REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

GUIDANCE NOTES FOR ESTABLISHING MEDICAL PRODUCTS AND HEALTH TECHNOLOGIES MANUFACTURING FACILITIES IN KENYA

FEBRUARY 2022

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HPT/ISE/GMP/MAN/006	**GUIDANCE NOTES FOR ESTABLISHING MEDICAL PRODUCTS AND HEALTH TECHNOLOGIES MANUFACTURING FACILITIES IN KENYA**	Revision No: 0	**Effective date** 21/02/2022 **Review Date:** 20/01/2027

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Reviewed by, Director Health Products and Technologies

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Abbreviations and Acronyms

EAC	East Africa Community
GMP	Good Manufacturing Practices
ICT	Information Communication Technology
MPHT	Medical Products and Health technologies
PPB	Pharmacy and Poisons Board
PIC/S	Pharmaceutical Inspection Co-operation Scheme
SDG	Sustainable Development Goals
WHO	World Health Organization

Glossary of terms

Medical Products and Health technologies This includes any product that is used in treatment, diagnosis or to prevent a disease or alter physiology in a human or in animals

Local Technical Representatives An entity bearing a wholesale dealers license in Kenya appointed to represent represent a third party in Kenya for purposes of engagement with PPB.

Preface

With increased applications for setting up manufacturing facilities in Kenya, and given the responsibility to regulate the manufacture and trade of Medical Products and Health technologies (MPHT), the Pharmacy and Poisons Board has developed this guidance for investors in Kenya. This guidance is intended to facilitate the setting up of pharmaceutical manufacturing facilities in Kenya fit for manufacture of good quality health products and technologies, that meet international standards as well as that protect personnel working in the premises.

These notes are intended to guide pharmaceutical regulation, establishment of manufacturing facilities for pharmaceutical and medical products as well as ease of doing business. For this purpose, the Pharmacy and Poisons Board has developed this first edition *'Guidance Notes For Establishing Pharmaceutical Products Manufacturing Facilities in Kenya'*

While this guidance will by no means eliminate any existing red tapes outside the purview of the Pharmacy and Poisons Board's mandate, it is hoped that the notes will augment efforts by other relevant government agencies in establishment of manufacturing facilities. In dealing with only bureaucracies related to pharmaceutical inspections and approvals, this guidance notes in a great way contribute towards achievement of vision 2030 and Sustainable Development Goal (SDG) 3, Sustainable Development Goal 9.

Over the years, pharmaceutical manufacturing including clean room technology has evolved so much that it is important for Pharmacy and Poison Board to establish a guidance document to ensure that the development and maintenance of new and existing clean room facilities are done according to current international standards.

Taking note that pharmaceutical manufacturing premises often require substantial resources to construct and maintain, standardization in the construction of Pharmaceutical Manufacturing is important for improving public health in Kenya and in the region. This guidance therefore, act as reference to ensure appropriate planning, development and upgrading of the pharmaceutical manufacturing facilities in Kenya.

Thank you.

DR. F.M SIYOI

Chief Executive Officer

1.0 Introduction

Persons or agencies intending to set up manufacturing facilities of Medical Products and Health technologies (MPHT) in Kenya, must apply to the Pharmacy and Poisons Board for approval in the form and format (Annexes I, II, IV, V). Their knowledge and acquaintance to PPB legal requirements and guidelines related to MPHT manufacturing in Kenya is a useful starting point.

