APPLICATION FOR GOOD DISTRIBUTION PRACTICE (GDP) CERTIFICATE

Please note that companies must register with Client Registration and Identification Service (CRIS) and applicants must have valid CRIS user rights in order to be able to submit applications on behalf of the company via apply@prism. For more information on CRIS, please refer to https://www.hsa.gov.sg/e-services/cris

1. This online form may take an average of 10 minutes to fill in.

   The time taken varies depending on the number and sizes of the file attachments, configurations of your computer and network system, internet performance etc. Please note that the time stated above excludes time taken for preparatory work in relation to filling the online form (e.g. scanning documents for file attachments).

2. The following information/item(s) are required to complete the form:
   (A) **Current layout plan for the premises**, specifying the storage area(s) (Mandatory)
       The layout floor plan will need to have the following information:
       (i) The full address of the warehouse
       (ii) The dimensions (length and width) of the warehouse
       (iii) Indication of various storage areas, e.g. receiving bay, quarantined product area, released product area, rejected product area, returned product area, recalled product area, outgoing staging area, etc.
   (B) **Good Distribution Practices Standard Operating Procedures**
   (C) **Good Distribution Practices Records or Recording Templates**
   (D) **Site Master File**
   (E) Other supporting Documents (if any)

3. The applicant will require a Corppass* or Singpass before he/she can login to PRISM to retrieve the application form. A person who drafts an application on behalf of his/her company and is not a Singaporean Citizen, Permanent Resident or Employment Pass holder can apply for a HSA PIN to login to PRISM. The Corppass* / Singpass or HSA PIN login is necessary for authentication and authorisation purposes.

   Note: From 11 April 2021, the login process for Corppass has been changed to verify the user's identity via Singpass first before accessing and transacting with government digital services. While Singpass is used for logins, Corppass will continue to be the authorisation system for access to government digital services.

   For more information on Corppass, please refer to http://www.corppass.gov.sg/

4. Mode of payment

   Payment is not required at the point of application submission and may be advised later following preliminary assessment of the application. Where payment is requested, the mode of payment available is as follows:

   - GIRO (Preferred mode of payment)

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

   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.

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

Application Form

Fields marked with an asterisk * are mandatory.

Part 1. GDP Certificate Particulars

The section requires applicant to choose the following options:

A) New GDP Certificate for companies that have been audited or to be audited for GDP/GMP compliance for licence/certificate applications pending approval

B) New GDP Certificate for companies not audited for GDP/GMP compliance

For Option A), this section requires applicant to furnish these information:

(1) Select Licence type – the licence that your company is holding/applying that would require a GDP audit.

(2) Input Licence No. or Application No. of the above licence type.

(3) Select the Categories of products which the scope of GDP certificate will apply. [Note: GDP certificate is not applicable to 'Active Pharmaceutical Ingredients (API)', 'Chinese Proprietary Medicines' and 'Medicinal Products as Clinical Research Materials (Investigational Medicinal Products)'. Please do not select these products.)

(4) Click **'Next'** button to proceed to **Part 2. Company Particulars** section.

1. GDP Certificate Particulars	
⦿ New GDP Certificate for companies that have been audited or to be audited for GDP/GMP compliance for licence/certificate applications pending approval	
○ New GDP Certificate for companies not audited for GDP/GMP compliance	
1.1 GDP Certificate Particulars : *	The company should be holding or applying for any one or more of the following licence.
	Please select one of the following licence type
	○ GMP Certificate
	○ Import licence for CPM
	○ Importer's Licence for Therapeutic Products
	○ Manufacture licence for CPM
	○ Manufacturer's Licence for Therapeutic Products
	○ Wholesale dealer licence for CPM
	○ Wholesaler's Licence for Therapeutic Products
	Please provide the information in only one of the fields below.
	1.1.1 Licence No. : [ ]
	1.1.2 Application No. : [ ]
1.2 Please indicate the categories of products which the scope of GDP certificate will apply : *	
☐ Active Pharmaceutical Ingredients (API) ☐ Chinese Proprietary Medicines	☐ Medicinal Products as Clinical Research Materials (Investigational Medicinal Products)
☐ Therapeutic Products	☐ Therapeutic Products as Clinical Research Materials (Investigational Medicinal Products)

Next

For Option B), this section requires applicant to furnish these information:

(1) Select Business Activity.

