assessed periodically

CHAPTER 3: PREMISES

Principle:

The premises for manufacturing should be suitably located, designed, constructed and maintained.

General:

3.1 Premises should be designed to ensure the logical flow of materials and personnel.

3.2 Effective measures should be taken to avoid any contamination from the surrounding environment and from pests.

3.3 Household products containing non-hazardous materials/ingredients and cosmetic products can share the same premises provided that due care is exercised to prevent cross contamination and risk of mix-up.

3.4 Painted line, plastic curtain and flexible barrier in the form of rope or tape may be employed to prevent mix-up.

3.5 Appropriate changing rooms and facilities should be provided. Toilets should be separated from the production areas to prevent product contamination/cross contamination.

3.6 Defined areas should be provided for, wherever applicable:

(a) Materials receiving.
(b) Materials Sampling.
(c) Incoming goods and quarantine.

(d) Starting materials storage.
(e) Weighing and dispensing.
(f) Processing.
(g) Storage of bulk products.
(h) Packaging.
(i) Quarantine storage before final release of products.
(j) Storage of finished products.
(k) Loading and unloading.
(l) Laboratories.
(m) Equipment washing.

3.7 Wall and ceiling where applicable, should be smooth and easy to maintain. The floor in processing areas should have a surface that is easy to clean and sanitise.

3.8 Drains should be clean and of adequate size and should be designed in such a way that not to allow flow back of water. Open channels should be avoided where possible, but if required they should be able to facilitate cleaning and disinfection.

3.9 Air intakes and exhausts and associated pipework and ducting, when applicable, should be installed in such a way as to avoid product contamination.

3.10 Buildings should be adequately lit and properly ventilated appropriate to the operations.

3.11 Pipework, light fittings, ventilation points and other services in manufacturing areas should preferably be installed in such a way as to avoid uncleanable recesses and run outside the processing areas.

3.12 Laboratories should preferably be physically separated from the production areas.

3.13 Storage areas should be of adequate space provided with suitable lighting, arranged and equipped to allow dry, clean and orderly placement of stored materials and products.

3.13.1 Such areas should be suitable for effective separation of quarantined materials and products. Special and segregated areas should be available for storage of flammable and explosive substances, highly toxic substances, rejected and recalled materials or returned goods.

3.13.2 Where special storage conditions e.g. temperature, humidity and security are required, these should be provided.

3.13.3 Storage arrangements should permit separation of different labels and other printed materials to avoid mix-up.

CHAPTER 4: EQUIPMENT

Principle:

Equipment should be designed and located to suit the production of the product.

General:

4.1 Design and Construction

4.1.1 The equipment surfaces coming into contact with any in-process material should not react with or adsorb the materials being processed.

4.1.2 Equipment should not adversely affect the product through leaking valves, lubricant drips and through inappropriate modifications or adaptations.

4.1.3 Equipment should be easily cleaned.

4.1.4 Equipment used for flammable substances should be explosion proof.

4.1.5 Fixed pipe work should be clearly labelled to indicate the contents and, where applicable, the direction of flow.

4.2 Installation and Location

4.2.1 Equipment should be located to avoid congestion and should be properly identified to assure that products do not become admixed or confused with one another.

4.2.2 Water, steam and pressure or vacuum lines, where applicable, should be installed so as to be easily accessible during all phases of operation. They should be clearly identified.

4.2.3 Support systems such as heating, ventilation, air conditioning, water (such as potable, purified, distilled), steam, compressed air and gases (example nitrogen) should function as designed and identifiable.

4.3 Maintenance

4.3.1 There should be equipment preventive maintenance plan.
4.3.2 Maintenance operations should not affect the quality of the product.
4.3.3 Defective equipment should be identified accordingly, excluded from use and isolated if possible.

4.4 Calibration

4.4.1 There should be procedures for internal calibration. External agencies should be used if necessary.

4.4.2 Weighing, measuring, testing and recording equipment should be calibrated regularly. All records should be maintained.

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

4.4.4 An out-of-calibration condition should be investigated.

CHAPTER 5: SANITATION AND HYGIENE

Principle:

Sanitation and hygiene should be practised to avoid contamination of the manufacturing of products. It should cover personnel, premises, equipment/apparatus and production materials and containers.

