NEW APPLICATION FOR A LICENCE TO MANUFACTURE/ASSEMBLE CHINESE PROPRIETARY MEDICINE (CPM)

You may wish to print a copy of this application guide for easy reference before proceeding with the application submission.

Please also note that companies must register with CRIS and applicants must have valid CRIS user rights in order to be able to submit applications on behalf of the company via PRISM@HSA.

For information and application for CRIS account, you can click here. For enquiry relating to CRIS, you can contact us at HSA_CRIS@hsa.gov.sg.

1. The online form is estimated to take an average of 15 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. The recommended computer and network configurations are as described at http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/PRISM_e-services/system-requirements-for-prism.html.

   Please note that the time stated above excludes the preparatory work in relation to filling the online form (e.g. scanning documents for file attachments).

2. You may need the following information/item(s) to fill the form:
   - Site Master File (This is a mandatory requirement and scanned copy of the document can be submitted as attachment to the application.) Please note that the Site Master File should be prepared in accordance with the PIC/S Explanatory Notes for Pharmaceutical Manufacturers on the Preparation of a Site Master File which is available from HSA website at http://www.hsa.gov.sg.
   - Certificate of Accreditation of the contract testing laboratory, if any
   - Letter of approval issued by the agency/institution that approves the use of the premises for the manufacturing and storage of health products, if applicable
   - Details of the dosage forms and products manufactured and/or assembled. Please also indicate if your company is acting as a contractor acceptor (i.e. manufactures partially/wholly for others) for these products.

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, please refer to http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/CRIS_Updates.html

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

For more information on HSA PIN, please refer to
http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/HSA_PIN.html

4. Mode of payment

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

The mode of payment available is as follows:

- Non-GIRO: eNETS (Credit/Debit Card)
- GIRO (Preferred mode of payment)

