National Agency for Food & Drug Administration & Control (NAFDAC)

Drug Evaluation & Research (DER) Directorate

NAFDAC GOOD MANUFACTURING PRACTICE GUIDELINES FOR COSMETICS PRODUCTS 2021

1. SCOPE

1.1 The objective of the Cosmetic Good Manufacturing Practice (GMP) guidelines is to ensure that products are consistently manufactured in conformance with quality standard. It is concerned with all aspects of production and quality control.

1.2 These guidelines are for the manufacture, storage and shipment of cosmetic products.

1.3 It is necessary to emphasize that, no cosmetics product should be manufactured, exported, advertised, sold or distributed in Nigeria unless it has been registered in accordance with the provisions of the Food, Drugs and Related Products Act Cap F33 LFN 2004 (formerly decree 19 of 1993) and the accompanying guidelines.

1.4 These guidelines cover the quality aspects of the product, but do not cover safety aspects for the personnel engaged in the plant, nor protection of the environment. Safety and environmental aspects are inherent responsibilities of the company and should be governed by local legislation and regulations.

1.5 These guidelines are not applicable to research and development activities and distribution of finished cosmetics.

2. GENERAL CONSIDERATION

2.1 In the manufacture of cosmetic products, monitoring is essential in ensuring that products of quality standards are produced.

3. PERSONNEL

3.1 There should be adequate number of personnel with adequate knowledge, experience, skill and capabilities relevant to their assigned function. They should be in good health and capable of handling the duties assigned to them.

4. ORGANIZATION, QUALIFICATION AND RESPONSIBILITIES

4.1 The organizational structure of the company shall be such that different persons head the production and quality control sections, neither of which shall be responsible to the other.

4.2 The head of production should be adequately trained and experienced in cosmetics manufacturing.

4.3 He should have authority and responsibilities to manage production; covering operations, equipment, production personnel, production areas and records.

4.4 The head of quality control should be adequately trained and experienced in the area of quality control. He should have full authority and responsibility in all quality control duties such as establishment, verification and implementation of all quality control procedures. He should have the authority to designate/assign when appropriate, personnel, to approve starting materials, intermediates, bulk and finished products that meet specification or to reject those which do not conform or those not manufactured in accordance with approved procedures.

4.5 The responsibilities and authorities of key personnel should be clearly defined.

5. TRAINING

5.1 All personnel directly involved in manufacturing activities should be appropriately and continuously trained in manufacturing operations in accordance with GMP principles. Special attention should be given to training of personnel working with hazardous materials.

5.2 Records of training should be maintained, and its effectiveness assessed periodically.

6. PREMISES

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

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

6.3 Household products containing non-hazardous materials/ingredients and cosmetic products can share the same premises and equipment provided that due care should is exercised to prevent cross contamination and risk of mix-up. Household products containing hazardous materials/ingredients should not be manufactured using the same equipment as other products.

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

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

6.6 Defined areas should be provided for, wherever possible and applicable:

6.6.1 Materials receiving bay.

6.6.2 Material Sampling.

6.6.3 Incoming goods and quarantine.

6.6.4 Starting materials storage.

6.6.5 Weighing and dispensing.

6.6.6 Processing.

6.6.7 Storage of bulk products.

6.6.8 Packaging.

6.6.9 Quarantine storage before final release of products.

6.6.10 Storage of finished products.

6.6.11 Loading and unloading.

6.6.12 Laboratories.

6.6.13 Equipment washing.

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

6.8 Drains should be of adequate size and have trapped gullies and proper flow. Open channels should be avoided where possible, but if required they should be able to facilitate cleaning and disinfection.

6.9 Buildings should be adequately lit and properly ventilated.

6.10 Pipework, light fittings, ventilation points and other service points in manufacturing areas should be installed in such a way to make for easy cleaning.

6.11 Laboratories should be separated from the production areas.

7. STORAGE AREAS

7.1 Storage areas should be of sufficient capacity to allow orderly placement of materials such as starting and packaging materials, intermediates, bulk and finished products, products in quarantine, released, rejected, returned, or recalled products.

