GMP DESKTOP ASSESSMENT APPLICATION FORM

National Pharmaceutical Regulatory Agency
Ministry of Health Malaysia
Lot 36, Jalan Profesor Diraja Ungku Aziz (Jalan Universiti),
46200 Petaling Jaya, Selangor.
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For Official Use Only	
Application No. (GDA)	
Application No. (FI)	
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:	

PART C LIST OF SUPPORTING DOCUMENTS

(The following documents **MUST** be submitted together with this application. However, this is non-exhaustive list; other documents may be requested as evaluation progress.)

		Tick (√) if provided	For Official Use Only
1.	Current Certificate of Outsourced Laboratory (If applicable)		
2.	Current Manufacturing Licence		
3.	Most recent GMP Inspection Report issued by local authority agency		
4.	Corrective Action and Prevention Action (CAPA) report for inspection stated in (3) above		
5.	Full GMP Inspection Report(s) for on-site inspection(s) performed by PIC/S Participating Authority (related report)		
6.	Quality Manual (or equivalent documentation)		
7.	One sample investigation report for product complaint and recall (related complaints and recall)		
8.	Latest Product Quality Review report (related products)		
9.	Process Validation protocol and report (related products)		
10.	Batch Manufacturing/Packaging Record (BMR/BPR) for batches produced within the last 6-12 months (related products)		

PART D APPLICANT DECLARATION

1. I am hereby authorised by the company to make this application.
2. I understand that Foreign GMP Inspection by NPRA will be conducted if the evaluation is found to be unsatisfactory.
3. I hereby declare that details furnished on this form are true, accurate and complete; the supporting documents are authentic or true copies.

(Signature) (Date) (Company Stamp)

(Name & Designation)