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

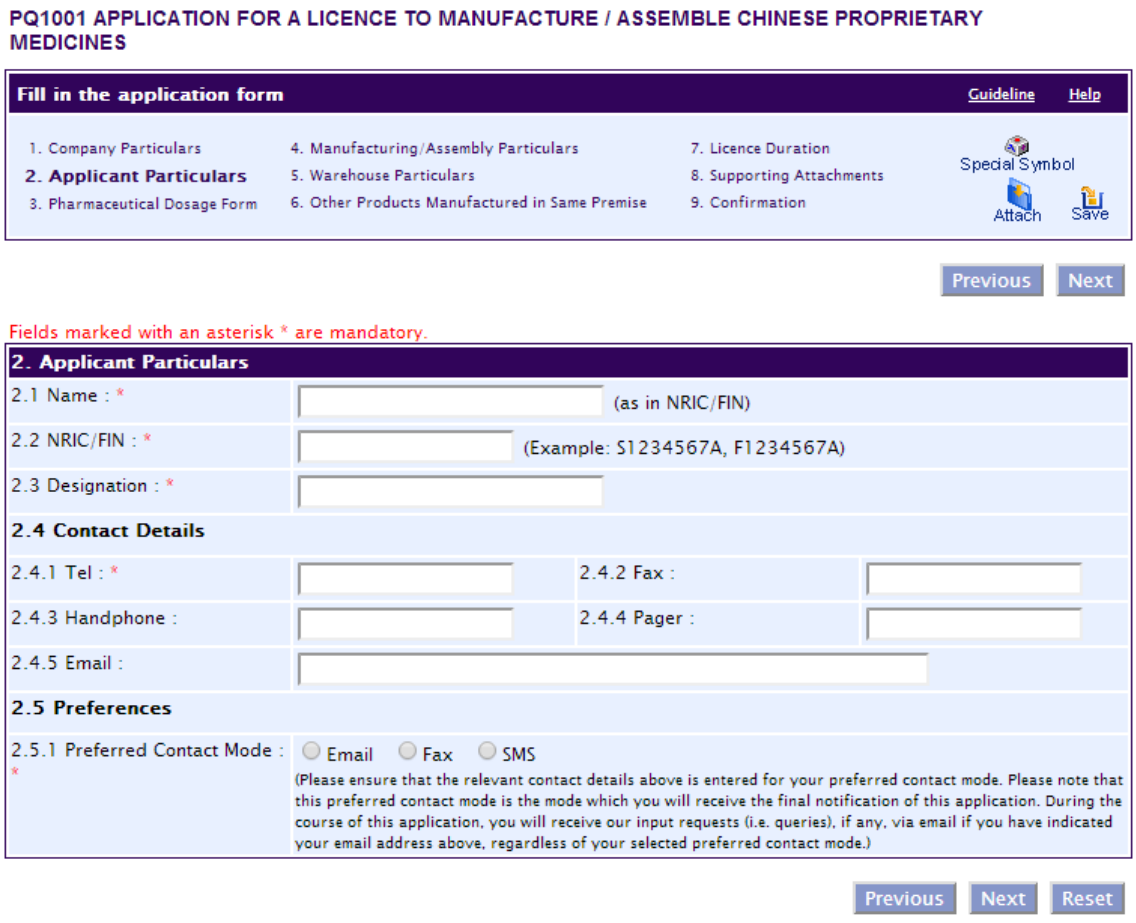
Part One - Company Particulars

The company 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 change via the "Amend Company Information" module.

Part Two – Applicant Particulars

The section requires the applicant to furnish the following information:

1) Applicant's Name
2) Applicant's NRIC/Fin
3) Applicant's Designation
4) Contact Details like Telephone/Fax/Handphone/Pager number and E-mail address
5) Preferred Contact mode
   (Please note that your preferred contact mode is the delivery mode of 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.)



PQ1001 APPLICATION FOR A LICENCE TO MANUFACTURE / ASSEMBLE CHINESE PROPRIETARY MEDICINES

Fill in the application form Guideline Help

1. Company Particulars
2. **Applicant Particulars**
3. Pharmaceutical Dosage Form
4. Manufacturing/Assembly Particulars
5. Warehouse Particulars
6. Other Products Manufactured in Same Premise
7. Licence Duration
8. Supporting Attachments
9. Confirmation

Special Symbol Attach Save

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Fields marked with an asterisk * are mandatory.

2. Applicant Particulars

2.1 Name : *	(as in NRIC/FIN)		
2.2 NRIC/FIN : *	(Example: S1234567A, F1234567A)		
2.3 Designation : *			
2.4 Contact Details			
2.4.1 Tel : *		2.4.2 Fax :	
2.4.3 Handphone :		2.4.4 Pager :	
2.4.5 Email :			
2.5 Preferences			
2.5.1 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.)		

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Part Three – Pharmaceutical Dosage Form

The section requires the applicant to furnish the following information:

1) **Dosage form**

You can select the dosage form(s) your company is dealing with from the list provided. If a dosage form you are dealing with is not included in the list provided, please select the option "Others" from the list provided, and give details of the dosage form in the field provided.

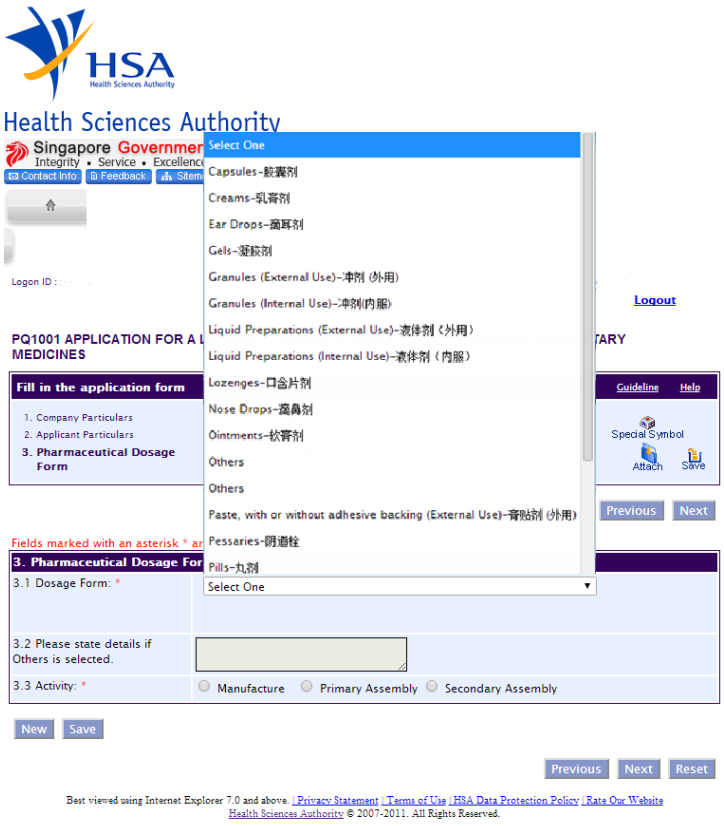
Dosage Forms	
Capsules	Paste, with or without adhesive backing (External Use)
Creams	Pessaries
Eye Drops	Pills
Gels	Powders (External Use)
Granules (External Use)	Powders (Internal Use)
Granules (Internal Use)	Sachet (External Use)
Liquid Preparations (External Use)	Suppositories
Liquid Preparations (Internal Use)	Tablets
Lozenges	Tea
Nose Drops	Others
Ointments	