7.2 Secured segregated area should be available for storage of flammable, explosive substances and highly toxic substances.

7.3 Storage areas should be provided with suitable lighting.

7.4 Storage areas should have good storage conditions. Where special storage conditions are required (temperature, humidity and security) these should be provided, checked and monitored.

7.5 Receiving and dispatch bays should protect materials and products from weather. Reception areas should be designed and equipped to allow cleaning of incoming materials if necessary before storage.

7.6 Wherever possible sampling area for starting materials should be provided to prevent contamination.

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

8. EQUIPMENT

8.1 Construction and Design

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

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

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

8.1.4 Equipment should be easily cleaned.

8.1.5 Equipment used for flammable substances should be explosion proof.

8.2 Installation and Location

8.2.1 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.

8.2.2 Support systems such as heating, ventilation, air conditioning, water (such as potable), steam, compressed air and gases should function as designed and identifiable.

8.3 Maintenance of Equipment

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

9. SANITATION AND HYGIENE

9.1 Sanitation and hygiene should be practiced to avoid contamination of products. It should cover personnel, premises, equipment, production materials and containers.

9.2 Personnel

9.2.1 Personnel engaged in the manufacture, processing, packing, or holding of Cosmetic products should wear clean clothing appropriate for *assigned duties*. Protective apparel, such as head, face, hand, feet and arm coverings, *should* be worn to ensure personnel safety and protect*ion of* cosmetic products from contamination.

9.2.2 Personnel should be healthy to perform their assigned duties. Regular medical examination should be conducted for all production personnel.

9.2.3 Personnel must practice good personal hygiene and sanitation.

9.2.4 Factory wears should not be worn out of the area they are meant for.

9.2.5 Any personnel shown at any time to be ill or have an 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.

9.2.6 Smoking, eating, drinking and chewing *of* food, drinks, cigarettes and/*or* other materials that might contaminate are not permitted in production, laboratory, storage or other areas where they might adversely affect product quality.

9.3 Premises

9.3.1 Adequate employee's washing and well-ventilated toilet facilities should be provided and separated from the production area.

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

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

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

9.4 Equipment and Apparatus

9.4.1 Equipment and utensils should be kept clean.

9.4.2 Vacuum or wet cleaning methods are preferred. Compressed air and brushes should be used with care and avoided if possible, as they increase the risk of product contamination.

9.4.3 Standard operating procedures must be followed for cleaning and sanitizing of major machines.

10. PRODUCTION

10.1 Water

10.1.1 Special attention should be paid to water since it is an important raw material. Water production equipment and water systems should supply quality water. Water systems should be sanitized according to well-established procedures.

10.1.2 The chemical and microbiological quality of water used in production should be monitored regularly, according to written procedures and any anomaly should be documented and followed up by appropriate corrective action.

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

10.2 Verification of materials

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

10.2.2 Samples of raw materials should be physically checked for conformity to specifications prior to release for use. The raw materials should be clearly labeled. All goods must be clean and checked for appropriate protective packing to ensure no leakage, perforation or exposure.

10.3 Rejected materials

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

10.4 Batch Numbering System

10.4.1 Every finished product should bear a production identification number, which enables the history of the product to be traced.

10.4.2 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.

10.4.3 Whenever possible, the batch number should be printed on the immediate and outer container of the product.

10.4.4 Records of batch number should be maintained.

10.5 Weighing and Measurement

10.5.1 Weighing should be carried out in the defined areas using calibrated equipment.

10.5.2 All weighing and measurement carried out should be recorded and where applicable, counterchecked.

10.6 Procedure and Processing

10.6.1 All starting materials used should be approved according to specifications.

10.6.2 All manufacturing procedures should be carried out according to written procedures.

10.6.3 All required in-process controls should be carried out and recorded.

10.6.4 Bulk products should be properly labelled until approved by Quality Control, where applicable.

10.6.5 Particular attention should be paid to problem of cross-contamination in all stages of processing.

10.7 Dry Products

10.7.1 Handling of dry materials and products should be given special attention. Where possible, dust-containing production system, central vacuum system or other suitable methods should be employed.