General:

5.1 Personnel

5.1.1 Personnel should be healthy to perform their assigned duties.

5.1.2 Personnel should maintain adequate personnel cleanliness, and be free from abnormal sources of microbiological contamination (for example, sores and infected wounds).

5.1.3 Any personnel shown at any time to have an apparent illness or open lesions that may adversely affect the quality of products should not be allowed to handle raw materials, packaging materials, in-process materials, and finished products.

5.1.4 Personnel should be trained to report to their immediate supervisor any conditions (plant, equipment or personnel) that they consider may adversely affect the products.

5.1.5 Direct physical contact with the product should be avoided to ensure protection of the product from contamination. Personnel should wear protective and clean attire appropriate to the duties they perform.

5.1.6 Eating, drinking, chewing or smoking should be restricted to appropriate designated areas away from production, quality control and storage areas.

5.1.7 Only authorized personnel should be allowed access into production, storage, and product control areas and

5.1.8 All personnel and visitors should be properly supervised while in the manufacturing facility.

5.2 Premises

5.2.1 Adequate washing, cleaning, plumbing and toilets should be available to allow for sanitary operation, cleaning of facilities, equipment and utensils as well as personal cleanliness.

5.2.2 Fixtures, ducts, pipes, and drainages should be installed to prevent condensate or drip contamination

5.2.3 Suitable locker facilities should be provided at appropriate location for the storage of employees' clothing and personal belongings.

5.2.4 Waste material should be regularly collected in suitable receptacles for removal to collection points outside the production area.

5.2.5 There should be adequate filth and pest controls (Examples of filth may include any objectionable matter, contributed by animal contamination such as rodent, insect, or bird matter; or any other objectionable matter contributed by insanitary conditions.)

5.2.6 Rodenticides, insecticides, fumigating agents and sanitising materials must not contaminate equipment, raw materials, packaging materials, in-process materials or finished products.

5.3 Equipment and Apparatus

5.3.1 The equipment (for example, utensils, pipe work, cosmetic contact surfaces and balances) should be maintained in a clean and orderly condition, sanitized at appropriate times, and stored in a manner that protects against splash, dust and other contaminants.

5.3.2 Standard operating procedures must be followed for cleaning and sanitising of major machines.

CHAPTER 6: MATERIALS

Principle:

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

General:

6.1 All deliveries of raw materials and packaging materials should be checked and verified for their conformity to specifications and be traceable to the product.

6.2 Deliveries of raw materials that do not comply with specification should be segregated and disposed according to standard operating procedures.

6.3 All goods must be clean and checked for appropriate protective packing to ensure no leakage, perforation or exposure.

6.4 Raw materials should be identified, stored, examined, tested, inventoried, handled, and controlled to ensure they conform to appropriate standards and specifications. It is particular important for manufacturers of cosmetics to maintain Material Safety data sheet (MSDs). In particular, raw materials should be:

(a) Stored and handled to prevent mistakes (i.e., mix-ups or selection errors), contamination with microorganisms or other chemicals, and degradation from exposure to excessive environmental conditions (e.g., heat, cold, sunlight, moisture, etc.)
(b) Held in closed containers and stored off the floor
(c) Maintained in containers that are labeled with the identity, lot number, and control status (release or quarantine)
(d) Sampled and tested for conformance with specifications and to ensure the absence microorganisms, adulterants and any other contaminants prior to processing or usage.
(e) Properly identified, labeled and controlled. The status of the contents (e.g. on quarantine, on test, released, rejected, returned, recalled) should be indicated.

6.5 Water

(a) Water production equipment and water systems should supply quality water. Water systems should be sanitized according to well-established procedures.

(b) The chemical and microbiological quality of water used in production should be

monitored regularly, according to written procedures and any anomaly should be followed by corrective action.

(c) The choice of method for water treatment such as deionisation, distillation or filtration depends on product requirement. The storage as well as delivery system should be properly maintained.

(d) The entire system for supplying water used as a cosmetic ingredient is set up to avoid stagnation and risks of contamination (This system should be routinely cleaned and sanitized according to an appropriate SOP that ensures no biofilm build-up.)