2) **Activity**

Please select the relevant activity for each dosage form you are dealing with, and save the entry. You will see the page refreshes, and the refreshed page will display the details of the dosage form with its associated activity you have added

- Manufacture (i.e. manufacturing of the bulk product only or as well as primary and/or secondary assembly of the selected dosage form)
- Primary Assembly (select this if your company is conducting primary assembly or both primary and secondary assembly for the selected dosage form only)
- Secondary Assembly (select this if your company is conducting secondary assembly for the selected dosage form only)

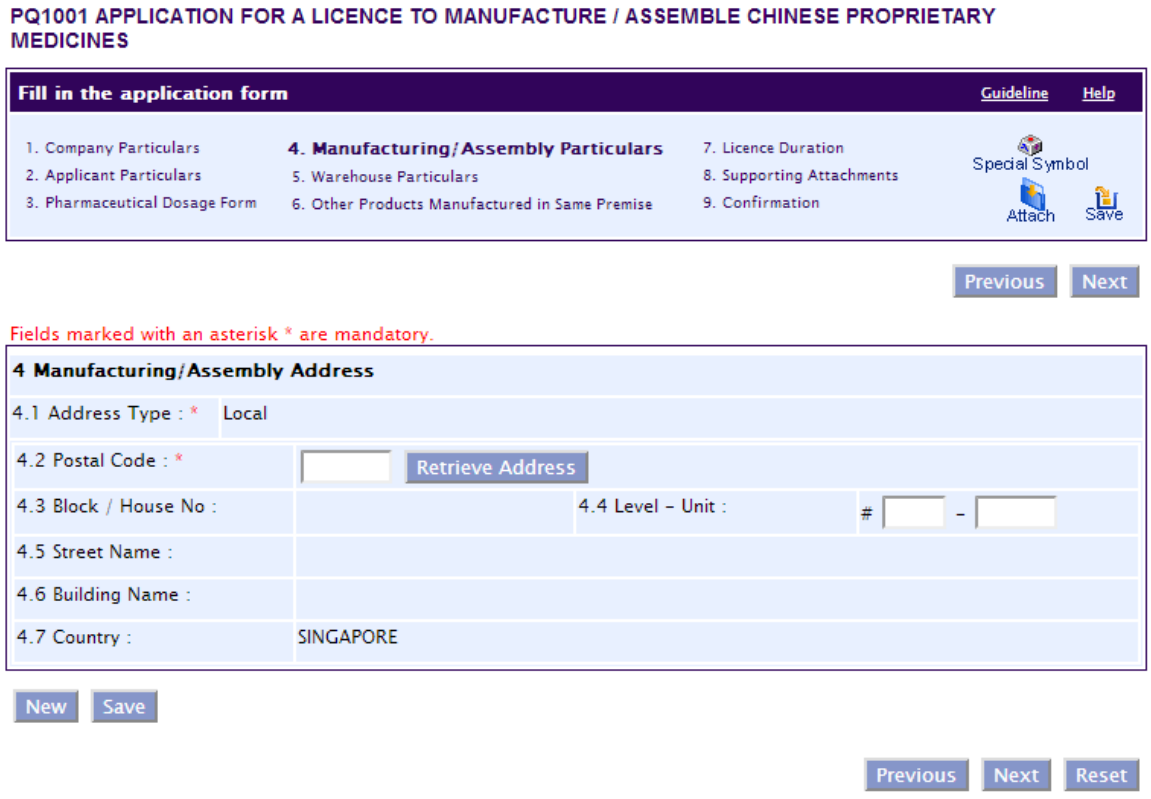
- Please note that manufacturer/assembler information is also required to be filed/updated in the product listing with **Traditional Medicine Unit of Complementary Health Products Branch** for the CPM products manufactured/assembled by them.