10.8 Wet Products

10.8.1 Liquids, creams and lotions should be produced in such a way as to protect the product from microbial and other contamination.

10.8.2 The use of closed systems of production and transfer is recommended.

10.8.3 Where pipelines are used for delivery of ingredients or bulk products, care should be taken to ensure that the systems are easy to clean.

10.9 Labeling and Packaging

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

10.9.2 Samples should be taken and checked at random during labeling and packaging operations.

10.9.3 Each labeling and packaging line should be clearly identified to avoid mix-up.

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

10.10 Finished Product: Quarantine and Delivery to Finished Stock

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

11. QUALITY CONTROL

11.1 Introduction

11.1.1 Quality control is an essential part of GMP. It provides assurance that cosmetic products will be of consistent quality appropriate to intended use.

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

11.1.3 Quality control involves sampling, inspecting and testing of starting materials, in process, intermediate, bulk, and finished products. It also includes (,) where

applicable, environmental monitoring programs, review of batch documentation, sample retention program, stability studies and maintaining correct specifications of materials and products.

11.1.4 Adequate laboratory facilities for the testing and approval or rejection of materials and Cosmetic products should be available to the quality control unit in-house where possible. Where these services are out sourced, the quality control unit should have facilities to conduct analyses of minimal parameters critical to the quality of the product.

11.2 Returned Products

11.2.1 Returned products should be identified and stored separately in allocated areas.
11.2.2 All returned products should be tested if necessary, in addition to physical evaluation before being released for distribution.
11.2.3 Returned products, which do not comply with the original specifications, should be rejected.
11.2.4 Rejected products should be disposed according to appropriate procedures.
11.2.5 Records of returned products must be maintained.

12. DOCUMENTATION

12.1 Introduction

12.1.1 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.
12.1.2 There should be a system for preventing the use of any superseded document.
12.1.3 If an error is made or detected on a document, it should be corrected in such a manner that the original entry is not lost and correction is made close to the original entry, initialed and dated.
12.1.4 Where documents bear instructions, they should be clearly written step by step.
12.1.5 Documents should be dated and authorized.
12.1.6 Documents should be readily available to relevant parties.

12.2 SPECIFICATIONS

12.2.1 All specifications should be approved by authorized personnel.
12.2.2 Raw and packaging material specifications should include:
12.2.3 Name of material
12.2.4 Description of the material
12.2.5 Testing parameters and acceptance limits
12.2.6 Technical drawings, (where applicable).
12.2.7 Special precautions e.g. storage and safety conditions, if necessary.
12.2.8 Bulk and finished product specifications should include:
12.2.9 Name of product
12.2.10 Description

12.2.11 Physical properties
12.2.12 Chemical assay and/or microbiological assays and their acceptance limits
12.2.13 Storage conditions and safety precautions, if necessary

12.3 DOCUMENTS FOR PRODUCTION

12.3.1 Master Formula

12.3.1.1 The Master formula should be available upon request. This document should contain the following information:
12.3.1.2 Product name
12.3.1.3 Intended packaging materials, and storage conditions
12.3.1.4 List of raw materials used
12.3.1.5 List of equipment used.
12.3.1.6 Description of the manufacturing process
12.3.1.7 In-process controls with their limits in processing and packaging, where applicable.

12.3.2 Batch Manufacturing Record (BMR)

12.3.2.1 Batch Manufacturing Records should be prepared for each batch of product.
12.3.2.1.1 Each BMR should include the following:
12.3.2.1.2 Name of product
12.3.2.1.3 Batch number
12.3.2.1.4 Batch formula and records of weighing of materials
12.3.2.1.5 Evidence of line clearance before commencement of batch processing
12.3.2.1.6 Manufacturing process and records of completion of each step
12.3.2.1.7 Date of the start and finish of processing and packaging
12.3.2.1.8 Identity of individual major equipment and lines or location used
12.3.2.1.9 Records of cleaning of equipment used for processing as appropriate
12.3.2.1.9.1.1 In-process control and laboratory results, such as pH and temperature test records
12.3.2.1.10 Packaging line clearance inspection record
12.3.2.1.11 Any sampling performed during various steps of processing
12.3.2.1.12 Any investigation of specific failure or discrepancies
12.3.2.1.13 Results of examination and testing of packed and labelled products.

