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

GUIDELINES FOR PRE- REGISTRATION 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 inspection of a facility for compliance with Good Manufacturing Practices for the registration of pharmaceutical products.

2. APPLICATION FOR INSPECTION

2.1. An application for Pre-registration 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 products intended for registration (including the active ingredients, strengths, dosage form and pack sizes) 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). The application can also be sent to der.pharmaquarters@nafdac.gov.ng. The following supporting documents should be added to the application:

2.2.1. Evidence of acceptance of product trademark by Trademarks Registry.

2.2.2. Artwork of product labels including Product Information Leaflets where applicable.

2.3. A request for Pre-Registration Inspection for pharmaceutical products for the applicant is received from the Drug Registration & Regulatory Affairs Directorate and the Director Drug Evaluation and Research (DER) issues a directive for the applicant to pay for the inspection.

2.4. The applicant should follow the below-listed steps to make payment for the inspection:

2.4.1. A payment advice for the inspection would be sent to the company's email.

2.4.2. Visit www.remita.net to generate a Remita invoice and print out a copy of the invoice.

2.4.3. Visit the nearest commercial bank to make the payment.

2.4.4. 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).

2.5. SCHEDULING OF FACILITY FOR INSPECTION

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

2.7. DOCUMENTATION

The following documents should be made available during the inspection

2.7.1. Copy of Letter of Authority to Manufacture on the formulation line
2.7.2. Current Annual License to Practice of all Pharmacists in the company issued by the PCN.
2.7.3. Batch Manufacturing Record & Batch Packaging Record for the products to be registered.
2.7.4. List of all company SOPs
2.7.5. SOPs for Production-related processes
2.7.6. SOPs for Quality Control processes
2.7.7. SOPs for Quality Management activities
2.7.8. SOPs for Material Management
2.7.9. SOPs for Equipment Cleaning and Maintenance
2.7.10. SOPs for Packaging and Labelling operations
2.7.11. Documentary evidence of Production Process Validation for the products to be registered.
2.7.12. Documentary evidence showing Cleaning Validation of process equipment
2.7.13. List of Production and Quality Control equipment and their sources of purchase
2.7.14. Retainership Agreement with a Hospital or Clinic (with names and signature of both parties.
2.7.15. Certificates of Medical Fitness for personnel which should include at least the following test:
2.7.15.1 Sputum Culture and Sensitivity
2.7.15.2 Urinalysis
2.7.15.3 Stool Microscopy
2.7.15.4 Chest X-ray
2.7.15.5 Penicillin hypersensitivity (for personnel in Beta-Lactam manufacturing facilities)
2.7.15.6 Visual Acuity test for sighters/visual inspectors.
2.7.16. Certificates of Analysis of Raw Materials and Finished Products.
2.7.17. Product(s) Labels including Product Information Leaflets where applicable
2.7.18. Any other relevant documents.

2.8. GOOD MANUFACTURING PRACTICE REQUIREMENTS

Please refer to the NAFDAC Good Manufacturing Practice for Pharmaceutical Products Guidelines 2021, available at www.nafdac.gov.ng for full guidance.

2.9. TARIFF

2.9.1. Please refer to the appropriate section in the NAFDAC Approved Tariffs available at www.nafdac.gov.ng
2.9.2. All fees attract 7.5% VAT.

2.10. 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.pharmaquarters@nafdac.gov.ng
Telephone Number:

Note:

- **All submissions should be made to der.pharmaquarters@nafdac.gov.ng or 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 a stop in the process clock until the applicant responds satisfactorily to the directives.**