(2) Select the Categories of products which the scope of GDP certificate will apply. [Note: GDP certificate is not applicable to 'Active Pharmaceutical Ingredients (API)', 'Chinese Proprietary

Medicines' and 'Medicinal Products as Clinical Research Materials (Investigational Medicinal Products)'. Please do not select these products.)

(3) Click **'Next'** button to proceed to **Part 2. Company Particulars** section.

1. GDP Certificate Particulars

○ New GDP Certificate for companies that have been audited or to be audited for GDP/GMP compliance for licence/certificate applications pending approval

⊙ New GDP Certificate for companies not audited for GDP/GMP compliance

1.1 GDP Certificate Particulars *

1.1.1 Business Activity *	Select One ∨

1.1.2 Categories of Products Involved *

1.2 Please indicate the categories of products which the scope of GDP certificate will apply: *

☐ Active Pharmaceutical Ingredients (API)	☐ Chinese Proprietary Medicines	☐ Medicinal Products as Clinical Research Materials (Investigational Medicinal Products)
☐ Therapeutic Products	☐ Therapeutic Products as Clinical Research Materials (Investigational Medicinal Products)	

Next

Part 2: Company Particulars

This section requires the applicant to verify and fill in any other relevant information relating to the company.

(1) Company details such as **Name** and **Address** will be pre-populated based on the registered CRIS records.

If you need to make changes to this information, please submit the changes via the **"Amend Company Information"** module under the amend@prism on PRISM e-Service webpage.

(2) Input the **Telephone** and/or **Fax** number.

(3) Indicate if the Billing Address is the same as the Company Address.

If the Billing Address is not the same as **Company Address**, please fill in the **Postal Code** field and click **'Retrieve Address'** button. The **Block/House No**, **Street Name** and **Building Name** will be populated.

(4) Fill in the **Level-Unit** field and any additional detail relating to the company in the **Other Address Details** field (if applicable)

(5) Click **'Next'** button to proceed to **Part 3. Applicant Particulars** section.

2. Company Particulars			
2.1 Name : *			
2.2 Location Code :	1		
2.3 Company Address			
2.3.1 Address Type : *	Local		
2.3.2 Postal Code : *			
2.3.3 Block / House No :		2.3.4 Level – Unit :	# –
2.3.5 Street Name :			
2.3.6 Building Name :			
2.3.7 Country :	SINGAPORE		
2.4 Tel : *		2.5 Fax : Your Fax No. is necessary for our future correspondence	
2.6 Is Billing Address the same as the Company Address ? *		⦿ Yes	○ No
2.8 Unique Entity No.(UEN) :			

Part 3. Applicant Particulars

This section allows the input of applicant particulars.

(1) Fill in **Name, ID No** and **Designation**.

(2) Fill in the **Contact Details** and **Preferred Contact Mode**.

(3) Click **'Next'** button to go to the **Part 4. Store Particulars** section.

3. Applicant Particulars			
3.1 Name: *		(as in NRIC/FIN)	
3.2 NRIC/FIN: *		(Example: S1234567A, F1234567A)	
3.3 Designation: *			
3.4 Contact Details			
3.4.1 Tel: *		3.4.2 Fax:	
3.4.3 Handphone:		3.4.4 Pager:	
3.4.5 Email:			
3.5 Preferences			
3.5.1 Preferred Contact Mode: *	○Email ○Fax ○SMS		
	(Please ensure that the relevant contact details above is entered for your preferred contact mode. Please note that this preferred contact mode is the mode which you will receive the final notification of this application. During the course of this application, you will receive our input requests (i.e. queries), if any, via email if you have indicated your email address above, regardless of your selected preferred contact mode.)		

Previous Next Reset

Part 4. Store Particulars

This section allows the input of store particulars.