The guidelines include but not limited to the documents in table 1 below:

Table 1: Applicable Guidelines in the manufacture of Medical products and Health technologies

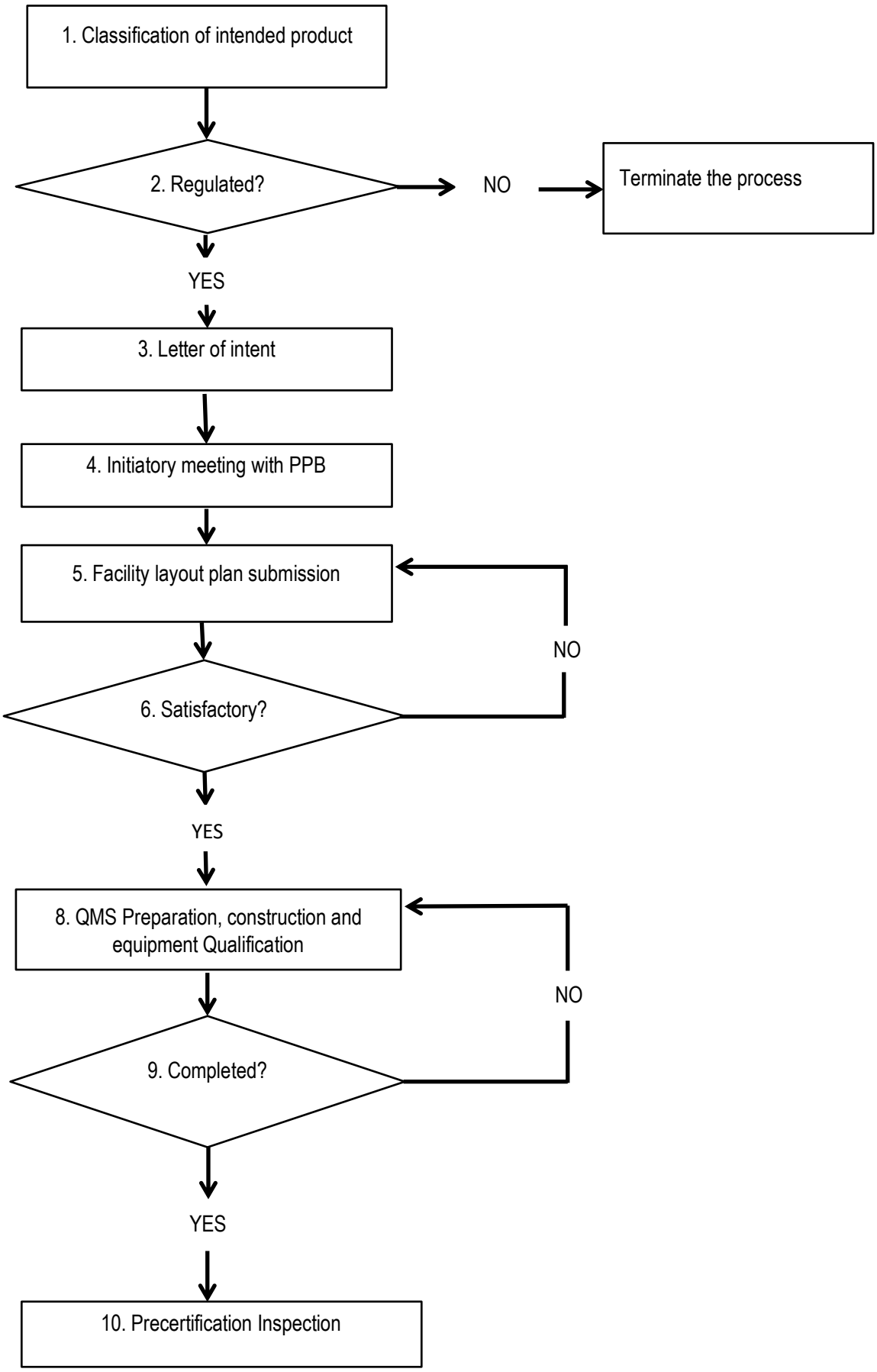
a) Regulations	The Pharmacy and Poisons Act Cap 244 of the Laws of Kenya, 2019
b) Guidelines	Applicable WHO GMP Guidelines:

	EAC Compendium on Good Manufacturing Practice for Medicinal Products for Use In East Africa Community, EAC.
	EAC Compendium on Drug Registration
	Guidelines on Good Distribution Practices
	Guidelines on Good Clinical Practices
	Guidelines for registration of medical devices
	Guidelines on transportation of pharmaceuticals
	Guidelines on safe disposal of pharmaceutical waste
	These guidelines are accessible on: *www.pharmacyboardkenya.org*

2.0 Application procedure

In order to establish a manufacturing facility for medical products and health technologies in Kenya, the following procedure shall apply;

Figure 1: General Process Flow Chart for setting up manufacturing facility for medical products and health technologies in Kenya.