6.6 Colour additives

Colour additives used in production of cosmetic products should be as listed in the third schedule of the Tanzania Food, Drugs and Cosmetics (Control of Cosmetics) Regulations, 2010, Annex III of the Guidelines for Submission of Documentation for Marketing Authorization of Cosmetic Products.

6.7 Prohibited Ingredients

Certain ingredients are prohibited from use in cosmetic products marketed in Tanzania. Ingredients whose use is prohibited are listed in the in the first schedule of the Tanzania Food, Drugs and Cosmetics (Control of Cosmetics) Regulations, 2010, Annex VI of the Guidelines for Submission of Documentation for Marketing Authorization of Cosmetic Products.

CHAPTER 7: PRODUCTION

Principle:

At each stage of manufacturing operations and packaging operations, measures should be taken with the objective of obtaining products of the requisite quality.

General:

7.1 Procedures and Processing

Production operations should follow clearly defined procedures. Procedures should include provisions to ensure that:

(a) The selection, weighing, and measuring of raw materials and the determination of finished yield are reviewed by a second individual.

(b) Major equipment, transfer lines, containers and tanks used for processing, holding, or filling are identified to indicate contents, batch identification/designation, stage of processing and control status.

(c) There are appropriate measures to prevent contamination with microorganisms, chemicals or other extraneous material.

(d) There are in-process controls to ensure product uniformity, integrity (for example, in-process batch weights), accurate fill of mixing containers, and adequacy of mixing.

(e) Bulk products should be properly labelled until approved by Quality Control, where applicable.

(f) The theoretical yield for a production batch is compared with the actual yield.

(g) Finished product packages bear a production identification number which enables the history of the product to be traced. A batch numbering system should be specific for the product and a particular batch number should not be repeated for the same product in order to avoid confusion.

(h) Measures are in place to control dusts during production of dry products.

(i) The closed systems including pipe-lines for delivery of ingredients or bulk products are easy to clean.

7.2 Labelling and Packaging

7.2.1 Each labelling and packaging line should be clearly identified to avoid mix-up.

7.2.2 Packaging line should be inspected for clearance prior to operation. All materials and products from previous packaging operation should have been removed.

7.2.3 Samples should be taken and checked at random during labelling and packaging operations.

7.2.4 Excess labels and packaging materials should be returned to store and recorded. Any rejected packaging materials should be disposed off accordingly.

7.2.5 The tamper-resistant packaging and labeling should be used for liquid oral hygiene products and vaginal products.

CHAPTER 8: QUALITY CONTROL

Principle:

Quality control is one of the essential part of GMP which provides assurance that cosmetic products will be of consistent quality appropriate to their intended use.

General:

8.1 A quality control system should be established to ensure that products contain the correct materials of specified quality and quantity and are manufactured according to standard operating procedures.

8.2 Quality control should involve sampling, inspecting and testing of starting materials, intermediate, bulk and finished products. It should also include review of batch documentation, sample retention program and maintaining correct specifications of materials and products.

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

8.4 All finished products should be approved by Quality Control Laboratory prior to release.

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

8.6 The quality of retained samples should be periodically randomly monitored and records should be kept.

8.7 Retained samples of finished products should be kept in their primary package for at least one year after expiry under the recommended storage conditions.

8.8 Returned products should be identified and stored separately either in allocated area or by moveable barrier such as rope or tape.

8.9 Returned products which do not comply with the original specification should be rejected.

8.10 Rejected products should be disposed according to appropriate procedures.

8.11 Records of returned products must be maintained

CHAPTER 9: DOCUMENTATION

Principle:

Manufacturer should establish, design, install and maintain its own system of documentation that is appropriate to its organizational structure and to the type of cosmetic products. The documentation system should include the complete history of each batch, from starting materials to finished products. The system should record executed activities for maintenance, storage, quality control, primary distribution and other specific matters related to GMP.

General:

9.1 Types of documents

Documents should include procedures, instructions, specifications, protocols, reports, methods and records appropriate to the activities covered by these guidelines. Documents can be hard-copy papers or electronic data processing records.

9.1.1 **Specifications**

(a) All specifications should be approved by authorised personnel.

