



APPLICATION FOR ANNUAL MANDATORY INSPECTION FOR PHARMACEUTICAL LICENCE HOLDERS

<i>For official use</i>	
Date of Submission: _____	Application number: _____
Payment Receipt number: _____	
Application Accepted (Proceed for inspection)	<input type="checkbox"/>
Application Rejected (Notify applicant on deficiencies)	<input type="checkbox"/>

1 Particulars of the Applicant

Applicant name and address	Name:..... Physical Address: Postal Address: Phone: Fax: Email:
Contact Person	Name: Designation: Phone: Fax: Email:

Proprietor(s)/Director(s)

No.	Name	Occupation	Nationality	Residential address
1.				
2.				
3.				
4.				
5.				
6.				

2 Particulars of Suitably Qualified Persons *(Select applicable section)*

a) Wholesale dealing

Name of Suitably Qualified/Responsible Person:

Registering body registration number:

Signature of a Suitably Qualified/Responsible Person.....

b) Manufacture *(Applicable to persons undertaking manufacturing activities)*

Name of Suitably Qualified Person:

Registering Body registration number:

Signature of Suitably Qualified Person:

Name of Head of Production.....

Qualifications.....

Registering Body registration number: (where applicable)

Practical experience (minimum 3 years):

Name of Head of Quality Control:

Qualification:.....

Registering Body registration number: (where applicable)

Practical experience (minimum 3 years)

3 Products manufactured in the premises

Please indicate dosage form(s) of medicine(s) being manufactured below:

- 1)
- 2)
- 3)
- 4)
- 5)
- 6)
- 7)
- 8)
- 9)
- 10)

4 Type of manufacture

(Please tick what is applicable below)

- Complete manufacture
- Repackaging and labelling
- Contract manufacture
- Partial manufacture

PART B

5 Enclosures

The following copies should accompany the application:

- ☞ Certificate of incorporation or registration certificate (*Not applicable for annual mandatory inspections*)
- ☞ Certificate of Payment-Business Levy;
- ☞ Valid annual practising certificates for suitably qualified person(s);
- ☞ Letter of agreement/contract between suitably qualified person and company;
- ☞ Site master file (*applicable to a holder of a licence to manufacture medicinal product(s)*);
- ☞ Fire Safety certificate;

DECLARATION AND SIGNATURE:

It is, hereby, confirmed that all the particulars in this application and all the information and attachments contained, therein, are correctly and truthfully stated. We also understand that submission of false information shall render the application null and void. Further, we declare that if approval is granted, with respect to this application, it shall not be used for any purposes other than what stated in this application.

It is hereby confirmed that fees will be paid/have been paid accordingly. ^a

Particulars of the Person Signing on Behalf of the Applicant ^b

- a) Name:
- b) Designation:
- c) Signature: d) Date:/...../..... (dd/mm/yyyy)

^a *Strike through what is not applicable; and if fees have been paid, attach proof of payment.*

^b *Should be signed by a contact person*