**Appendix I:**

TFDA
Tanzania Food & Drugs Authority

**F01/DMC/MI&E/SOP/013**
**Rev #: 0**

**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 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 product in the country YES ☐ NO ☐

Have you submitted dossier for registration? YES ☐ NO ☐

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

_____

_____

_____

_____

## 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. 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)*

## 9. FOR OFFICIAL USE ONLY

### 9.1 INSPECTION TYPE (*Please tick where applicable*)

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

### 9.2 OFFICERS ASSIGNED FOR INSPECTION)

| NO. | NAME OF INSPECTOR | DEPARTMENT | CONTACT (e-mail & telephone) |
|---|---|---|---|
| 1. | | | |
| 2. | | | |
| 3. | | | |
| 4. | | | |