12.3.3 Records for Quality Control

12.3.3.1.1 Records for each testing, assay result and release or rejection of starting materials, intermediates, bulk and finished product should be maintained, and records may include:
12.3.3.1.2 Date of test
12.3.3.1.3 Identification of the material
12.3.3.1.4 Supplier name
12.3.3.1.5 Date of receipt
12.3.3.1.6 Original batch number if any

12.3.3.1.7 Batch number
12.3.3.1.8 Quality control number
12.3.3.1.9 Quantity received
12.3.3.1.10 Date of sampling
12.3.3.1.11 Quality control results.

13. INTERNAL AUDIT

An internal audit consists of an examination and assessment of all or part of a quality system with the specific purpose of improving it. Outside or independent specialists may conduct an internal audit, or a team designated by the management for this purpose. Such internal audits may also be extended to suppliers and contractors, if necessary. A report should be made at the completion of each internal audit.

13.1 There should be an SOP for conducting Internal Audit and there should be an Internal Audit Team.

13.2 All observations made during the internal audit should be evaluated and shared with appropriate management.

13.3 Internal audit follow-up should confirm the satisfactory completion or implementation of corrective action.

14. MATERIALS MANAGEMENT

14.1 Standard operating procedures on the sourcing, receipt, identification, storage, handling, sampling, testing, and approval or rejection of materials should be established and followed.

14.2 Materials should be handled and stored at all times in a manner to prevent degradation and contamination.

14.3 All materials and products should be stored under the appropriate conditions established by the material manufacturer and in an orderly fashion to permit batch segregation and batch rotation following the first expire, first out (FEFO) principle.

14.4 Upon receipt, each incoming delivery should be checked against the relevant documentation and physically verified by label description, type and quantity.

14.5 The consignment should be carefully inspected for defects and damage. Records should be retained for each delivery.

14.6 Records should be maintained showing all receipts and issues of products.

14.7 All labels and containers of products should not be altered, tampered or changed.

14.8 There should be a supplier certification process, which will define minimum acceptable conditions for approval of suppliers. Agents and suppliers in the supply chain should be identifiable and their activities should be adequately controlled not to jeopardize the identity, performance or quality of the material.

15. CONTRACT MANUFACTURING AND ANALYSIS

15.1 The conditions of contract manufacturing and analysis should be clearly defined,

agreed, and controlled so as to avoid misunderstandings, which could result in a product or work of unsatisfactory quality.

15.2 All aspects of contracted work should be specified to obtain a quality product conforming to the agreed standards.

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

16. COMPLAINTS

16.1 A person should be designated.to handle complaints and decide on measures to be taken.

16.2 There should be written procedures describing the action to be taken, including the need to consider a recall, in the case of a complaint involving a possible product defect.

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

16.4 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.

16.5 Where necessary, appropriate follow-up action, possibly including product recall, should be taken after investigation and evaluation of the complaint.

16.6 All the decisions and measures taken as a result of a complaint should be recorded and referenced to the corresponding batch records.

16.7 Complaint records should be regularly reviewed for an indication of specific or recurring problems that require attention and (*which*) might justify the recall of marketed products.

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

17. PRODUCT RECALLS

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

17.2 A person responsible for the execution and co-ordination of recalls should be designated.

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

17.4 The primary distribution records should be readily available to the person(s) responsible for recalls, and they should contain sufficient information of distributors.

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

17.6 The effectiveness of the arrangements for recalls should be evaluated from time to time.

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

18. DEVIATIONS

18.1 Deviations from the specified requirements should be authorized with sufficient data to support the decision.

18.2 Corrective action should be taken to prevent recurrence of the deviation.

19. CHANGE CONTROL

19.1 Changes that could affect the quality of product should be approved and performed by authorized personnel on the basis of sufficient data.

20. TERMS AND DEFINITIONS

For the purposes of this document, the following terms and definitions apply.