1. Classification of intended product
2. Regulated?
NO
Terminate the process
YES
3. Letter of intent
4. Initiatory meeting with PPB
5. Facility layout plan submission
NO
6. Satisfactory?
YES
8. QMS Preparation, construction and equipment Qualification
NO
9. Completed?
YES
10. Precertification Inspection

2.1 Classification of medical products and health technologies intended to be manufactured

The Pharmacy and Poisons Board shall classify the product intended to be manufactured in the establishment proposed based on the requirements of the Pharmacy and Poisons Board Act of the laws of Kenya (Cap 244). Cap 244 specifies the products that are regulated by PPB. The classification of the product of intent shall be communicated once the application for classification is made.

The applicant is expected to make the application to the Pharmacy and Poisons Board in Annex 1 (product classification application form) using the email: gmp@pharmacyboardkenya.co.ke. This step is compulsory for the applicant intending to launch an application.

2.2 Letter of intent

Once the applicant receives a classification response mail, an online application may be made on the prescribed format Annex 2 (letter of intent)[1], to the Pharmacy and Poisons Board.

Letter of intent is meant to arrange a meeting with the relevant PPB Department before the commencement of the manufacturing facility construction. The meeting will discuss highlights of the proposed manufacturing facility as discussed under section 3.3 below.

Only applicants whose application forms have been received shall be allowed to proceed as in Figure 1 (*Procedure for establishing medical products and health technologies manufacturing facility in Kenya*) above representing general setup process. Any other arrangements will not be admissible

2.3 Initiatory PPB meeting with the applicant

During the Initiatory meeting, the company is expected to make a 30 minutes presentation within PPB premises. The company team should preferably constitute a minimum of 3 persons that are technically conversant with the

[1] *Annex 2: Letter of intent to set up a pharmaceutical manufacturing facility in Kenya:*

project. No less than 3 senior GMP inspectors shall represent the Board in the meeting.

During the inaugural meeting, the applicant will be required to make a concise presentation on but not limited to;

a) Background,
b) Information of the product(s) proposed to be manufactured,
c) Concept design report/notes
d) Other related information

Following the inaugural meeting and the company's presentation, PPB's GMP inspectors will assess the suitability of the proposed location for setting up of the manufacturing facility. This assessment may constitute an onsite inspection. This will be considered with reference to activities to be undertaken in the proposed site against all the neighboring facilities, activities and human settlement among other considerations.

Approval from proximal Government Installations may be required for the establishment of the facility. These could include Kenya Airports Authority and Ministry of Internal Security (MIS).[2]

An application response shall be sent to the applicant by mail within 10 working days in the prescribed PPB GMP report format Annex 3 (PPB GMP report format).[3] The response will contain at the minimum an assessment of the suitability of the location for setting up medical products and health technologies manufacturing establishment.

