NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION & CONTROL (NAFDAC)

NAFDAC GOOD MANUFACTURING PRACTICE GUIDELINES FOR CHEMICALS AND CHEMICAL PRODUCTS 2023

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1.0 SCOPE

1.1 The objective of the Chemical 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, distribution and shipment of chemicals and chemical products in Nigeria.

1.3 It is necessary to emphasize that, no chemical products shall 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.

2.0 GENERAL CONSIDERATIONS

21. In the manufacture of chemicals and chemical products, monitoring is essential in ensuring that products of quality standards are produced.

3.0 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.

4.0 ORGANIZATION, QUALIFICATION AND RESPONSIBILITIES

3.2 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. The key officers should have a minimum qualification of BSc or equivalent in Chemistry/Chemical Engineering or any related science disciplines

4.1 The head of production should be adequately trained, experienced and qualify in chemical manufacturing. He/she should have authority and responsibilities to manage production; covering operations, equipment, production personnel, production areas and records.

4.2 The head of quality control should be adequately trained and experienced in the area ofquality 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 also 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 not manufactured in accordance with approved procedures.

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

5.0 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.

6.0 PREMISES

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

6.2 Effective technical and administrative measures should be taken to avoid any cross contamination to the environmentand the production facility.

6.3 Appropriate changing rooms and toilet facilities should be provided.

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

6.4.1 Materials receiving bay

6.4.2 Material Sampling.

6.4.3 Incoming goods and quarantine.

6.4.4 Starting materials storage.

6.4.5 Weighing and dispensing.

6.4.6 Processing.

6.4.7 Storage of bulk products.

6.4.8 Packaging.

6.4.9 Quarantine storage before final release of products.

6.4.10 Storage of finished products.

6.4.11 Loading and unloading.

6.4.12 Laboratories.

6.4.13 Equipment washing.

6.5 Walls and floors, where applicable should be smooth and easy to maintain. The floor in processing areas should be industrial concrete floor with surface that is easy to clean.

6.6 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.

6.7 Buildings should be adequately lit and properly ventilated.

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

6.9 Laboratories should be separated from the production areas. The premises for manufacturing should be suitably located, designed, constructed and maintained

7.0 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 chemicals of safety and security concerns.

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

8.0 EQUIPMENT

8.1 Constructions 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 (HVAC), steam, compressedair 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 andcalibrated regularly. All records should be maintained.

9.0 SANITATION AND SAFETY

9.1 Sanitation and safety should be practiced to cover personnel, premises, equipment, production materials and containers.

9.2 Personnel

9.2.1 Personnel engaged in the manufacture, processing, packaging, or holding of chemical andchemical products should wear appropriate personnel protective equipment for assigned duties.

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

9.3 Premises

9.3.1 Adequate employee's washing and 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 employee's clothing and personal belongings.

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

9.3.4 Restricted areas to unauthorized personnel should be clearly defined with signage displayed appropriately.

10.0 PRODUCTION

10.1 Verification of Materials

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

10.1.2 Samples of raw materials should be physically checked for conformity to specifications priorto release for use. The raw materials should be clearly labeled. All goods must be clean and checked for appropriate protective packing to ensure no leakages, perforationsor exposures.

10.2 Rejected materials

10.2.1 Deliveries of raw materials that do not comply with specifications should be segregated anddisposed according to Standard Operating Procedures.

10.3 Batch Numbering System

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

10.3.2 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.

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

10.3.4 Records of batch number should be maintained.

10.4 Weighing and Measurement

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

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

10.5 Procedure and Processing

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

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

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

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

10.6 Dry Chemical Products

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

10.7 Wet Chemical Products

10.7.1 Liquid chemical products should be produced in such a way as to protect the product from spillage and other hazard contamination.

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

10.8 Labeling and Packaging

10.8.1 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

10.8.2 Samples should be taken and checked at random during labeling and packaging

operations.

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

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

10.9 Finished Product: Quarantine and Delivery to Finished Stock

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

11.0 QUALITY CONTROL

11.1 Introduction

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

11.1.2 A quality control system should be established to ensure that chemical products contain thecorrect 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 programs,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 chemical products should be available to the quality control unit in-house where possible. Where these services are outsourced, 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 written procedures, safety and environmental standards.

11.2.5 Records of returned products must be maintained.

12.0 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 Specification

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:

12.2.8.1 Name of product

12.2.8.2 Description

12.2.8.3 Physical properties

12.2.8.4 Storage conditions and safety precautions, if necessary

12.3 Batch Manufacturing Record (BMR)

12.3.1 Batch Manufacturing Records should be prepared for each batch of product.

12.3.2 Each BMR should include the following:

12.3.2.1 Name of product

12.3.2.2 Batch number

12.3.2.3 Batch formula and records of weighing of materials

12.3.2.4 Evidence of line clearance before commencement of batch processing

12.3.2.5 Manufacturing process and records of completion of each step

12.3.2.6 Date of the start and finish of processing and packaging

12.3.2.7 Identity of individual major equipment and lines or location used

12.3.2.8 Records of cleaning of equipment used for processing as appropriate

12.3.2.9 In-process control and laboratory results, such as pH and temperature test records

12.3.2.10 Packaging line clearance inspection record

12.3.2.11 Any sampling performed during various steps of processing

12.3.2.12 Any investigation of specific failure or discrepancies

12.3.2.13 Results of examination and testing of packaged and labelled products

12.4 Records For Quality Control

12.4.1. 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:

12.4.1.1 Date of test

12.4.1.2 Identification of the material

12.4.1.3 Supplier name

12.4.1.4 Date of receipt

12.4.1.5 Original batch number if any

12.4.1.6 Batch number

12.4.1.7 Quality control number

12.4.1.8 Quantity received

12.4.1.9 Date of sampling

12.4.1.10 Quality control results.

13.0 INTERNAL AUDIT

13.1 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.

13.2 There should be an SOP for conducting Internal Audit and there should be an Internal Audit team.

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

13.4 Internal audit follow-up should confirm the satisfactory completion or implementation ofcorrective action.

14.0 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.

15.0 COMPLAINTS

15.1 A person should be designated.to handle complaints and decide on measures to betaken.

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

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

15.4 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 afected.

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

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

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

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

16.0 PRODUCTS RECALL

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

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

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

16.4 The primary distribution records should be readily available to the person(s)

responsiblefor recalls, and they should contain sufficient information of distributors.

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

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

16.7 A written instruction should be established to ensure recalled products are stored securelyin a segregated area while awaiting decision.

17.0 Contract Manufacturers (including Laboratories)

17.10 All contract manufacturers (including laboratories) should comply with the GMP defined in this Guide. Special consideration should be given to the prevention of cross contamination and to maintaining traceability.

17.11 Contract manufacturers (including laboratories) should be evaluated by the contract giver to ensure GMP compliance of the specific operations occurring at the contract sites.

17.12 There should be a written and approved contract or formal agreement between the contract giver and the contract acceptor that defines in detail the GMP responsibilities, including the quality measures, of each party.

17.13 The contract should permit the contract giver to audit the contract acceptor's facilities for compliance with GMP.

17.14 Where subcontracting is allowed, the contract acceptor should not pass to a third party any of the work entrusted to him under the contract without thecontract giver's prior evaluation and approval of the arrangements.

17.15 Manufacturing and laboratory records should be kept at the site where the activity occurs and be readily available.

17.16 Changes in the process, equipment, test methods, specifications, or other contractual requirements should not be made unless the contract giver is informed and approves the changes

18 Brokers, Traders, Distributors, Repackers, and Relabellers

18.1 Applicability

18.10 This section applies to any party other than the original manufacturer who may trade and/or take possession, repack, relabel, manipulate, distribute or store chemicals or intermediate.

18.11 All agents, brokers, traders, distributors, repackers, and relabellers should comply with GMP as defined in this Guide

19.0 TERMS AND DEFINATIONS

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

19.0 Batch; a quantity of any chemical product produced in a given cycle of manufacture that is uniform in character and quality.

19.10 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.

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

19.12 Calibration; combination of checking an instrument and adjusting it to bring it within itslimits for accuracy according to recognized standards.

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

19.14 Control; verification that acceptance criteria are met.

19.15 Chemicals; are substances with a definite chemical composition or mixtures or preparations represented for industrial or domestic use such as specialty chemicals, rawmaterials, finished/semi-finished products, laboratory reagents, industrial chemicals, diagnostic reagents, inks and polymers.

19.16 Chemical products; are substances that are formed as a result of a chemical reaction to yield one or more products, such as cleaning chemicals, adhesives, wood preservatives & polishers, photographic chemicals, agrochemicals, biocides, fertilizers,car care chemicals but excludes medicines, radioactive and any other substance that hastherapeutic effects.

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

19.18 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.

19.19 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 whetherthese arrangements are implemented effectively and are suitable for achieving objectives.

19.20 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 distributionof the finished product.

19.21 Packaging; the part of production cycle applied to a bulk product to obtain thefinished product.

19.22 Packaging Material; any material used in the packaging of a bulk product toobtain the finished product.

19.23 Plant; location for production of chemical products.

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

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

19.26 Production; all operations starting from processing to packaging to obtain afinished product.

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

19.28 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.

19.29 Raw Materials; any ingredient to be used in the formulation of a chemical product.

19.30 Recall; decision made by a company to call back a product batch that has been put

on the market.

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

19.32 Specification; a description of a starting material or finished product in terms of its chemical, physical and biological characteristics, if applicable.

19.33 Starting Materials; raw materials and packaging materials used in theproduction o f products.

18.0 REFERENCES

18.1 United Nation Globally Harmonized System of Classification and Labelling of Chemicals (GHS) Eighth revised edition GHS (Rev.8) (2019)

18.2 NAFDAC Good Manufacturing Practice Guidelines for Cosmetic Products Guidelines 2018

18.3 ICH Topic Q 7 Good Manufacturing Practice for Active Pharmaceutical Ingredients November 2000 CPMP/ICH/4106/00 www ich-q-7-good-manufacturing-practice-active-pharmaceutical-ingredients-step-5_en.pdf