



National Drug Authority
Plot No. 19, Rume Towers, Lumumba Avenue,
P.O. Box 23096, Kampala, Uganda.
email: ndaug@nda.or.ug; website: www.nda.or.ug
Tel: +256-414-255665, +256-414-347391/2

Doc. No.: INS/FOM/067
Revision No.: 2
Effective Date: 10 Nov. 2017

Page 1 of 5

Application for Good Manufacturing Practice Inspection for Finished Pharmaceutical Products and Active Pharmaceutical Ingredients Manufacturing Facilities

<i>This box is to be filled by NDA official only</i>			
Assigned to:	Lead GMP Inspector	Team GMP Inspector(s)	
Name			
Assigned by :			
Name	Title:	signature:	Date:

Applicant to fill the following sections

1. Particulars of the Applicant/License Holder

Name _____

Physical Address _____

Country _____ Telephone _____

Fax _____ E-mail _____

2. Particulars of Manufacturing Site to be Inspected

Name of site _____

Physical Address (if different from 1. above)

Country _____ Tel _____

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 Uganda

Name of Local Technical Representative _____

Tel: _____ E-mail: _____



National Drug Authority
Plot No. 19, Rume Towers, Lumumba Avenue,
P.O. Box 23096, Kampala, Uganda.
email: ndaug@nda.or.ug; website: www.nda.or.ug
Tel: +256-414-255665, +256-414-347391/2

Doc. No.: INS/FOM/067
Revision No.: 2
Effective Date: 10 Nov. 2017

Page 2 of 5

Application for Good Manufacturing Practice Inspection for Finished Pharmaceutical Products and Active Pharmaceutical Ingredients Manufacturing Facilities

5. Type of Medicines/ Active Pharmaceutical Ingredients

Type of medicines manufactured (*Tick where applicable*)

Human ☐

Veterinary ☐

Human and Veterinary ☐

6. Registration of Products in Uganda

Have you registered any products in Uganda YES ☐ NO ☐

Have you submitted product dossier for registration from the production line(s) applied for inspection? YES ☐ NO ☐

If "YES", provide list of the products as an Attachment to this form)

7. Inspection Applied for (*Please tick where applicable*)

- ☐ First Inspection
- ☐ Routine re-inspection (state previous inspection datesDD/MM/YYYY)
- ☐ Re-inspection (after failure)
- ☐ Joint Inspection
- ☐ Other (please specify).....

8. Major Site Changes Since Last Inspection

Provide summary of changes to personnel, equipment, buildings, specifications, computer systems, products (type, range or category), suppliers and contractors since last inspection, as an Attachment to this form.

National Drug Authority
Plot No. 19, Rume Towers, Lumumba Avenue,
P.O. Box 23096, Kampala, Uganda.
email: ndaug@nda.or.ug; website: www.nda.or.ug
Tel: +256-414-255665, +256-414-347391/2



National Drug Authority
 Plot No. 19, Rume Towers, Lumumba Avenue,
 P.O. Box 23096, Kampala, Uganda.
 email: ndaug@nda.or.ug; website: www.nda.or.ug
 Tel: +256-414-255665, +256-414-347391/2

Doc. No.: INS/FOM/067
 Revision No.: 2
 Effective Date: 10 Nov. 2017

Page 5 of 5

Application for Good Manufacturing Practice Inspection for Finished Pharmaceutical Products and Active Pharmaceutical Ingredients Manufacturing Facilities

		Yes	No	Building Block name/ number	Number of production lines	Non β -lactam	β -lactam					
							Penicillin	Cephalosporin	Cytotoxic	Hormones	Human	Veterinary
c)	Chemical/Physical											
d)	Biological											
e)	Animal											
f)	Stability											

10. Declaration

I hereby certify that the above information is correct and apply for Good Manufacturing Practice inspection of the above-named site(s). I also commitment to welcome the GMP inspectors for the inspection.

Signature of applicant.....Date.....

Print Name..... Designation.....

Notes:

1. Please submit a copy of the Site Master File (not more than 25 pages) together with this application (refer to Guideline on preparation of a Site Master File)
2. This application must be submitted together with proof of payment of the appropriate fee to the Executive Secretary/Registrar, National Drug Authority