2.4 Plant layout submission

Applicants intending to proceed with the application after the presentation, and having considered PPB's response are required to submit application

through Annex 4 (Assessment of Plant Layout Application)[4] along with the following documents specified in the application form:

a) Certified copies of the memorandum and articles of association.
b) An environment impact assessment report from National Environment Management Authority (NEMA).
c) Where appropriate, clearance from the Radiation Protection Board
d) As may be applicable, Authorization from the Kenya Investment Authority and county governments.
e) Company Profile
f) Architectural layout plan of the site
g) A clear, defined facility layout plan
h) Proposed manufacturing process flow
i) Approval or no-objection letter from applicable proximal government Installations whose approval may be required for establishment of your proximal facility would be required. These could include Kenya Airports Authority and Ministry of Internal Security (MIS).[5]

The facility layout must be an integrated design that satisfies the following:

a) Process requirements
b) Personnel flows
c) Material flows (product, component and raw material movements)
d) Equipment layout requirements
e) Operational access requirements
f) Maintenance access requirements

The documents will be reviewed with the view of assessing the suitability of the layout in the manufacture of the MPHT as required in the *Table 1: Applicable Guidelines in the manufacture of Medical products and health technologies.* An assessment will also be made to determine the suitability of

[4] Annex 4:Application Form for the Evaluation of Manufacturing Plant Layout
[5] Airports, security installations among others

the proposed establishment in providing sufficient protection to the environment and personnel involved in production.

If necessary, additional information may be requested for review alongside the above documents. After satisfactory review of the preliminary documentation, the company will be given *approval to start construction* and to establish a Quality Management System appropriate for the manufacture of MPHT. This shall be in the form an "approved for execution" rubber stamp, date and sign of a layout plan.

Unforeseen minor changes that do not result in significant change in the layout plan may be inevitable during construction. The Pharmacy and Poisons Board shall be notified of any such deviations in writing. Final approval of the plan shall be made after construction and commissioning of the plant. This shall be in the form an "Approved" rubber stamp, sign and date of the final layout plan.

A deviation from an approved plan shall have to be pre-approved by PPB. This shall require a submission of a new layout, which should be re-presented from stage 5 in the flow chart above. Depending on the extent of deviation, a presentation by the company may be waived for the approval of the updated version.

2.5 Preparation of Quality Management System

The Pharmacy and Poisons Board shall assess and approve/disapprove an application based the documents attached including facility layout plan and approvals from other Government of Kenya authorities. Once the applicant is approved the facility may begin the construction of the facility, undertake qualifications of equipment and development of Quality Management System including documentation preparation according to guidelines mentioned in *Table 1: Applicable Guidelines in the manufacture of Medical products and* health technologies above.

Preliminary inspections are carried out at various stages of construction and setting up the site and reports prepared for each of the step. These may include:

a) Site inspection before and during construction of premises

b) Completion of construction of the premises

c) Completion of installation and qualification/Validation of support systems and equipment.

In case of any delay, the applicant shall be responsible for informing PPB through official letters or e-mails prior to the agreed completion date. Failure to which, may result in new application submission.

2.6 Pre-certification inspection

A Pre-Certification inspection will be conducted once the company indicates to have completed construction, validation/qualification and preparation of quality management system. At this point the company would have commissioned the facility and submitted a formal application for GMP inspection of the applicable areas and a license to manufacture drugs or devices.

Having paid the prescribed fee, application should be made on Annex 5 (application for pre-assessment inspection) alongside all the attachments included therein before inspection is conducted. The documents shall include:

a. Letter requesting for inspection
b. Completed application form for manufacture of medical products and health technologies
c. Site Master File
d. List of products to be manufactured at the facility

No inspection shall be performed until the application is received.

3.0 Responsible Department

The Inspectorate directorate carries out GMP pre-certification and certification inspection of establishments used for the manufacture of pharmaceutical products and/or medical device for human and veterinary use. However, licensing is granted by licensing department.

Companies intending to establish manufacturing facilities within Special Economic Zones or Export Economic Zones will be required to comply with any additional requirements.