(b) Raw and packaging material specifications should include:
- (i) Name of material
- (ii) Description of the material
- (iii) Testing parameters and acceptance limits
- (iv) Special precautions e.g. storage and safety conditions, if necessary.

(c) Bulk and finished product specifications should include :
- (i) Name of product
- (ii) Description
- (iii) Physical properties
- (iv) Chemical assay and/or microbiological assays and their acceptance limits ; if necessary
- (v) Storage conditions and safety precautions, if necessary

9.1.2 **Documents for Production**

(a) Master Formula

This document should contain the following information :

- (i) Product name and product code/number

(ii) Intended packaging materials, and storage conditions
(iii) List of raw materials used
(iv) List of equipment used.
(v) In-process controls with their limits in processing and packaging, where applicable**.**

(b) Batch Manufacturing Record (BMR)

Batch Manufacturing Records should be prepared for each batch of product. Each BMR should include the following:

(i) Name of product
(ii) Batch formula
(iii) Brief manufacturing process
(iv) Batch or code number
(v) Date of the start and finish of processing and packaging
(vi) Identity of individual major equipment and lines or location used
(vii) Records of cleaning of equipment used for processing as appropriate
(viii) In-process control and laboratory results, such as pH and temperature test records
(ix) Packaging line clearance inspection records
(x) Any sampling performed during various steps of processing
(xi) Any investigation of specific failure or discrepancies
(xii) Results of examinations on packed and labelled products

(c) Records for Quality Control

Records for each testing, assay result and release or rejection of starting materials, intermediates, bulk and finished product should be maintained. These records may include :

(i) Date of test
(ii) Identification of the material
(iii) Supplier name
(iv) Date of receipt
(v) Original batch number if any
(vi) Batch number
(vii) Quality control number
(viii) Quantity received
(ix) Date of sampling
(x) Quality control results

9.2 Writing, approval and distribution

9.2.1 Where documents bear instructions they should be clearly written step by step.

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

9.2.3 Documents should be:

(a) Approved, signed and dated by authorized persons before being used
(b) Updated, when necessary, and the revision number indicated
(c) Referenced to ensure that obsolete documents are not used
(d) Distributed and be accessible to appropriate personnel
(e) Removed from the job area and destroyed if they are out-dated.

9.2.4 Records which require the entry of handwritten data should:

(a) Indicate what is to be entered
(b) Be written legibly with permanent ink
(c) Be signed and dated
(d) Be corrected if needed, leaving the original entry still readable; where appropriate, the reason for the correction should be recorded.

CHAPTER 10: CONTRACT MANUFACTURING AND ANALYSIS

Principle:

Contract production and analysis must be correctly defined, agreed and controlled in order to avoid misunderstandings that could result in a product or work or analysis of unsatisfactory quality.

General:

10.1 All aspects of contracted work should be specified to obtain a quality product conforming to the agreed standards as well as the marketing authorization for the product concerned.

10.2 There should be a written contract between the principal and the contract manufacturer to clearly establish the duties and responsibilities of each party.

10.3 The contract should permit the contract giver to audit the facilities of the contract accepter

CHAPTER 11: COMPLAINTS

Principle:

All complaints and other information concerning potentially defective products must be carefully reviewed according to written procedures.

General:

11.1 There should be written procedures for handling complaints.

11.2 All complaints communicated to the manufacturer should be reviewed, investigated and followed up as appropriate.

11.3 Complaints involving product defects should be recorded with all the original details and investigated.

11.4 If a product defect is discovered or suspected in a batch, consideration should be given to whether other batches should be checked in order to determine whether they are also affected.

11.5 All the decisions and measures taken as a result of a complaint should be recorded and referenced to the corresponding batch records. Complaint records should be regularly reviewed for an indication of specific or recurring problems that require attention and might justify the recall of marketed products.

11.6 The Authority should be informed if a manufacturer is considering action following possibly faulty manufacture and product deterioration, which may lead to serious safety issues.

CHAPTER 12: PRODUCT RECALLS

Principle:

There should be a system of recall from the market of products known or suspected to be defective.

General:

12.1 Written procedures for recall should be established and regularly reviewed. Recall operations should be capable of being initiated promptly.