Part Four – Manufacturing / Assembly Particulars

All manufacturing or assembly addresses where the manufacturing and/or primary or secondary assembly activities are performed should be detailed, providing the Level and Unit number, where applicable.

Fill up the details as shown in the page and click the 'Save' button. Please check that the page displays the correct information that you entered. To add new Manufacturing/Assembly Address, click on the "New" button. Please remember to click the 'Save' button after updating the address.

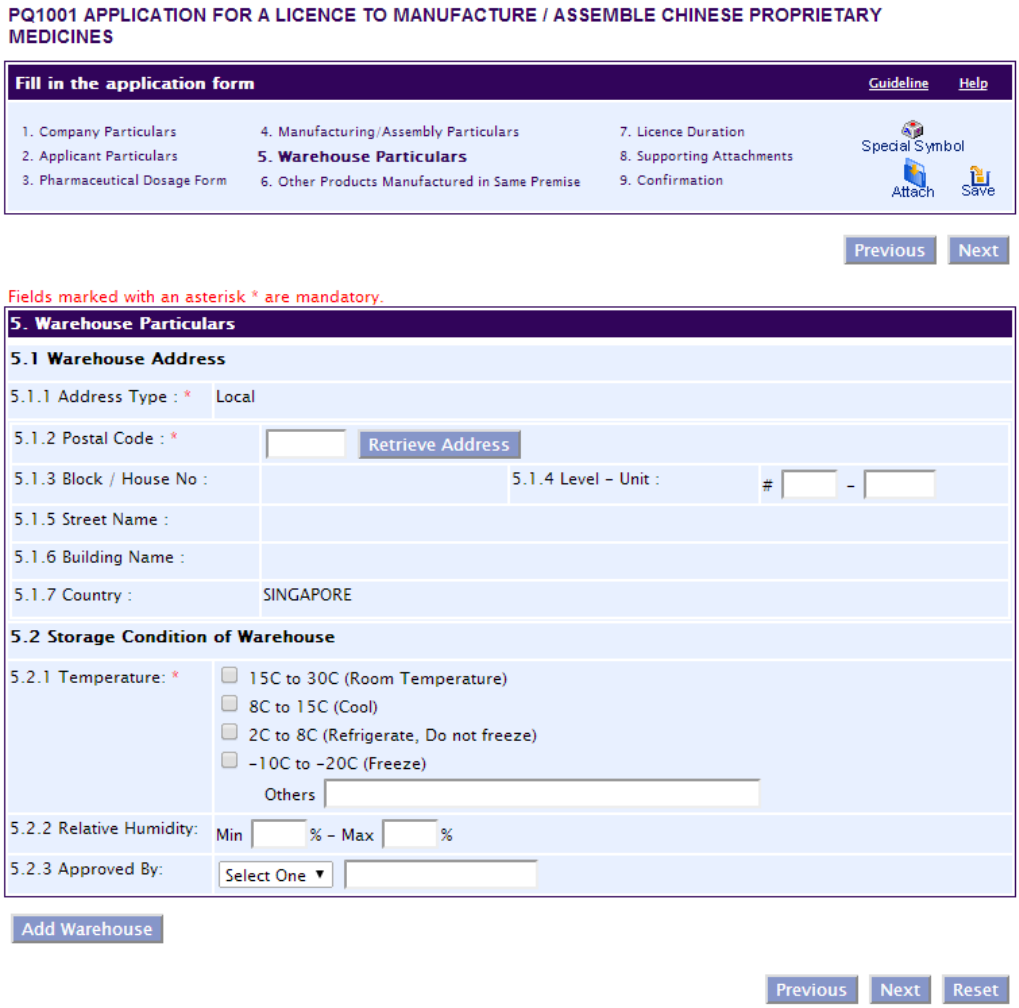


Part Five – Warehouse Particulars

All storage and handling addresses for raw and bulk materials, packaging materials and finished products should be detailed, providing the Level and Unit number, where applicable.