Applicants may get more information and answers by contacting;

Department	GMP Division, Pharmacy and Poisons Board of Kenya
Telephone Number	+254720608811
Email	gmp@pharmacyboardkenya.co.ke
Postal Address	27663
Postal Code	00506

References

1. WHO Technical Report Series 986, Annex 2
2. EAC Compendium for Good Manufacturing Practices.

Contributors/Reviewers

S.No.	NAME	POSITION
1.	Dr F.M Siyoi	CEO, PPB

2.	Dr Ahmed Mohamed	Director, Health Products and Technologies
3.	Dr Dominic Kariuki	Deputy Director, Inspectorate and Enforcement
4.	Dr Sichei Cheworei	Deputy Director, Quality Control
5.	Dr Shaban Sifuma	HEAD, GMP
6.	Dr Wanza Katatha	CEO assistant
7.	Dr Tom Kauki	

ANNEXES

ANNEX I: PRODUCT CLASSIFICATION APPLICATION FORM

Part I: Instructions

1. Please fill in this application form.
2. One application form for all products.
3. The information provided is to be used solely for classification purposes.
4. The result of product classification shall be informed through email.
5. False and incomplete data may result in rejection of this application and new application would be required.
   Kindly ensure the relevant Act & Regulations as well as guideline is complied with after the product has been classified.
6. **Part II: Product/s Details**

Dose form (e.g. Oral Solids, Oral Liquids, Parenteral e.t.c)	*Active Ingredient (Where applicable)*	*Category and subcategories (e.g. powder/ liquid/ tablet/ chewable tablet/ capsule/ teabag etc.)*	*Proposed manufacturing activities*	*Category of product at country of origins (where applicable)*	*Is this an innovator product? (If applicable)*

Part III: Product Owners details

Company's Name and complete adress	Click here to enter text.

Part IV: Manufacturing Details

Company's Name and complete adress	Click here to enter text.

Part V: Applicant Declaration

I confirm that a. *All the information provided is true and complete.* b. *I will submit relevant documents pertaining to this application when needed.* c. *I am aware on the consequences of rejection of this application if I failed / refused to submi document(s)/ information as requested* d. *I will be fully responsible for this product.*	*Applicant's Name Signature and Company's official stamp*

ANNEX 2: LETTER OF INTENT

Part I: Company Details	
Company name:	Click here to enter text.
Physical Address in Kenya:	Click here to enter text.
Postal Address:	
Name and address of applicant to whom correspondence should be addressed to:	

Part II: Applicant Details	
Name:	Click here to enter text.
Identity card / Passport no. :	
Contact phone no.:	Click here to enter text.
Contact fax no.:	Click here to enter text.
Email address of applicant:	Click here to enter text.

Part III: Product/s Details		
Product/s type and source: (please (x))	*Product/s name*:*	*Product/s active ingredients*:*
☐ Non biological origin	Click here to enter text.	
☐ Animal or plant source; non transgenic	Click here to enter text.	Click here to enter text.
☐ Virus or bacteria / fermentation / cell culture	Click here to enter text.	Click here to enter text.
☐ Biotechnology fermentation / cell culture	Click here to enter text.	Click here to enter text.
☐ Animal sources; transgenic	Click here to enter text.	Click here to enter text.
☐ Human sources	Click here to enter text.	Click here to enter text.
☐ Human and/or animal sources	Click here to enter text.	Click here to enter text.
☐ Others: *(please specify)*	Click here to enter text.	Click here to enter text.
**Please separate different product/s name and active ingredients by semi colon (;) respectively*		

Part IV: Manufacturing Details	
Manufacturing facility address:	Click here to enter text.
Repacker/s facility address: (*if applicable*)	Click here to enter text.
Storage facility address: (*if applicable*)	Click here to enter text.
Require to be licensed by PPB*	☐ Yes; (*please provide supporting document*) ☐ No

Part V: Other Guidelines Used	
Please provide information on guidelines used other than mentioned in the guide	
Part VI: Proposed Initiatory meeting date	
Three different dates for the initiatory meeting	should be at least 2 weeks form the submission of this form

Part VII: Applicant's Declaration

With this application, I hereby declare that;

☐ the above particulars are, to the best of my knowledge and belief, correct.