Add store(s)

(1) Fill in the **Postal Code** and click **'Retrieve Address'** button. Details such as **Block/House No**, **Street Name** and **Building Name** will be populated.

(2) Fill in the **Level-Unit** field and any additional detail relating to the store in the **Other Address Detail** field (if applicable).

(3) Fill in the **Storage Condition of Store.**

(4) Click **'Add Store'** button.

The screen will be automatically refreshed and the refreshed page will display the details of the store particulars that were added.

(5) Repeat Step (1) to (4) to add other store(s).

Addresses of all stores where the products will be stored should be provided.

(6) Click **'Next'** button to proceed to **Part 5. Other Products Stored in the Same Premises** section.

Update store(s)

(1) Click on the store to be updated from the **Store List** table.

(2) Make the required update.

(3) Click **'Update Store'** button.

Remove store(s)

(1) Click on the checkbox adjacent to the store from the **Store List** table.

(2) Click **'Remove'** button to delete the store.

Part 5. Other Products Stored in Same Premises

The section requires the applicant to furnish this information (as necessary).

(1) Select the Categories of Products stored in the same premises

Important note: If "Others" is chosen, please state if the products contain hazardous or toxic substances.

(2) Click **'Next'** button to proceed to **Part 6. Supporting Documents** section.

5. Other Products Stored in Same Premise		
5.1 Categories of Products : *		
☐ Cytotoxics	☐ Biologics (including vaccines)	☐ Cold Items (Materials required to be stored under 8 degree Celsius)
☐ Others	☐ Not Applicable	
5.2 If Others, please state whether contain hazardous or toxic substances :		

Part 6. Supporting Documents

This section allows the attachment of the supporting documents for the application.

Add Attachment

(1) Click **'Browse'** button to select the document to be attached into this application and click **'Open'** button in the pop-up window.

(2) Click **'Attach Files'** button to attach the selected document into this application.

(3) Fill in the remarks in the **'Remark'** field with regards to the document attached (if required).

(4) Repeat Step (1) to (3) to add other documents. All supporting documents should be provided.

(5) Click **'Next'** button to proceed to **Part 7. Confirmation and Declaration** section.

Remove Attachment

(1) Click on the checkbox adjacent to the attachment(s) from the **List of Attachments** Table.

(2) Click **'Remove'** button to delete the document.

The file extensions, which are acceptable and supported for attachments, are:

tif (Black & White)	jpg (graphics files)
pdf (Adobe Acrobat files)	doc (Microsoft Word files)
xls (Microsoft Excel files)	ppt (Microsoft PowerPoint files)
avi (audio visual, if required)	mpeg (audio visual, if required)

Note: If the file size is too big (estimate about 2MB and above), the uploading time may be longer.

Part 7. Confirmation and Declaration

This section shows the information provided in all sections of the Application Form.

(1) Applicant is required to confirm the information provided in all sections are correct and click **'Validate'** button.

*(Note: Applicant may click **'Save'** button to save a copy of the draft application if he/she wishes to complete the application at a later time.)*

(2) Once validation is successful, applicant is advised to read through the declaration carefully before accepting to undertake the conditions.

(3) Click **'Submit'** button to submit the application.

Declaration

1.   I, on behalf of my company, confirm that the information submitted in this application is true and accurate.

Accept ○ Decline ○

Payment Advice

No payment is required at this point of application. Payment may be advised later.

Previous | Validate | Submit | Reset

Fill in the application form | Guideline

1. CDP Certificate Particulars   4. Store Particulars   7. Confirmation
2. Company Particulars   5. Other Products Stored in Same Premise
3. Applicant Particulars   6. Supporting Attachments

Special Symbol
Attach   Save

Previous

Acknowledgment

This section acknowledges that the application has been submitted to HSA for processing. An application number will be generated for the successful application submitted.

Applicant may wish to print a copy of this acknowledgement page or take note of the application number for ease of reference. Applicant may provide the application number if he/she wishes to communicate with HSA.

