

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

http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/CRIS.htm

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).

The recommended computer and network configurations can be found at

http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/PRISM_e-services/system-requirements-for-prism.html

2. The following information/item(s) are required to complete the form:
 - **Current layout plan for the premises**, specifying the storage area(s) (Mandatory)
 - **Good Distribution Practices Standard Operating Procedures**
 - **Good Distribution Practices Records or Recording Templates**
 - **Site Master File**
 - 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.

** During the transition period from now to 31 August 2018, both SingPass and CorpPass can be used to login to PRISM. However, as CorpPass will eventually replace SingPass for business transactions with the government, companies / business entities are encouraged to familiarise themselves with the usage of CorpPass.*

** With effect from 1 September 2018, the applicant will require a CorpPass before he/she can login to PRISM.*

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: Cheque (made payable to 'Health Sciences Authority')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.

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

1. GDP Certificate Particulars	
<input checked="" type="radio"/> New GDP Certificate for companies that have been audited or to be audited for GDP/GMP compliance for licence/certificate applications pending approval	
<input type="radio"/> 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
	<input type="radio"/> GMP Certificate
	<input type="radio"/> Import licence for CPM
	<input type="radio"/> Importer's Licence for Therapeutic Products
	<input type="radio"/> Manufacture licence for CPM
	<input type="radio"/> Manufacturer's Licence for Therapeutic Products
	<input type="radio"/> Wholesale dealer licence for CPM
	<input type="radio"/> Wholesaler's Licence for Therapeutic Products
	Please provide the information in only one of the fields below.
	1.1.1 Licence No. : <input type="text"/>
	1.1.2 Application No. : <input type="text"/>
1.2 Please indicate the categories of products which the scope of GDP certificate will apply : *	
<input type="checkbox"/> Active Pharmaceutical Ingredients (API)	<input type="checkbox"/> Chinese Proprietary Medicines
<input type="checkbox"/> Therapeutic Products	<input type="checkbox"/> Therapeutic Products as Clinical Research Materials (Investigational Medicinal Products)
	<input type="checkbox"/> Medicinal 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.
- (3) Click '**Next**' button to proceed to **Part 2. Company Particulars** section.

1. GDP Certificate Particulars		
<input type="radio"/> New GDP Certificate for companies that have been audited or to be audited for GDP/GMP compliance for licence/certificate applications pending approval		
<input checked="" type="radio"/> New GDP Certificate for companies not audited for GDP/GMP compliance		
1.1 GDP Certificate Particulars *		
1.1.1 Business Activity *	<input type="text" value="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: *		
<input type="checkbox"/> Active Pharmaceutical Ingredients (API)	<input type="checkbox"/> Chinese Proprietary Medicines	<input type="checkbox"/> Medicinal Products as Clinical Research Materials (Investigational Medicinal Products)
<input type="checkbox"/> Therapeutic Products	<input type="checkbox"/> 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 : *	<input type="text"/>		
2.2 Location Code :	<input type="text" value="1"/>		
2.3 Company Address			
2.3.1 Address Type : *	<input type="text" value="Local"/>		
2.3.2 Postal Code : *	<input type="text"/>		
2.3.3 Block / House No :	<input type="text"/>	2.3.4 Level – Unit :	# - <input type="text"/>
2.3.5 Street Name :	<input type="text"/>		
2.3.6 Building Name :	<input type="text"/>		
2.3.7 Country :	<input type="text" value="SINGAPORE"/>		
2.4 Tel : *	<input type="text"/>	2.5 Fax :	<input type="text"/>
		Your Fax No. is necessary for our future correspondence	
2.6 Is Billing Address the same as the Company Address ? *	<input checked="" type="radio"/> Yes	<input type="radio"/> No	
2.8 Unique Entity No.(UEN) :	<input type="text"/>		

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: *	<input type="text"/>	(as in NRIC/FIN)	
3.2 NRIC/FIN: *	<input type="text"/>	(Example: S1234567A, F1234567A)	
3.3 Designation: *	<input type="text"/>		
3.4 Contact Details			
3.4.1 Tel: *	<input type="text"/>	3.4.2 Fax:	<input type="text"/>
3.4.3 Handphone:	<input type="text"/>	3.4.4 Pager:	<input type="text"/>
3.4.5 Email:	<input type="text"/>		
3.5 Preferences			
3.5.1 Preferred Contact Mode: *	<input type="radio"/> Email <input type="radio"/> Fax <input type="radio"/> SMS <small>(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.)</small>		

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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.