☐ understand the purpose of this application

Signature (applicant) and company stamp:	
Name:	Click here to enter text.
Title / Position:	Click here to enter text.
Date:	Click here to enter a date.
Part VIII: For Office Use Only	
Reviewing Officer:	Click here to enter text.
Date of review	
Date of initiatory meeting:	Click here to enter a date.

Part IX: Reminder (*for applicant's reference*)

The following information must be prepared prior to meeting with the Pharmacy and Poisons Board.

No.	Checklist for Presentation	☒
1.	Presentation slide	
	Company's background	☐
	Product/s information; type and source, name of active ingredient	☐
	Concept design report/notes	☐

2.	Own laptop (compatible with VGA/HDMA cable connector)	☐

Submit to;

The Pharmacy and Poisons Board
Lenana Road, Opposite Department of Defence
P.O Box 27663-00506
Nairobi Kenya
Tel no.: +254720608811
Email: gmp@pharmacyboardkenya.org

Please ensure that all the requirements have been fulfilled ahead of the presentation date.

ANNEX 3: PPB SETUP INSPECTION REPORT	
Part 1	**General information**
Manufacturers details	
Company information	
Name of manufacturer	
Corporate address of manufacturer	
Contact person, telephone number and email address	
Inspected site	
Address of inspected manufacturing site if different from that given above	
Unit / block / workshop number	
Manufacturing license number	
LTR in Kenya	
Inspection details	
Dates and objective of inspection	
Inspector(s)	
Representative from the State/National Regulatory Authority	
Introduction	
Brief summary of the manufacturing activities	
General information about the company and site	
History	
Brief report of inspection activities	**undertaken**
Areas inspected	
Restrictions	
Out of scope	
PPB product registration numbers covered by the inspection	
Key persons met	
Abbreviations	

Part 2	Brief summary of the findings and comments (Where applicable)

Miscellaneous	
Samples taken	
Assessment of the site master file	
Annexes attached	

Part 3	List of deficiencies	
Deficiencies		**References**
1. Critical		
2. Major		
3. Minor		

Comments: **PART 4** ***Initial conclusion – inspection outcome***	
Name(s)	
Signature(s)	
Date	

definitions

PART 5

List of GMP guidelines referenced in the inspection report

1.

PART 6	Assessment of company response, final conclusio rating and next due date
Brief narrative on the adequacy of the company's response to issues to be addressed	
Final conclusion	
Risk rating following the inspection	
Date next inspection due	

Name	
Signature	
Date	

ANNEX 4: ASSESSMENT OF PLANT LAYOUT APPLICATION	
INTRODUCTION	
1. Please fill in this application form. 2. Please tick (√) the appropriate boxes. 3. Processing Fee (not refundable) should be submitted in the form and manner specified by PPB. 4. False and incomplete data may result in rejection of this application and a new application would be required.	
Processing fees (where applicable) New premises layout Revision of existing premises layout	
Note: only completed application form with confirmed payment will be processed	
Checklist for application and attachments	
Please complete the application checklist	***Please tick*** *(√)*
1. *Part I, II and III were filled in properly*	☐
2. *Documents to be attached are as below:*	☐
a) *The Summary of Manufacturing Processes for each dosage form manufactured*	☐
b) *Personnel, Raw Material, Packaging Materials and Finished Product Flow*	☐
c) *Name and size (with measurement) of Production Rooms/Area and Laboratory*	☐
d) *Waste Flow*	☐
e) *Pressure Differential Flow*	☐
f) *Cleanroom Classification (as may be applicable)*	☐
g) *Please specify the details of utilities used as below and attach the diagram for the utilities:* i. *Heating, Ventilation and Air-Conditioning System:* _____ ii. *Water System:* _____	☐
h) Please specify the location and equipment prepared in all Production Room and Laboratory.	☐
i) For application to revise the existing layout, please attach a copy of existing layout and highlight the proposed changes.	☐