PQ1001 APPLICATION FOR A

Acknowledgement

Your application have been successfully submitted

Please note that your application number is 1600797N

Client Code   :
Licensee
Name   :
Amount   :

Show Printer-Friendly version

Note: Applicant can click **'Show Printer-Friendly version'** *button to print or view the application.*

Input Request

This section illustrates how applicant can respond to the Input Request raised to the application.

Input Request arises when the reviewing HSA officer requires further clarification from the applicant regarding the Application Form.

A notification will be sent to the applicant to inform the applicant to log on to track@prism to make the necessary changes.

Input request can be classified as Primary or Secondary:

- Primary Input Request requires changes to be made directly in the application form.
- Secondary Input Request requires applicant's explanation to certain matters pertaining to the application form.

Responding to Primary Input Request

(1) Log on to track@prism -> select the correct Application / Submission Type -> select Licence Type -> select Enquiry Type -> key in the Application No. -> click **'Search'** button.

(2) When the search result is displayed, click the 'Application No.'

(3) The webpage will display the application form as per previously submitted.

(4) Proceed to make the necessary changes for the section(s) that required amendment, click **'Save'** button and submit the revised application form.

Responding to Secondary Input Request

(1) Log on to track@prism -> select the correct Application / Submission Type -> select Licence Type -> select Enquiry Type -> key in the Application No. -> click **'Search'** button.

PZ0951 TRACK@PRISM

Important Notes:
For HSA CRIS registered companies, user has to be authorised with the appropriate access rights via CRIS management module to access the required eservices.

General Search

Enter Transaction No or Application/Submission No for fast and exact matched look-up

Application/Submission Type *	New Application/Submission ▾
Licence/Permit/Certificate/Listing/Notification/Registration Type *	▾
Enquiry Type *	Input Request ▾
Transaction No.	
Application/Submission No.	
Licence/Permit/Certificate/Listing/Notification/Registration No.	
Product Name.	
Submission Date (dd/mm/yyyy)	To
Last Update Date (dd/mm/yyyy)	To

[Search] [Reset]

(2) When the search result is displayed, click under the **'HSA Input Request'** to view the comments left by the HSA officer and the necessary action to be taken with regards to the Application.

Please click here to extend your draft
Please do not access the record using the new window via right mouse click.

1 Matching Record(s)   Page 1 Of 1 [First] | [Previous] | [Next] | [Last]

Amendment for _____ (Input Request)

S/No	Application No	Transaction No	Licence/Registration No	Product Name	Application/Submission Status	Date Required	Last Updated Date	HSA Input Request
1	1600783J	T1601374K	MCPH1600024	NA	Input Request	11/07/2016	04/07/2016	Click here for Secondary IR (04/07/2016)

Please do not access the record using the new window via right mouse click.

1 Matching Record(s)   Page 1 Of 1 [First] | [Previous] | [Next] | [Last]

Note:
Application resubmission is required for Primary IR but not for Secondary IR.
For Secondary IR, please response with your comments accordingly or else it will not be considered as submitted.

(3) Fill in any response in the text box under 'Applicant's Response (if any)' and click **'Submit'** button.

Input Request List - Internet Explorer

https://www-uat.hsa.gov.sg/prism/common/InputReqActList/list.do?action=list&irType=S&app_no=1600771U&eService=130&NOTI

INPUT REQUEST LIST (SECONDARY)

Application No : 1600771U

Please reply with comments for each item in the action list and submit this secondary input request.
Please note that resubmission of the application is not required.

1 Records

Action List

SN	Action	Due Date	Applicant's Response (if any)
1.	For Secondary Screenshot	15/07/2016	

[Submit] [Cancel]

Other useful information

1. Applicant may check on the status of the application upon submission at track@prism.

2. Kindly contact the HSA Helpdesk if any technical issues (IT problems) during the application submission are encountered.

   HSA HelpDesk
   Hotline : 6776 0168 (from 7:00 am to midnight daily)
   Email   : helpdesk@hsahelp.gov.sg

3. For general enquiries or questions related to licences and certificates of manufacturers, importers and wholesalers, please contact the Audit and Licensing Division at Tel: 6866 1111.