

FOREIGN GMP INSPECTION APPLICATION FORM



National Pharmaceutical Regulatory Agency
Ministry of Health Malaysia
 Lot 36, Jalan Universiti, 46200 Petaling Jaya, Selangor.
 Tel. No. : 03-78835400
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 Website : <http://npra.moh.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: _____

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		
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 (<i>preferably</i> GMP certificate/report issued by a PIC/S Participating Authority)		

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 undertake to pay all required inspection expenses which include flight ticket, accommodation, and other associated expenses (such as allowances, insurance, etc.). 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	
5.	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.	
6.	I understand that the remainder of the contribution will be retained in the trust fund for future purposes as outlined in the <i>Arahan Amanah Penilaian, Pengiktirafan Akreditasi dan Pemeriksaan APB</i> .	
7.	I hereby confirm that the foreign manufacturer has agreed and is ready to be inspected by NPRA, Malaysia.	
8.	I undertake to ensure that the medicinal products are manufactured in accordance with the current PIC/S Guide to Good Manufacturing Practice for Medicinal Products.	
9.	I confirm that the new products to be registered in Malaysia are licensed/certified for sale in the country of manufacture/product owner.	
10.	I undertake to ensure that application for new product registration will be submitted to Centre for Product Registration within 90 days after submission of this application.	
11.	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 (<i>only applicable if the facility is manufacturing registered products for other PRH</i>)	
I confirm that:		
1.	The information stated in Annex IV I 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)		

FOREIGN GMP INSPECTION APPLICATION FORM**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