4. Store Particulars

4.1 Store Address

4.1.1 Address Type : * Local

4.1.2 Postal Code : *

4.1.3 Block / House No : 4.1.4 Level - Unit : # -

4.1.5 Street Name :

4.1.6 Building Name :

4.1.7 Other Address Details : (To Input specific identification number for the warehouse which is not reflected above, e.g. for address of 1, ABC Road, #01-01, XYZ Building, Annex A, SINGAPORE 123456, 'Annex A' can be entered in the 'Other Address Details')

4.1.8 Country : SINGAPORE

4.2 Storage Condition of Store

4.2.1 Temperature : * 15°C to 20°C (Room Temperature)
 8°C to 15°C (Cool)
 2°C to 8°C (Refrigerate, Do not freeze)
 -10°C to -20°C (Freeze)
 Others

4.2.2 Relative Humidity: Min % - Max %

4.2.3 Approved By:

SN	Select All	Store List
1	<input type="checkbox"/>	

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 : *

<input type="checkbox"/> Cytotoxics	<input type="checkbox"/> Biologics (including vaccines)	<input type="checkbox"/> Cold Items (Materials required to be stored under 8 degree Celsius)
<input type="checkbox"/> Others	<input type="checkbox"/> 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.

6. Supporting Documents

To add an attachment, type in the path or hit the browse button. Then **hit the Attach Files button to save the attachment to the list below.**
Please click [here](#) for guideline on document attachment.

Documents		
6.1 Store Layout Plan : *		Browse...
6.2 Good Distribution Practices Standard Operating Procedures :		Browse...
6.3 Good Distribution Practices Records :		Browse...
6.4 Site Master File :		Browse...
6.5 CD Submission :		Browse...
6.6 Other Supporting Documents :		Browse...

Attach Files

Note :
Please fill up the template ([download here](#)) if you are sending the supporting attachment(s) via CD, after which you are required to save a copy and attach it under "CD Submission."

Select All to delete all attachment records

Sn	☐	Attachment Name	Attachment Type	Size (Kb)	Remarks
1	<input type="checkbox"/>		Store Layout Plan	375	
2	<input type="checkbox"/>			1736	

To remove an attachment, click on the checkbox. Then hit the Remove button to remove the attachment from the list.

Remove

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Next
Reset

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.

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Fill in the application form [Guideline](#)

1. CDP Certificate Particulars 2. Company Particulars 3. Applicant Particulars	4. Store Particulars 5. Other Products Stored In Same Premise 6. Supporting Attachments	7. Confirmation	<div style="text-align: right;"> Special Symbol Attach Save </div>
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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.

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 *

Licence/Permit/Certificate/Listing/Notification/Registration Type *

Enquiry Type *

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

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

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]

New Application/Submission for [REDACTED] (Input Request)							
S/No	Application No	Transaction No	Product Name	Application/Submission Status	Date Required	Last Updated Date	HSA Input Request
1	1600670D	T1601220K	NA	Input Request	22/06/2016	14/06/2016	Click here for Primary IR (15/06/2016)

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

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- (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 services.

General Search

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

Application/Submission Type *

Licence/Permit/Certificate/Listing/Notification/Registration Type *

Enquiry Type *

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

- (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.

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1 Matching Record(s)

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.

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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

SN	Action	Due Date	Applicant's Response (if any)
1.	For Secondary Screenshot	15/07/2016	<input type="text"/>

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)

Fax : 6872 3054

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 or write to <https://crm.hsa.gov.sg/event/feedback.aspx>