**National Agency for Food & Drug Administration & Control (NAFDAC)**
**Drug Evaluation & Research (DER) Directorate**

# GUIDELINES FOR PRE-PRODUCTION INSPECTION OF PHARMACEUTICAL MANUFACTURING FACILITIES IN NIGERIA

## 1. GENERAL

1.1 These guidelines are for the interest of the general public and in particular the pharmaceutical manufacturing companies in Nigeria.

1.2 It is necessary to emphasize that, no regulated 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 F33 LFN 2004 (formerly decree 19 of 1993) and the accompanying guidelines.

1.3 A drug product should not be manufactured in Nigeria unless the facility has been inspected, found to comply with Good Manufacturing Practices and an Authority to Manufacture pharmaceutical products is issued by NAFDAC.

1.4 These guidelines prescribe the minimum requirements necessary for the issuance of Authority to Manufacture Pharmaceutical products.

## 2. APPLICATION FOR INSPECTION

2.1 An application for Pre-Production Inspection should be made on the company's letter-headed paper and addressed to:

The Director-General, National Agency for Food and Drug Administration and Control (NAFDAC),

ATTENTION: Director, Drug Evaluation & Research Directorate, NAFDAC Office Complex, Apapa-Oshodi Expressway. Isolo, Lagos. The exact location address (NOT P.O. Box) of the proposed factory, functional e-mail address, telephone number(s) and intended product formulation lines should be stated.

2.2 The application letter should be submitted to The Director, Drug Evaluation & Research Directorate; 1st Floor, NAFDAC Office Complex, Isolo, Lagos or the nearest NAFDAC office (for applicants outside Lagos) with the following supporting documents:

- 2.2.1 Site Master File of the proposed facility
- 2.2.2 Evidence of company incorporation
- 2.2.3 Evidence of License to Practice of the Superintendent and Production Pharmacists by the Pharmacists Council of Nigeria (PCN)
- 2.2.4 Company Quality Manual
- 2.2.5 Validation Master Plan for the facility

2.3 Upon submission of the application letter the below-listed steps should be followed to make payment for the inspection:

- 2.3.1 Collect a payment advice for the inspection from the Drug Evaluation & Research (DER) Directorate; 1st 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** 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 Collect an official receipt of payment from the Finance & Accounts Section; 3rd Floor, NAFDAC Office Complex, Isolo, Lagos or the nearest NAFDAC office (for applicants outside Lagos).

## 3. SCHEDULING OF FACILITY FOR INSPECTION

3.1 Upon submission of evidence of payment to DER Directorate, the facility is scheduled for inspection at the earliest convenient date.

## 4. DOCUMENTATION

The following documents should be made available during the inspection

4.1 Site Master File

4.2 Current Annual Licence to Practice of the Superintendent and Production Pharmacists issued by the PCN.

4.3 Letters of Appointment and Acceptance of key officers.

4.4 Credentials of the key officers. (minimum qualification should be first degree in the relevant disciplines)

4.5 Job Descriptions for the key personnel

4.6 Validation master Plan for the facility

4.7 Documentary evidence showing Qualification of Production and Laboratory Equipment

4.8 Documentary evidence showing Analytical Method Validation/Verification

4.9 Documentary evidence showing Water System Validation (where applicable)

4.10 List of Production and Quality Control equipment and their identification numbers

4.11 Any other relevant documents.

## 5. GOOD MANUFACTURING PRACTICE REQUIREMENTS

5.1 Please refer to the NAFDAC Good Manufacturing Practice for Pharmaceutical Products Guidelines 2016 for full guidance. The guidelines are available at www.nafdac.gov.ng

## 6. TARIFF

6.1 Please to refer to the appropriate section in the NAFDAC Approved Tariffs available at www.nafdac.gov.ng

6.2 All fees attract 5% VAT.

## 7. CORRESPONDENCE

All correspondence should be addressed to:
The Director-General (NAFDAC)
**Attn:** The Director,
Drug Evaluation & Research Directorate
1st Floor, NAFDAC Office Complex, Isolo Industrial Estate, Oshodi-Apapa Expressway Isolo, Lagos State.
NAFDAC website: www.nafdac.gov.ng

E-mail address: der.headquarters@nafdac.gov.ng
Telephone Number:

**Note:**

- **All submissions should be made at the Office of the Director, DER; 1st Floor, NAFDAC Office Complex, Isolo Industrial Estate, Apapa-Oshodi Expressway Isolo, Lagos or the nearest NAFDAC Office (for applicants outside Lagos).**
- **Unsatisfactory outcome of inspection leads to issuance of compliance directives and a stop in the process clock until the applicant responds satisfactorily to the directives.**