12.2 The primary distribution records should be readily available and they should contain sufficient information of distributors.

12.3 The progress of the recall process should be recorded and a final report issued, including a reconciliation between the delivered and recovered quantities of the products.

12.4 A written instruction should be established to ensure recalled products are stored securely in a segregated area while awaiting decision.

CHAPTER 13: SUPPLEMENTARY INFORMATION

13.1 CLASSIFICATION OF GMP INSPECTION NON-CONFORMANCE OBSERVATIONS

The intention of this chapter is to classify the non-conformances observed during GMP inspection which eventually will establish the GMP status of the cosmetic manufacturing facility. Non-conformance observations can be classified as "critical", "major" and "minor". Details on the classification of non-conformances are as follows:

13.1.1 Critical non-conformances

Such non conformances would directly result in products/ingredients not complying with the specifications. These would seriously violates the safety, identity, and quality of the product, resulting in a product recall, regulatory action or harm to consumer. Examples of such non conformances are mislabelling, microbial contamination, fraud, misrepresentation or adulteration of products or falsification of data etc.

When critical non-conformances are observed in a manufacturing facility, the Authority may withdraw the manufacturing license and/or marketing authorization of a particular cosmetic product.

13.1.2 Major non-conformances

These are non-conformances that may have an impact on the cosmetic product but not as significant as a critical observation. Such non conformances show a substantial failure that could result in non compliant products/ingredients or another non compliance with the standard. e.g. reduced quality control testing of raw materials and finished product; undocumented preparation of laboratory reagents; lack of cleaning procedures; no or inappropriate equipment status labeling; no or inappropriate status labeling and identification of material in process; line clearance not properly done e.t.c.

When a major non-conformance is observed, the manufacturer will be required to take corrective actions within a given time frame. A follow up inspection or desk work evaluation of compliance report should be done to check the implementation. In case TFDA is not satisfied by the actions taken by the manufacturer may temporarily withdraw the manufacturing license and/or marketing authorization of the product and direct a manufacturer to take an immediate corrective action.

13.1.3 Minor non-conformances

These are non-conformance that are not likely to affect the safety and quality of the product,

but do not meet the GMP expectations. eg. record keeping errors; overdue SOP reviews; equipment is not calibrated by due date; use of white-out correction liquid on documents, overwriting without signatures, some signatures missing in the batch record etc.

The manufacturer will be directed to take immediate corrective actions.

BIBLIOGRAPHY

1. ISO 22716: 2007 for cosmetics Good Manufacturing Practice (GMP), 2007
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4. Cosmetics Good Manufacturing Practices, COLIPA – The European Cosmetic Toiletry and Perfumery Association, 1994
5. European Union Scientific Committee on Consumer Products (SCCP)- Guidance for Testing of cosmetic ingredients and their safety evaluation, 2006
6. TFDA Guidelines for Good Manufacturing Practices for Pharmaceuticals, 2008
7. Compendium of Good Manufacturing Practices (GMP) - Technical Documents for Harmonization of Medicines Regulation in the East African Community, 2014
8. Guidelines for Submission of Documentation for Marketing Authorization of Cosmetic Products, 2015

Annexes

Annex I: GMP certificate

TANZANIA FOOD AND DRUGS AUTHORITY

CERTIFICATE OF GOOD MANUFACTURING PRACTICES (GMP)

Made under Section 20(2a) of Tanzania Food, Drugs and Cosmetics Act, Cap 219

GMP Certificate No. _____

On the basis of the inspection carried out on _____ we certify that _____ located at _____, _____ has been found to comply with Good Manufacturing Practice requirements for the manufacturing of the following cosmetics.

S.N	Categories of Cosmetics	Manufacturing Operations
1.		
2.		
3.		

The responsibility for the quality of the individual batches of the cosmetics manufactured lies with the manufacturer and/or marketing authorisation holder.

This certificate shall remain valid until _____. It becomes invalid if the operations and/or categories certified herewith are changed or if the site is no longer considered to be in compliance with current GMP.

_____ _____

Date **HIITI B. SILLO**
DIRECTOR GENERAL

Note:
1. This certificate certifies the status of the site described above.
2. This certificate shall remain valid for a period of 3 years from the date of issue