APPLICATION FORM FOR GOOD MANUFACTURING PRACTICE INSPECTION FOR PHARMACEUTICAL MANUFACTURING FACILITIES

1. PARTICULARS OF THE APPLICANT/LICENSE HOLDER

Name _____

Physical address _____

Country _____ Telephone _____

Fax _____ Email _____

2. PARTICULARS OF THE SITE TO BE INSPECTED

Name of site _____

Physical address (if different from 1 above

_____

_____

Country _____ Tel _____

Fax _____ Email _____

Note: *Separate application to be filled in for each individual site*

3. CONTACT PERSON ON SITE

Name of contact person _____

Tel _____ Fax _____

Email _____

4. AUTHORISED REPRESENTATIVE/AGENT IN THE COUNTRY

Name of Local Technical Representative _____

Tel _____

5. TYPE OF MEDICINES

Type of medicines manufactured *(Tick where applicable)*

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

6. REGISTRATION OF PRODUCTS

Have you registered any products in the country YES ☐ NO ☐

Have you submitted application(s) dossier(s) for registration? YES ☐ NO ☐

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

……

7. NAME(S) AND NUMBER OF MANUFACTURING BLOCKS APPLIED FOR INSPECTION

S/N	NAME OF MANUFACTURING BLOCK(S)	NUMBER OF BLOCKS	ACTIVITIES CARRIED OUT

8. 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 (penicillin or cephalosporin), Non beta lactam (General pharmaceuticals), 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)**

9. APPLICANT DECLARATIONS

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

Signature of Applicant and stamp…… Date…….

Print name ……

NOTES:

1. *Please submit a hard and soft copy of the Site Master File together with this application.*

2. *This application must be submitted together with the appropriate GMP inspection fee as prescribed in TFDA Fees and Charges Regulations in force.*

3. *As part of product registration process, only applicant who submitted dossiers for registration will apply for GMP inspection. GMP inspection will not be conducted for facilities which have not submitted product registration dossier(s).*

10. FOR OFFICIAL USE ONLY

10.1 INSPECTION TYPE *(Please tick where applicable)*

☐ First inspection

☐ Re inspection after failure

☐ Renewal inspection (Previous inspection date…….)

☐ Other (please specify) …….

10.2 OFFICERS ASSIGNED FOR INSPECTION

NO.	NAME OF INSPECTOR	SECTION	CONTACT (E-mail and telephone)
1.			
2.			
3.			
4.			