20.1 **Audit**; Systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable for achieving objectives.

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

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

20.4 **Bulk Product**; any processed product, which will have to undergo the packaging operation in order to become a finished product.

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

20.6 **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.

20.7 **Complaint**; external information claiming a product does not meet defined acceptance criteria.

20.8 **Contamination**; occurrence of any undesirable matter such as chemical, physical and/or microbiological matter in the product.

20.9 **Contract acceptor**; person, company or external organization carrying out an operation on behalf of another person, company or organization.

20.10 **Control**; verification that acceptance criteria are met.

20.11 **Documentation**; all written procedures, instructions and records involved in the manufacture and quality control of products.

20.12 **Finished Product**; a product, which has undergone all stages of manufacturing operations.

20.13 **Guideline**; a guideline is a statement by which to determine a course of action. A guideline aims to streamline particular processes according to a set routine or sound practice.

20.14 **In-Process Control**; checks and tests instituted and carried out in the course of the manufacture of a product including checks and tests done on environment and equipment in order to ensure that the end product will comply with its specification.

20.15 **Internal audit**; systematic and independent examination made by competent personnel inside the company, aimed 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.

20.16 **Maintenance**; any periodic or unplanned support and verification operations designed to keep premises and equipment in proper working condition.

20.17 **Major equipment**; equipment specified in production and laboratory documents which is considered essential to the process.

20.18 **Manufacture or Manufacturing**; the complete set of activities to produce a 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.

20.19 **Packaging**; the part of production cycle applied to a bulk product to obtain the finished product.

20.20 **Packaging Material**; any material used in the packaging of a bulk product to obtain the finished product.

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

20.22 **Plant**; location for production of cosmetic products.

20.23 **Premises**; physical location, buildings and supporting structures used to conduct receipt, storage, manufacturing, packaging, control and shipment of product, raw materials and packaging materials.

20.24 **Processing**; the part of production cycle starting from weighing of raw materials to obtaining a bulk product.

20.25 **Production**; all operations starting from processing to packaging to obtain a finished product.

20.26 **Quality Control**; all measures taken during manufacturing which are designed to

ensure the uniform output of product that will conform to established specifications.

20.27 **Quarantine**; 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.

20.28 **Raw Materials**; any ingredient to be used in the formulation of a cosmetic product.

20.29 Recall; decision made by a company to call back a product batch that has been put on the market.

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

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

20.32 **Returned Product**; finished products sent back to the manufacturer.

20.33 **Sample**; one or more representative elements selected from a set to obtain information about that set.

20.34 **Sampling**; set of operations relating to the taking and preparation of samples.

20.35 **Sanitation**; hygienic control on manufacturing premises, personnel, equipment and material handling.

20.36 **Shipment**; set of operations relative to the preparation of an order and its transportation in a vehicle.

20.37 **Specification**; a description of a starting material or finished product in terms of its chemical, physical and biological characteristics, if applicable. A specification normally includes descriptive and numerical clauses stating standards and tolerated deviations.

20.38 **Starting Materials**; raw materials and packaging materials used in the production of products.

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

21. REFERENCES

21.1 Australian Code of Good Manufacturing Practice for Therapeutic Goods – Sunscreen Products, Therapeutic Goods Administration (TGA), Australia, February 1994.

21.2 Cosmetic Good Manufacturing Practices, COLIPA – The European Cosmetic Toiletry and Perfumery Association, July 1994.

21.3 Guidelines on Good Manufacturing Practice (GMP) for Traditional Medicines,

National Pharmaceutical Control Bureau, Malaysia, 1st Edition, 1999.

21.4 Good Manufacturing Practices for Pharmaceutical Products, World Health Organization (WHO) Technical Report Series No: 986; 2014.

21.5 Good Storage Practice, 1st Edition, January 1995, ISBN 983-9870-14-9, National Pharmaceutical Control Bureau, Malaysia.

21.6 ISO 22716:2007 Cosmetics good Manufacturing Practices (GMP) Guidelines.

21.7 NAFDAC Good Manufacturing Practice for Pharmaceutical Products Guidelines 2016.