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FORM NQCL/INP/GMP

APPLICATION No.....
(For official use only)

APPLICATION FORM FOR GOOD MANUFACTURING PRACTICE INSPECTION FOR PHARMACEUTICAL MANUFACTURING FACILITIES

PART 1: PARTICULARS OF APPLICANT/LICENSE HOLDER

Name_____

Physical Address_____

Country_____Telephone_____

Fax_____E-mail_____

PART 2: PARTICULARS OF SITE TO BE INSPECTED

Name of site_____

Physical Address_____

Country_____Telephone_____

Fax_____E-mail_____

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

PART 3: CONTACT PERSON ON SITE

Name of contact person_____

Tel:_____Fax:_____

E-mail:_____

PART 4: AUTHORISED REPRESENTATIVE/AGENT IN KENYA

Name of Local Technical
Representative_____

Physical Address_____

Telephone_____

Fax_____E-mail_____

PART 5: TYPE OF DRUGS

Type of drugs manufactured (*Tick where applicable*)

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

PART 6: INSPECTION TYPE *(Please tick where applicable)*

☐ First Inspection☐ Re – inspection after failure of
☐ Routine Re- inspection previous inspection
☐ Other (please specify).....

Date.....

PART 7: LINES/SCOPE OF INSPECTION

Select the category of products to be inspected: (Please tick the appropriate box)

NOTE: 1 inspection is only for one (1) <u>Category/Line</u> of product.

☐ STERILE ☐ NON STERILE

Select from the following **<u>categories/Lines</u>** of products that are to be included in the scope of inspection:

☐ Penicillins or Cephalosporins
☐ Cytotoxics or Anti-Cancer Preparations
☐ Biologicals (eg vaccines, blood products, biotechnology products)
☐ Hormones
☐ Steroids
☐ None of the above

Select pharmaceutical dosage form of products to be inspected: (Please tick the appropriate box)

☐ Large Volume Parenterals
☐ Small Volume Parenterals
☐ Liquid (External)
☐ Liquid (Internal)
☐ Cream / Ointment
☐ Lotion
☐ Tablet
☐ Capsule
☐ Powder
☐ Granule
☐ others (please state):

_____

_____

PART 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.

……

PART 9: LIST OF SUPPORTIVE DOCUMENTS

Please attach a site master file of not more than 30 pages

PART 10: APPLICANT DECLARATION

1. I am hereby authorized by the company to make this application.

2. I declare that the particulars given in this application and the supporting documents are true or authentic or true copies and undertake to notify NQCL within one week of any change in the particulars submitted in this application.

3. I hereby confirm that I agree with any decision from NQCL regarding this application.

_____

Signature

_____

Name

_____

Designation

_____

Date Company Stamp

PART 11: FOR OFFICIAL USE ONLY

Application No:……

……
……
Name and signature of Officer processing this application

……
……
Amount of Fee and any other Requirement for inspection