FOREIGN GMP INSPECTION APPLICATION FORM

National Pharmaceutical Regulatory Agency
Ministry of Health Malaysia
Lot 36, Jalan Profesor Diraja Ungku Aziz, 46200 Petaling Jaya, Selangor.
Tel. No. : 03-78835400
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Website : http://www.npra.gov.my/

For Official Use Only	
Application No.	_____
Date Received:	
Date Completed:	

PART A APPLICANT / PRODUCT REGISTRATION HOLDER INFORMATION

Name of Applicant:		
Name of Product Registration Holder:		
Address:		
Company/Business Registration Number:		
Contact Telephone:	Contact Fax:	Email Address:

PART B FOREIGN MANUFACTURER INFORMATION

Name:				
Address:				
Country:		Previous Date of Inspection by NPRA (if any):		
GPS Coordinate:	Latitude		Longitude	

PART C PURPOSE OF APPLICATION (Please tick the appropriate box)

☐ Product Registration (New)	☐ Change of Site to Existing Manufacturer
☐ Product Registration (Renewal)	☐ Others (Specify):

PART D FACILITY AND PRODUCT INFORMATION (Please tick the appropriate box)

Category of products to be inspected (choose only ONE)	☐ Sterile	☐ Non-sterile	
Product Dosage Form	☐ Large Volume Liquid	☐ Tablet	☐ Cream/Ointment
	☐ Small Volume Liquid	☐ Capsule	☐ Solution
	☐ Liquid for external use	☐ Powder	☐ Suspension
	☐ Liquid for internal use	☐ Granule	☐ Suppository
	☐ Other (Specify):		
Type of Product:	☐ Penicillin or Cephalosporin		☐ Hormone
	☐ Cytotoxic or Anti-Cancer preparation		☐ Steroid
	☐ Biologic (e.g. vaccines, blood products, biotechnology products)*		☐ None of the above
*For Biological product: (choose only ONE)	☐ Drug Substance	☐ Drug Product	
Is the facility manufacturing registered products for other Product Registration Holder (PRH)?	☐ Yes (Annex IV has to be completed)	☐ No	

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PART E	LIST OF SUPPORTING DOCUMENTS (The following documents **MUST** be submitted together with this application)	Tick (√) if provided	For Official Use Only
1.	Payment of Processing Fee RM5,000.00		
2.	A copy of Company/Business Registration Certificate (for Product Registration Holder)		
3.	Details of new products to be registered in Malaysia (Annex I)		
4.	Details of existing registered products of renewal of product registration (Annex II)		
5.	Details of existing registered products for change of manufacturing site (Annex III)		
6.	Details of product registration holder and their respective registered products (Annex IV)		
7.	Site Master File		
8.	Validation Master File		
9.	Proposed flight route and hotel rate per night		
10.	Hotel quotation [Details required: i) Hotel Name, ii) Official Website (if any), iii) Distance between hotel and manufacturing facility iv) Accommodation during transit (if any)]		
11.	Declaration letter from manufacturer stating that the premise is ready to be inspected at any time		
12.	Valid GMP evidence (preferably GMP certificate/report issued by a PIC/S Participating Authority)		

If company is eligible for **GMP DESKTOP ASSESSMENT (GDA)** (refer GDA acceptance criteria as mentioned below), the **ADDITIONAL** following documents (13-19) **MUST** be submitted together with this application (*Soft copy*).

GDA acceptance criteria:

- Manufacturing sites inspected by NPRA previously with an acceptable GMP status for the same dosage form(s)
- Applicable for sterile and non-sterile facilities (excluding biopharmaceuticals)
- Application of BPFK-501 is submitted at least 1 year before the expiry of GMP status (3 years after the last inspection date)

13.	GMP evidence by National Pharmaceutical Regulatory Agency (NPRA) i.e. GMP certificate		
14.	Regulatory Inspection List (all on-site inspections conducted within the past three years)		
15.	Warning letter or equivalent regulatory action issued by any authority [If none, refer to (16)]		
16.	Declaration from manufacturer (on company letter head) for item 15		
17.	Product complaint and recall register for the past three years		
18.	Change Control, Deviation, Quality Risk Assessment (QRM) register for the past three years		
19.	List of products manufactured within the last 6 - 12 months for the relevant products		
20.	GDA Pre-assessment (Please refer to Annex V)		

