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

GUIDELINES FOR PRODUCTION INSPECTION OF HERBAL MEDICINES AND NUTRACEUTICALS MANUFACTURING FACILITIES

1. GENERAL

1.1 These guidelines are for the interest of individuals intending to engage in manufacturing of herbal medicines and related products in Nigeria.

1.2 This guidance document prescribes the minimum Good Manufacturing practice (GMP) requirements for the facilities and controls to be used in the manufacture of herbal medicines and related products to ensure quality and safety.

1.3 These document also prescribes the minimum requirements necessary for inspection of a facility for compliance with Good Manufacturing Practices for the registration of herbal medicine and related products.

1.4 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.

1.5 A regulated product should not be manufactured in Nigeria unless the facility has been inspected and found to comply with Good Manufacturing Practices.

1.6 Herbal medicines and related products are products that contain exclusively active ingredients of one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations presenting with therapeutic and prophylactic claims.

1.7 Herbal medicines and related products may include unsynthesized natural plant substances such as seeds, berries, roots, leaves, bark, rhizomes, flowers, fruit bodies or other parts presented as herbs, herbal materials, herbal preparations and finished herbal products.

NOTE: Alcoholic Bitters are only considered to be herbal products when the alcohol content is less than 23% absolute alcohol by volume.

2. APPLICATION FOR INSPECTION

2.1 An application for 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 products intended for registration (including the active ingredients, 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) with the following supporting documents:

2.2.1 Evidence of business registration or company incorporation from CAC
2.2.2 Evidence of acceptance of product trademark by Trademarks Registry.
2.2.3 Artwork of product labels including Product Information Leaflets where applicable.

2.3 A request for Production Inspection for pharmaceutical products for the applicant is received from the 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 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).

2.4.2 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.

2.5 The applicant should 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. GOOD MANUFACTURING PRACTICE REQUIREMENTS FOR HERBAL MEDICINES AND NUTRACEUTICALS

4.1 **Personnel**

4.1.1 There should be sufficient number of personnel to suit operations of the facility.

4.1.2 Persons in charge of production should have a minimum of OND in a relevant science discipline or provide evidence of Licensure with the Traditional Medicines Board.

4.1.3 Personnel should wear protective apparel/gears, such as head, face, hand and arm coverings.

4.1.4 Personnel should practice good hygiene and sanitation practices.

4.1.5 Personnel should undergo medical fitness test at least once a year.

4.1.6 Personnel should undergo periodic and continuous training.

4.1.7 Personnel should undergo the following medical fitness tests and be certified medically fit:

4.1.7.1 Sputum Culture
4.1.7.2 Urinalysis
4.1.7.3 Stool Culture
4.1.7.4 Chest X-ray

4.1.7.5 Widal Test

4.2 **Building/Facilities**

4.2.1 The building should be segregated into production areas, storage areas and cloak rooms. The materials used for segregation should be non-shedding.

4.2.2 The production facility should have adequate space to ensure free flow of personnel and materials.

4.2.3 The rooms should be adequate for the orderly placement of equipment and materials to prevent mix-ups between different categories of materials.

4.2.4 Windows and entrance doors should be screened with insect-proof netting and the doors should be self-closing to prevent contamination.

4.2.5 Adequate ventilation and illumination should be provided.

4.2.6 The facility should be kept clean at all times.

4.2.7 There should be adequate storage areas for raw materials, packaging materials and finished products. These should be stored on pallets or shelves as appropriate.

4.2.8 Access into the facility should be controlled.

4.3 **Equipment**

4.3.1 The equipment must be cleanable, non-reactive, non-leaching, non-absorptive and non-adsorptive.

4.3.2 The water treatment plant for water-based products must be adequate to consistently produce the required physical, chemical and microbiological quality.

4.3.3 Equipment should be washed and dried before and after use.

4.4 **Raw/Packaging Materials and Sources**

4.4.1 Raw and packaging materials should be purchased from traceable sources.

4.4.2 They should be of good quality and standards.

4.4.3 All materials should be stored under appropriate storage conditions.

4.4.4 Materials should be stored in a manner that reduces pest attack.

4.5 **Environmental Sanitation**

4.5.1 Waste should be disposed in an appropriate and sanitary manner.

4.5.2 Fumigation of the facility should be carried out quarterly.

4.5.3 Water system toilets and hand washing facilities should be appropriately located away from the production area and kept clean.

4.5.4 Eating, drinking and smoking should not be permitted in the production area.

4.6 **Documentation**

The following documents should be made available during the inspection:

4.6.1 Company's Organogram

4.6.2 Standard Operating Procedure (SOP) for Production

4.6.3 Batch Formulation of the Product

4.6.4 SOP for Quality Control Checks

4.6.5 SOP for Cleaning of Equipment and Factory Premises
4.6.6 SOP for water treatment (where applicable)
4.6.7 SOP for Product Distribution and Recall
4.6.8 Certificate of analysis of raw and treated water.
4.6.9 Medical certificate of fitness for production staff
4.6.10 List of raw materials and their sources
4.6.11 List of production equipment and sources
4.6.12 Certificate of analysis of all raw materials and finished product(s)
4.6.13 Toxicological Analysis Report of Finished Product
4.6.14 Certificate of fumigation of the facility
4.6.15 Personnel Records (Letter of Appointment and Acceptance of offer, certificates, job description, training records)
4.6.16 Evidence of acceptance of Trade Mark
4.6.17 Product labels should be in English language and should contain the following:
4.6.17.1 Name of product
4.6.17.2 Net weight/volume
4.6.17.3 Batch Number
4.6.17.4 Manufacturing Date
4.6.17.5 Expiry Date
4.6.17.6 Provision for NAFDAC REG. NO
4.6.17.7 List of ingredients
4.6.17.8 Exact factory location address (Not P.O. Box)
4.6.17.9 Directions for use
4.6.17.10 Storage conditions
4.6.17.11 Cautions (where necessary)
4.6.17.12 A disclaimer: *These claims have not been evaluated by NAFDAC*

4.7 **Distribution System**

4.7.1 Records of product distribution network must be properly kept for easy recall of defective products.
4.7.2 Distributors names, addresses, telephone numbers, email addresses, quantity of products issued, batch numbers, dates of manufacture and expiry should be maintained.

4.8 **Transportation and Handling**

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

5. TARIFF

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

5.2 All fees attract 5% VAT.

6. 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.**