For official use only
Application No: ……

FORM PMPB/INS/GMP/

PHARMACY, MEDICINES & POISONS BOARD

ALL CORRESPONDENCE SHOULD BE ADDRESSED TO THE REGISTRAR

Mission: To provide regulatory mechanisms that promotes availability and use of safe, efficacious, good quality and affordable medicines and medical devices in Malawi for reliable health care and economic development.

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APPLICATION FORM FOR GOOD MANUFACTURING PRACTICE FOR PHARMACEUTICAL MANUFACTURING FACILITY

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 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 MALAWI

Name of Local Technical Representative_____

Tel;_____ E-mail ……

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**
(a) Tablets			
(b) Capsules			
(c) Injections (SVP)			
(d) Injections (LVP)			
(e) Oral liquids			
(f) Creams/Ointments/lotions			
(g) Others (specify)			

*Category means any of the following
Beta lactam, 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

8. REGISTRATION OF PRODUCTS

Have you submitted dossier for registration? Yes ☐… No ..☐.
If **Yes**, list the products applicable. (*Attach a separate sheet*)

…….

9. ADDTITIONAL INFORMATION

Expected Inspection dates
In order to schedule a GMP Inspection, the applicant should indicate the period within which the site will be ready for inspection. If this period changes after the application is submitted, the inspectorate department should be notified as soon as possible.

The period when the facility will be ready for GMP Inspection Month/Year …../……

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.

Signature of applicant……. Date……

Print Name……..

Title……..