PART F APPLICANT DECLARATION

1. I am hereby authorised by the company to make this application. I undertake to pay the non-refundable processing fee of RM 5,000 upon application and inspection fee of RM 20,000 at least one month before the foreign inspection is conducted using a banker's cheque payable to **BIRO PENGAWALAN FARMASEUTIKAL KEBANGSAAN.** [Note: Only complete application form with confirmed payment will be processed by NPRA]
2. I have read and understood the contents of the Drug Registration Guidance Document and Guidance Document Foreign GMP Inspection.
3. I hereby declare that details furnished on this form are true, accurate and complete; the supporting documents are authentic or true copies and undertake to notify NPRA, in writing, within one week of any changes in the particulars submitted in this application.
4. I understand that the final decision on performing GDA is based on the acceptance criteria stated in Part E and screening process through GMP Desktop Assessment Selection Tools (GDAST).
5. I undertake to pay all required inspection expenses which include flight ticket, accommodation, and other associated expenses (such as allowances, insurance, etc.) if inspection is required by NPRA. I shall make the payment in the form of contribution into a trust fund established under the Malaysian Ministry of Health (MOH) namely Akaun Amanah Penilaian, Pengiktirafan Akreditasi dan Pemeriksaan APB (Main Code: 886341, Sub Code: 4001) through a banker's cheque made payable to:
   Name : KETUA SETIAUSAHA KEMENTERIAN KESIHATAN MALAYSIA
   Account No : 21401360003459
6. I undertake to add more contribution to the trust fund if the expenses for the inspection are more than expected. I understand that in the event where the foreign inspection cannot be conducted, the contribution will be refunded.
7. I understand that the remainder of the contribution will be retained in the trust fund for future purposes as outlined in the *Arahan Amanah Penilaian, Pengiktirafan Akreditasi dan Pemeriksaan APB*.
8. I hereby confirm that the foreign manufacturer has agreed and is ready to be inspected by NPRA, Malaysia.
9. I undertake to ensure that the medicinal products are manufactured in accordance with the GMP guidelines as determined by the NPRA.
10. I confirm that the new products to be registered in Malaysia are licensed/certified for sale in the country of manufacture/product owner.

11. I undertake to ensure that application for new product registration will be submitted to Centre for Product and Cosmetic Evaluation within 90 days after submission of this application.
12. I have read and agree to the terms and conditions stated in the current Guidance Document Foreign GMP Inspection and accept the decision by NPRA regarding this application.

(Signature)	(Date)	(Company Stamp)

(Name & Designation)

PART G ADDITIONAL DECLARATION *(only applicable if the facility is manufacturing registered products for other PRH)*

I confirm that:
1. The information stated in Annex IV is true, complete and accurate.
2. All the other PRH are aware and understand that the outcome of this GMP inspection may affect the registration status of all the products manufactured at this facility.

(Signature)	(Date)	(Company Stamp)

(Name & Designation)

ANNEX I
(Details of new products to be registered in Malaysia)

No.	Product Name (Reference No. - If any)	Active Ingredient	Dosage Form	The product is licensed/certified for sale in the country of manufacture/product owner (Yes/No)

ANNEX II
(Details of existing registered products for renewal of product registration)

No.	Product Name	Registration Number	Registration Period

ANNEX III
(Details of existing registered products for change of manufacturing site)

No.	Product Name	Registration Number	Registration Period	Current Manufacturer Name & Address

ANNEX IV
(Details of product registration holder and their respective registered products)

No.	Product Registration Holder	Product Name	Registration Number

ANNEX V
(GDA Pre-assessment)

No.	GDA Parameters of Pre-assessment	Please (✓) only one
1.	Number of employees.	☐ more than 150 employees ☐ 50 – 150 employees ☐ less than 50 employees
2.	The maximum number of different manufacturing/distribution process.	☐ More than 7 processes ☐ 4 – 6 processes ☐ 1 – 3 processes
3.	The level of dedication of equipment and facilities that is in place at the site (for eg: No dedication, partial dedication, full dedication).	☐ No dedication ☐ Partial dedication ☐ Full dedication
4.	Involvement of Real Time Release Testing (RTRT)	☐ Real Time Release Testing (RTRT) activities ☐ No Real Time Release Testing (RTRT) activities
5.	Complexity of products manufactured (for eg: low concentration/high potency, sustained release, normal product, biological).	☐ Complex product type (low concentration / high potency, sustained release) ☐ Normal product ☐ Repacking only
6.	The maximum number of unit operations in a non-sterile manufacturing process (e.g: dispensing, mixing, granulate, drying, coating, blister, packing, testing, IPQC)	☐ More than 6 processes ☐ 4 – 5 processes ☐ Less than 3 processes
7.	Involvement of repackaging activities (for eg: primary, secondary).	☐ Packing of products for clinical trials, primary repack ☐ Secondary repack ☐ No repack activities
8.	Engagement of sub-contract activities (for eg: contract lab, transport). *Can tick more than one*	☐ Subcontracting of processes / stages of manufacturing, primary packaging and QC ☐ Subcontracting services: contract lab, transport etc. ☐ No subcontracting

9.	The maximum number of components in a product, include final pack (for eg: vial, diluent, syringe, leaflet).	☐ More than 4 components ☐ 2 – 3 components ☐ 1 component (primary packaging)
10.	Any product with specific storage requirement. *Can tick more than one*	☐ Cold chain, shorter shelf life ☐ Specified storage requirement ☐ No specific storage requirement

*Please refer to Guidance Document for Foreign Inspection (Appendix 3) for the description of the parameters.