

## HEALTH SCIENCES AUTHORITY

### NOTES ON APPLICATION FORM TO REQUEST FOR GMP EVIDENCE EVALUATION [OR GMP DOCUMENTARY EVIDENCE VERIFICATION (GMP DEVA)]

This form may take you 20 minutes to fill in.

You will need the following information to fill in the form:

- a) Valid documentary evidence of GMP conformance. The document should be translated into English if they are in other foreign language. If valid period is not stated on the Documentary Evidence of GMP conformance submitted, the evidence should not be older than one year at time of submission.
- b) Details of overseas manufacturing site.

1. This application form is for requesting the GMP evidence evaluation (also known as GMP Documentary Evidence Verification (GMP DEVA)]. The completed application form must be submitted together with the GMP evidence to the Therapeutic Products Branch (TPB) at the address listed at paragraph 6.
2. The application should be made by a Singapore registered firm/company who should authorize a responsible person (e.g. Managing Director, Pharmacist, Regulatory Personnel) to request for GMP evidence evaluation. This person must have an Account and Corporate Regulatory Authority of Singapore (ACRA) account.
3. All entries shall be made in English. All the information required in the form should be supplied as far as they are applicable. Incomplete information may cause unnecessary delay in processing the application or rejection of the application.
4. If the space provided in the application form is insufficient, a separate sheet (A4 size) may be used. However, proper enclosure numbers should be made at the top right hand corner of such extension sheets.
5. All enclosures should be listed in the "List of Enclosures" provided, with the enclosure numbers corresponding to those in the columns of the application form.
6. The complete application form and GMP evidence must be sent to:

**Therapeutic Products Branch (TPB)**  
Pre-marketing Division  
Health Products Regulation Group  
Health Sciences Authority  
11 Biopolis Way #11-03 Helios  
Singapore 138667

7. Mode of Payment:

**Please note that there will be no refund of any payment made in relation to applications submitted.**

The mode of payment available is as follows:

- Non-GIRO: eNETS (Credit/Debit Card)
- GIRO

Payment by GIRO requires pre-registration. The [GIRO application form](#) is required to be submitted by post to the HSA Finance Department. The correspondence address can be found in the application form. The registration process will take around 3 to 4 weeks after the submission of the application form.

8. Useful links:

For more details on Services Charges, please refer to:

[https://www.hsa.gov.sg/content/hsa/en/Health\\_Products\\_Regulation/Manufacturing\\_Importation\\_Distribution/Overview/Audit\\_and\\_Licensing\\_of\\_Manufacturers/GMP\\_Conformity\\_Assessment/Service\\_Charges.html](https://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Manufacturing_Importation_Distribution/Overview/Audit_and_Licensing_of_Manufacturers/GMP_Conformity_Assessment/Service_Charges.html)

For more details on GMP Conformity Assessment of an Overseas Manufacturer, please refer to:

[https://www.hsa.gov.sg/content/hsa/en/Health\\_Products\\_Regulation/Manufacturing\\_Importation\\_Distribution/Overview/Audit\\_and\\_Licensing\\_of\\_Manufacturers/GMP\\_Conformity\\_Assessment/Guidance\\_Documents.htm](https://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Manufacturing_Importation_Distribution/Overview/Audit_and_Licensing_of_Manufacturers/GMP_Conformity_Assessment/Guidance_Documents.htm)

For information on Guidance Documents for Industry and Applicants, please refer to:

[http://www.hsa.gov.sg/content/hsa/en/Health\\_Products\\_Regulation/Manufacturing\\_Importation\\_Distribution/Overview/Guidance\\_Documents\\_for\\_Industry\\_and\\_Applicants.html](http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Manufacturing_Importation_Distribution/Overview/Guidance_Documents_for_Industry_and_Applicants.html)

9. For details on listing of PIC/S Members, please refer to PIC/S PARTICIPATING AUTHORITIES at:

<http://www.picscheme.org>

**HEALTH SCIENCES AUTHORITY**

**REPUBLIC OF SINGAPORE**

**APPLICATION FORM TO REQUEST FOR  
GMP EVIDENCE EVALUATION  
[OR GMP DOCUMENTARY EVIDENCE VERIFICATION (GMP DEVA)]**

Please read the Notes On Application Form To Request For GMP Evidence Evaluation Or GMP Documentary Evidence Verification (GMP DEVA) before filling up this form.

*\*Delete where applicable*

*Tick where applicable*

**[A] APPLICANT INFORMATION**

A1. Name of company: .....  
(IN BLOCK LETTERS)

.....

Address: .....

.....

.....

Tel No.: ..... Fax No.: .....

Company Registration No.: .....  
(Enclose photocopy of certificate)

A2. Person authorised to submit the application on behalf of the company

Name (\*Mr/Ms/Mrs/Mdm/Dr): .....  
(IN BLOCK LETTERS)

\*NRIC (Pink/Blue)/Passport No./FIN No.: .....

Designation: .....

Tel No.: ..... Fax No.: .....

Handphone No.: .....

Official Email Address: .....

**[B] OVERSEAS MANUFACTURER INFORMATION**

Name of Manufacturer: .....  
 (IN BLOCK LETTERS)

.....

Manufacturer's Site Address: .....

.....

.....

Tel No.: ..... Fax No.: .....

**[C] PHARMACEUTICAL DOSAGE FORM OF PRODUCTS MANUFACTURED / ASSEMBLED BY THE OVERSEAS MANUFACTURER**

	Manufacture	Primary Assembly	Secondary Assembly
<input type="checkbox"/> Injection	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Admixtures for intravenous infusion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Reconstituted cytotoxic preparations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Total parenteral nutrition preparations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Implants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Sterile powder for injection	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Sterile non injectable liquid preparation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Liquid preparations for inhalation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Sterile semi-solid preparations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Sterile powder for irrigations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Others (please specify)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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	Manufacture	Primary Assembly	Secondary Assembly
<input type="checkbox"/> Sterile powder for topical application	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Intraocular drug delivery systems	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Sterile strips	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Oral liquid preparations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Tablets for oral administration	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Soft Capsules	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Hard Capsules	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Pills	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Powders and granules for oral liquid preparations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Oral powder and granules	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Pastille	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> External liquid preparations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

<input type="checkbox"/> Ear drops	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Nasal solution	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Foams	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Heamodialysis solution	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Non-sterile semi-solid preparations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Non sterile powders for topical applications	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Powder for haemodialysis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Powder Preparations for inhalation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Suppositories	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Pessaries	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Medicated soap bars	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Transdermal patches	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Medicated gums	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Tablet for external administration	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Beads	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Medicated Tampons	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Solution for contact lens	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Dry powder inhalers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Medicinal gases	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Others (please specify):	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**[D] SUPPORTING DOCUMENTS**

Please submit a valid GMP evidence that is issued by a PIC/S member authority and provide the details of the document/s submitted in the LIST OF ENCLOSURES.

**[E] DECLARATION**

1. I have been duly authorised by my company to submit this application on its behalf.
2. I hereby confirm that the information submitted in this application is true and accurate.
3. I understand that if any information submitted in this application is found to be false or inaccurate, I and my company may be liable to prosecution.

Name of Applicant : .....

Signature : .....

Date : .....

