



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

**GUIDELINES FOR PRODUCTION INSPECTION OF  
CHEMICAL MANUFACTURING FACILITIES  
IN NIGERIA 2023**

**Chemical Evaluation & Research (CER) Directorate**  
cer@nafdac.gov.ng

## 1. GENERAL

- 1.1 These requirements are for the interest of Individuals intending to engage in the manufacture of chemicals in Nigeria.
- 1.2 This prescribes the minimum Good Manufacturing practice (GMP) requirements for the facilities and controls to be used in the manufacture of chemicals to ensure quality and safety.
- 1.3 It also prescribes the requirement for conducting a Production Inspection of the chemical manufacturing facility
- 1.4 It is necessary to emphasize that, no chemical product should be Manufactured, Imported, 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 F33LFN 2004 (formerly decree 19 of 1993) and the accompanying guidelines.
- 1.5 A chemical product should not be manufactured in Nigeria unless the facility has been inspected.
- 1.6 All required documents as stated below must be available for review while photocopies of documents listed in 2.1 to 2.3 will be required for submission.

## 2. APPLICATION FOR INSPECTION

- 2.1. An application for Production Inspection shall be made on the company's letterhead and addressed to:  
  
The Director-General,  
  
National Agency for Food and Drug Administration and Control (NAFDAC),  
  
ATTENTION: Director, Chemical Evaluation & Research Directorate, NAFDAC Office Complex, Apapa-Oshodi Express way Isolo, Lagos. The exact location address (NOT P.O. Box) of the factory, functional e-mail address, telephone number(s) and product(s)intended for registration (including the pack sizes) should be stated.
- 2.2. The application letter shall be submitted to The Director, Chemical Evaluation & Research Directorate; 1<sup>st</sup> Floor, NAFDAC Office Complex, Isolo, Lagos or the nearest NAFDAC office (for applicants outside Lagos) with the following supporting documents:
  - 2.2.1. Evidence of company's incorporation with Corporate Affairs Commission
  - 2.2.2. Evidence of acceptance of product trademark by Trademark Registry.
  - 2.2.3. Product labels (or Artwork) with hazards pictogram in line with United Nations Globally

Harmonized System of Classification and Labelling of Chemicals (UN- GHS).

- 2.2.4. Certificate of analysis of the product(s) duly endorsed by a public analyst.
- 2.2.5. Safety Data Sheet (SDS) of the manufactured substance which should have sixteen (16) sub- headings in line with UN- GHS.
- 2.2.6. The Production and Quality Control Managers should have a minimum qualification of HND/BSc or its equivalent in Chemistry/Chemical Engineering or any related science disciplines
- 2.2.7. Credentials, medical certificate of fitness, two (2) passport photographs each and letter of appointment/acceptance of the Production and Quality Control Managers.
- 2.3. The applicant shall follow the below-listed steps to make payment for the inspection:
  - 2.3.1. Collect a payment advice for the inspection from the Chemical Evaluation & Research (CER) Directorate; 1<sup>st</sup> Floor, NAFDAC Office Complex, Isolo Industrial Estate, Apapa-Oshodi Express Way Isolo, Lagos or the nearest NAFDAC office (for applicants outside Lagos).
  - 2.3.2. Visit [www.remita.net](http://www.remita.net) to generate a Remita invoice and print out a copy of the invoice.
  - 2.3.3. Visit the nearest Commercial bank to make the payment.
  - 2.3.4. The applicant shall collect an official receipt of payment from the Finance & Accounts Section; 3<sup>rd</sup> Floor, NAFDAC Office Complex, Isolo, Lagos or the nearest NAFDAC office (for applicants outside Lagos).

### **3. SCHEDULING OF FACILITY FOR INSPECTION**

- 3.1 Upon satisfactory review of the submitted documents, the facility is scheduled for inspection at the earliest convenient date.

### **4. GOOD MANUFACTURING PRACTICE REQUIREMENTS**

- 4.1 Please refer to the NAFDAC Good Manufacturing Practice Guidelines for Chemical and Chemical Products for full guidance. The guidelines are available at [www.nafdac.gov.ng](http://www.nafdac.gov.ng)

### **5. DOCUMENTATION**

The following documents should be made available during the inspection

- 5.1 Product labels in English language and with the following information:

- 5.1.1 Name of product
- 5.1.2 GHS symbols (hazard pictograms)
- 5.1.3 Signal Word
- 5.1.4 Precautionary statements/first aid
- 5.1.5 Hazard statements
- 5.1.6 Net weight/volume
- 5.1.7 Batch Number
- 5.1.8 Manufacturing Date
- 5.1.9 Expiry Date
- 5.1.10 Provision for NAFDAC REG. NO
- 5.1.11 Exact factory location address (Not P.O.Box)
- 5.2 Company's Organogram
- 5.3 Certificate of analysis of all raw materials and finished product(s)
- 5.4 Personnel File Records (Letter of appointment and acceptance of offer, Certificates, Job description, Training records)
- 5.5 Standard Operating Procedure (SOP) for Production
- 5.6 Batch Formulation of the Product
- 5.7 SOP for Quality Control Checks
- 5.8 SOP for Cleaning of Equipment and Factory Premises
- 5.9 SOP for Product Distribution and Recall
- 5.10 SOP Line clearance for facility producing multiple products
- 5.11 List of Production Equipment/Quality Control Equipment
- 5.12 Medical certificate of fitness for production staff
- 5.13 List of raw materials and their sources
- 6.0 DISTRIBUTION SYSTEM**

- 6.1 Records of product distribution network must be properly kept for easy recall of defective products.
- 6.2 Distributor's names, addresses, telephone numbers, email addresses, quantity of products issued, batch numbers, dates of manufacture and expiry should be maintained.

## 7.0 TRANSPORT AND HANDLING

- 7.1 Products should be handled and transported under conditions which prevent deterioration, contamination, and leakages to ensure that the product quality is maintained up to the time of delivery to the consumer.

## 8.0 TARIFF

- 8.1 Please refer to the appropriate section in the NAFDAC Approved Tariffs available at [www.nafdac.gov.ng](http://www.nafdac.gov.ng)
- 8.2 All fees attracts 7.5% VAT.

## 9.0 DEFINATIONS

- 9.1 Chemicals are substances with distinct molecular composition and properties that are used in a reaction involving changes to atom or molecule especially specialty chemicals, raw materials, finished/semi-finished materials, laboratory reagents, industrial chemicals, varnishes, inks, polymers etc.
- 9.2 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 has therapeutic effects.

## 1.0 CORRESPONDENCE

All correspondence shall be addressed to:

The Director-General (NAFDAC)

**Attn:** The Director,

Chemical Evaluation & Research (CER) Directorate

1<sup>st</sup> Floor, NAFDAC Office Complex, Plot 1 Isolo Industrial Estate,

Apapa-Oshodi Expressway, Lagos State.

NAFDAC website: [www.nafdac.gov.ng](http://www.nafdac.gov.ng)

E-mail address: [cerlagos@nafdac.gov.ng](mailto:cerlagos@nafdac.gov.ng)