FACILITY STATUS VERIFICATION FORM

1. Name of Applicant……

   ……...

2. Address of Applicant……

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3. Name of Manufacturer.....

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4. Address of Manufacturer.....

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   …….....

5. Products for Registration
   [Full details of every product for which classification is needed e.g. Brand name, Generic (where applicable), dosage form strength].

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6. Product Class(es) (Please tick the relevant box(es)

   Human Drugs ☐ Human Biologics ☐ Cosmetics ☐ Medical Devices ☐

   Herbal Products ☐

7. Manufacturer's Contact Person.....

   Telephone No…….....

   E-mail…….....

8. Has the manufacturing facility ever been inspected by NAFDAC? YES/NO…….....

9. If YES, provide dates.....

   Attach evidence of (9) above resources

10. Have any other Regulatory Agencies inspected the facility within the last two years? Yes/No…….

11. If yes, provide details

    i. .....

    ii. ……..

    iii. ……..

Attach the under listed documents as applicable;

i. Application letter to D(DER)
ii. Evidence of payment of inspection fees for concerned products

PHARMACEUTICALS

i. Valid GMP Certificate from Stringent Regulatory Authority (SRA) that inspected the facility
ii. GMP Inspection report (hard or e-copy) in support of the valid GMP certificate from the inspecting Stringent Regulatory Authority (SRA)
iii. Evidence of WHO Pre-qualification of product or compliance with WHO GMP (verifiable from WHO Public Inspection Report Site.
iv. Current Notification of Outcome of GMP Audit by NAFDAC

HERBAL MEDICINES, NUTRACEUTICALS & COSMETICS

i. Current Notification of Outcome of GMP Audit by NAFDAC
ii. ISO Certification-Audit Report by Recognized ISO certification body (for cosmetics)

MEDICAL DEVICES

i. ISO Certification-Audit Report by Recognized ISO Certification Body
ii. Certification (Declaration) of Conformity or Performance Evaluation Report for specialized devices
iii. Evidence of Valid GMP Certification for Medical Device by USFDA, EUDRA, MHRA or other Stringent Regulatory Authority (SRA)
iv. Evidence of WHO Pre-qualification of product
v. Current Notification of Outcome of GMP Audit by NAFDAC

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Name of Applicant	Designation.	Signature	Date

Note: All information provided is subject to verification and it is an offence to provide false information.
Each facility requires a separate form.