

NATIONAL DRUG AUTHORITY



Secretariat Office P.O Box 23096 Kampala Plot 46 – 48 Lumumba Avenue
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The National Drug Policy and Authority Act [Cap 206]

APPLICATION FORM FOR GMP ASSESMENT OF A FOREIGN PHARMACEUTICAL MANUFACTURING FACILITY

- *This form should be completed by or for each foreign manufacturer of Pharmaceutical products intended to be marketed in Uganda*
- *Incomplete forms may be returned to the applicant. Please type or print. Any alterations must be initialed and dated.*
- *The audit fees must be paid before the audit is scheduled, and the manufacturer must agree to the audit. Otherwise, the audit will not take proceed.*
- *The completed form must be submitted to:*

*The Executive Secretary/Registrar
National Drug Authority
Plot 46-48, Lumumba Avenue,
P.O Box 23096, Kampala
UGANDA*

1. PARTICULARS OF APPLICANT/LICENCE HOLDER

Name _____

Physical Address _____

Country _____ Telephone _____

Fax _____ E-mail _____

2. PARTICULARS OF SITE TO BE INSPECTED

Name of site _____

Physical Address (if different from 1. above)

Country _____ Tel _____

Fax _____ E-mail: _____

Note: *Separate application form should be filled for each individual site*

3. CONTACT PERSON ON SITE

Name of contact person_____

Tel:_____ Fax:_____

E-mail:_____

4. AUTHORISED REPRESENTATIVE/AGENT IN UGANDA

Name of Local Technical Representative_____

Tel;_____

5. TYPE OF DRUGS MANUFACTURED (Tick where applicable)

(a) Human only (b) Veterinary only (c) Human & Veterinary

6. INSPECTION TYPE (Please tick where applicable)

- First Inspection
- Routine Re- inspection (Previous inspection date.....)
- Re – inspection after failure
- Other (please specify).....

7. LINES TO BE INSPECTED

| DOSAGE FORM | Tick where applicable | *CATEGORY | **ACTIVITIES |
|-------------------------------|-----------------------|-----------|--------------|
| Tablets | | | |
| Capsules | | | |
| Injections (SVP) [#] | | | |
| Injections (LVP) [#] | | | |
| Oral liquids | | | |
| Powders for oral suspension | | | |
| Creams/Ointments/lotions | | | |
| Others (specify) | | | |
| | | | |
| | | | |

*Category means any of the following
Beta lactam (Penicillin), Beta lactam (Cephalosporins), Non-beta lactam, Biologicals, Vaccines, Hormones, Cytotoxic products

**Activity means any steps in manufacturing that are conducted at this site, e.g complete manufacture of dosage form, primary or secondary packaging, Quality control, warehousing e.t.c

[#] Small Volume Parenterals (SVP) refers to packs of 100ml or less and Large Volume Parenterals (LVP) are packs of more than 100ml.

8. REGISTRATION OF PRODUCTS

Have you submitted dossier for registration? Yes ... No .

If Yes, list the products applicable. (Attach a separate sheet if needed)

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9. ADDITIONAL INFORMATION

Inspection dates

In order to schedule a GMP Inspection, the applicant should indicate an approximate date from which they will be ready. If this date changes after the application is submitted, the inspectorate department (GMP Desk) should be notified as soon as possible.

Approximate date when the facility will be ready for GMP Inspection/...../.....

(For re-inspections, not more than three months after expiry of GMP validity)

The actual date of the audit will be advised to the company/applicant.

Site Master File

It is requested that you enclose with this application form a copy of the Site Master File (not more than 25 pages).

Enclosed - Yes No ...

I hereby certify that the above information is correct and apply for Good Manufacturing Practice inspection of the above-named site(s).

Signature of applicant..... Date.....

Print Name.....