PART I: DETAILS OF APPLICANT & COMPANY		
Applicant Name		
I.D Card No.		
Gender	*Male* ☐	*Female* ☐
Position		
Company's Name		
Telephone No.		
Mobile No.		
	Industry ☐	

Address of manufacturing premise	*Commercial* ☐	
	Other; specify ☐	
Type of Building:	*Go down*	☐
	Storey building	☐
	Others; specify	☐
Correspondence address [*If different from the address above*]		
PART II: DETAILS OF THE APPLICATION		
Application type	☐ *New Premises Layout (please proceed to Product Categories Section)*	
	☐ *Revision of Existing Premises Layout*	
Description about the revision of existing premises layout	☐ *Addition of New Block*	
	☐ *Addition of New Production Line*	
	☐ *Change of Room*	
	☐ *Others*; ☐ *Specify*_____	
Product Categories (Please strike through those that are not relevant)	***Section I. Pharmaceuticals***	
	☐ *Solid Dosage (*tablet/ powder/ granules/capsules/ pills)*	
	☐ *Semi-solid (including cream, lotion and gel)*	
	☐ *Liquids for (*internal/ external) use*	
	☐ *Sterile Preparation (*LVP/ SVP/ Gel)*	
	☐ *Others* *Specify:* _____	
Product Categories (Please strike through those that are not relevant)	***Section II. Biotechnology***	
	☐ Sterile Preparation (*LVP/ SVP/ Gel)	
	☐ Others Specify _____	
	Section III. Veterinary	
	☐ *Solid Dosage (*tablet/ powder/ granules/capsules/ pills)*	
	☐ *Semi-solid (including cream, lotion and gel)*	
	☐ *Liquids for (*internal/ external) use*	
	☐ *Sterile Preparation (*LVP/ SVP/ Gel)*	
	☐ *Others* *Specify:*_____	
	Section IV. Traditional	
	☐ *Solid Dosage (*tablet/ powder/ granules/ hard shell capsules/ soft shell capsules/ pills)*	
	☐ *Semi-solid (*cream/ lotion/ gel)*	
	☐ *Liquids for (*internal/ external) use*	
	☐ *Others* *Specify:*_____	
	Section V. Active Pharmaceutical Ingredients	
	☐ *Solid Dosage (*powder/ granules)*	
	☐ *Liquid for (*internal/ external) use*	

	☐ Sterile Preparation (*LVP/ SVP/ Gel)
	☐ *Others* *Specify:*_____
PART III: ESTABLISHMENT CERTIFICATION	
I confirm and agreed that *a. The applicant is an employee/ owner of the above-mentioned company.* *b. The company will be co-operative in providing any additional information required from time to time for the purposes of evaluation. If the company will not provide any feedback to the PPB within the specified time frame, this application will be proposed for rejection without option of refund of any processing fee (where applicable).* *c. The applied manufacturing premises *HAS NOT BEEN BUILT/ IS BEING BUILT/ IS ALREADY BUILT when the application is submitted.* *d. The company has referred to the current Good Manufacturing Practice (GMP) Guidelines in accordance with product categories* *e. All the information and attachment provided are true, accurate and verifiable*	
Signature of *Company's Owner/ Manager/ Director & Company Stamp	
Name	
Date	

