For official use only
APPLICATION No…….

FORM PPB/INSP/GMP

PHARMACY AND POISONS BOARD

P.O Box 27663-00506 LENANA ROAD
Tel:+254- 20-2716905/6, , 254- 733 884 411/720608811
E-mail: info@pharmacyboardkenya.org Website: http://www.pharmacyboardkenya.org

APPLICATION FORM FOR GOOD MANUFACTURING PRACTICE INSPECTION FOR PHARMACEUTICAL MANUFACTURING FACILITIES

1. PARTICULARS OF APPLICANT/LICENSE 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 to be filled in for each individual site*

3. CONTACT PERSON ON SITE

Name of contact person_____

Tel:_____Fax:_____

E-mail:_____

4. AUTHORISED REPRESENTATIVE/AGENT IN KENYA

Name of Local Technical Representative_____

Tel;_____

5. TYPE OF DRUGS

Type of drugs manufactured (*Tick where applicable*)

(a)Human (b) Veterinary (c)Both (a) and (b)

6. INSPECTION TYPE *(Please tick where applicable*)

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

7. LINES TO BE INSPECTED

DOSAGE FORM	**Tick where applicable**	***CATEGORY**	****ACTIVITIES**
Tablets			
Capsules			
Injections (SVP)			
Injections (LVP)			
Oral liquids			
Creams/Ointments/lotions			
Others (specify)			

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

**Activity means any of the following:

- Formulation(dispensing, mixing, blending)
- Processing(compression, emulsification etc)
- Packing
- Quality Control
- Warehousing(raw material, finished products)

8. REGISTRATION OF PRODUCTS

Have you registered any products in Kenya
or
Have you submitted dossier for registration? YES ☐ NO ☐
If YES, list the products applicable. (*Attach a separate sheet if needed*)
…….

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……..

Notes:

1. Please submit a copy of the Site Master File (not more than 25 pages) together with this application.

   Annex 1: Guide to developing a Site Master File
   Annex 2: Guidelines for GMP Inspection of pharmaceutical manufacturing plants

2. This application must be submitted together with the appropriate fee (see annex 2) to:
   The Registrar
   Pharmacy and Poisons Board
   P.O Box 27663- 00506
   Nairobi, Kenya