**Please strike through what is not applicable*

ANNEX 5: APPLICATION FOR PRE-CERTIFICATION GMP INSPECTION	
Applicants that would like to request for non-routine GMP inspection, including on a new manufacturing establishment/new manufacturing line certification and healthcare establishments, should complete this GMP inspection application form in full. This form is not applicable for licensed manufacturers that are subjected to routine GMP inspection by the Pharmacy and Poisons Board. **Note: Incomplete Application Form Will Not Be Processed.**	
Part I: Particulars of the applicant	
Name of Applicant (Authorized person)	
Registration Number	
Name of the company	
Address of the company	
Part II: Particulars of Manufacturers	
Name of Manufacturer	
Physical address of the manufacturing site	
Telephone No.	
Email	
Website (if any)	
Part III: Types of Good manufacturing Practice (GMP) Inspection (Select one only)	
Pre-Licensing	☐
Verification	☐
Pre-approval	☐
Initial inspection	☐
Pre-certification	☐
Pre-qualification of healthcare establishments	☐
Definition of terms	
Pre-Licensing	*Inspection conducted on new premises that have never been licensed*
Verification	*Inspection conducted following a punitive action*
Pre-approval	*Inspection conducted only on new cosmetic premises, which is not in the Routine Inspection Schedule).*
Initial inspection	*Inspection conducted on premises that manufacture products that are not regulated by the Pharmacy and Poisons Board*
Pre-certification	*Inspection conducted on a new production line of licensed manufacturer*
Pre-qualification of healthcare establishments	*Related to Good Preparation Practice (GPP) and the inspection is conducted on new/renovated pharmacy hospital and nuclear medicine facility*

Part IV: Supporting documents required	
Registration of company certificate	☐
Site Master File *(In PPB defined format)*	☐

Part V: Particulars of Dosage Form of Product Manufactured (Please tick which is appropriate)	
Product Categories (Please strike through those that are not relevant)	***Section I. Pharmaceuticals***
	☐ *Tablet*
	☐ *Capsule*
	☐ *Granule/Powder*
	☐ *Sterile preparation (LVP/SVP/Gel)*
	☐ *Sachet*
	☐ *Lotion*
	☐ *Cream*
	☐ *Ointment*
	☐ *Gel*
	☐ *Liquids for (internal/ external) use*
	☐ *Others* *Specify:* _____
	Section II. Biotechnology
	☐ *Sterile Preparation (LVP/ SVP/ Gel)*
	☐ *Others* *Specify* _____
	Section III. Veterinary
	☐ *Tablet*
	☐ *Capsule*
	☐ *Granule/Powder*
	☐ *Sterile preparation (LVP/SVP/Gel)*
	☐ *Sachet*
	☐ *Liquids for (internal/ external) use*
	☐ *Others* *Specify:* _____
	Section IV. Traditional
	☐ *Tablet*
	☐ *Capsule*
	☐ *Granule/Powder*
	☐ *Sterile preparation (LVP/SVP/Gel)*
	☐ *Sachet*
	☐ *Lotion*
	☐ *Cream*
	☐ *Ointment*
	☐ *Gel*
	☐ *Liquids for (internal/ external) use*

Product Categories (Please strike through those that are not relevant)	***Section V. Active Pharmaceutical Ingredients***
	☐ *Powder/ granule*
	☐ *Liquid for external/Internal use*
	☐ *Sachet*
	☐ Sterile Preparation (LVP/ SVP/ Gel/Dill)
	☐ *Others* *Specify:*_____

	Section VI. Dietary Supplements
	☐ *Tablet*
	☐ *Capsule*
	☐ *Granule/Powder*
	☐ *Sachet*
	☐ *Liquids for (internal/ external) use*
	Section VII. Cosmetic
	☐ *Lotion*
	☐ *Cream*
	☐ *Ointment*
	☐ *Gel*
	☐ *Lipstick*
	☐ *Aerosol*
	☐ *Granule/Powder*
	☐ *Liquid for external*
	☐ *Others* *Specify:* _____
	Section VIII. Health Establishment
	☐ *Radiopharmaceuticals*
	☐ *CDR*
	☐ *Non-CDR: TPN/IV Admixture/Eye Drop*
	Section IX. Others
	Specify: _____ _____

Part VI: Applicant declaration	
Information provided are true and complete;	☐
Understand the purpose of this application;	☐
I will always cooperate and provide any additional documents if needed by PPB.	☐

END OF DOCUMENT