To add new warehouse address, fill in all the details in the page and click on the "Add Warehouse" button.

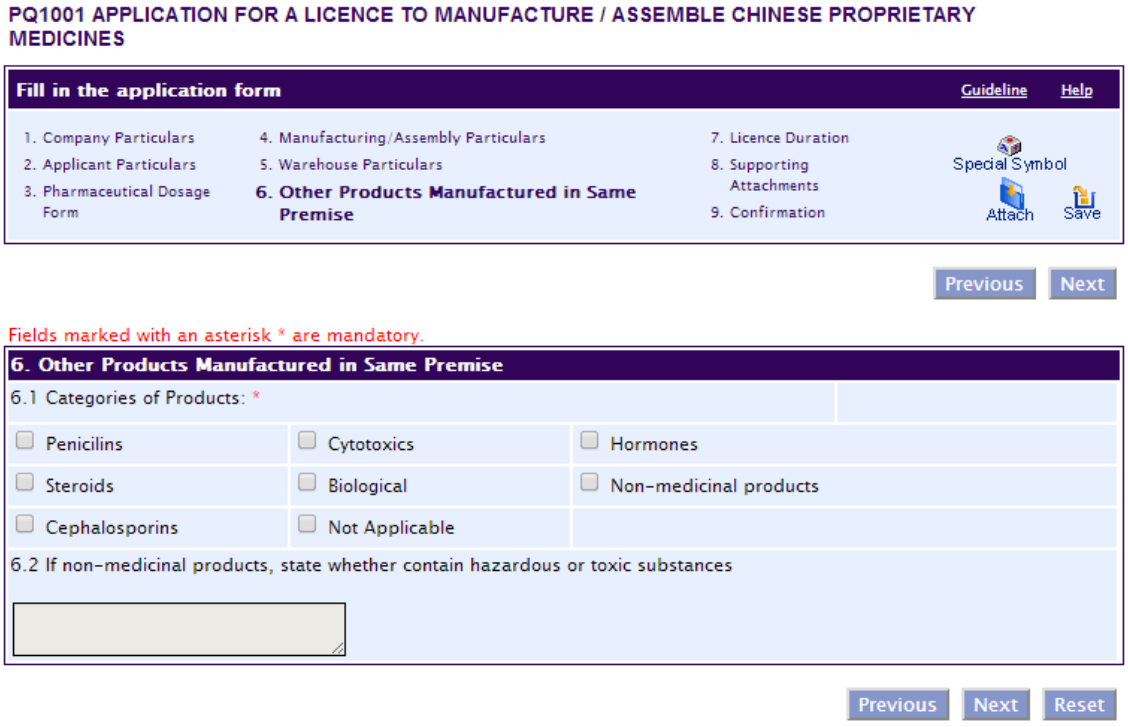
1) Note: Storage condition of the warehouse. You will have to provide the optimized warehouse temperature and relative humidity. You can select more than one option for the warehouse temperature
2) Approval of warehouse. Please give details of the agency/institution that approves the use of the warehouse(s) for the storage of health products



Part Six – Other Products Manufactured in Same Premise

The section requires applicant to furnish the following information:

1) Categories of products. Please select from the list provided the substance(s) your company is also manufacturing/assembling. You can select more than one option.



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Fill in the application form — Guideline | Help

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6. **Other Products Manufactured in Same Premise**
7. Licence Duration
8. Supporting Attachments
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Special Symbol | Attach | Save

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Fields marked with an asterisk * are mandatory.

6. Other Products Manufactured in Same Premise

6.1 Categories of Products: *

☐ Penicilins	☐ Cytotoxics	☐ Hormones
☐ Steroids	☐ Biological	☐ Non-medicinal products
☐ Cephalosporins	☐ Not Applicable	

6.2 If non-medicinal products, state whether contain hazardous or toxic substances

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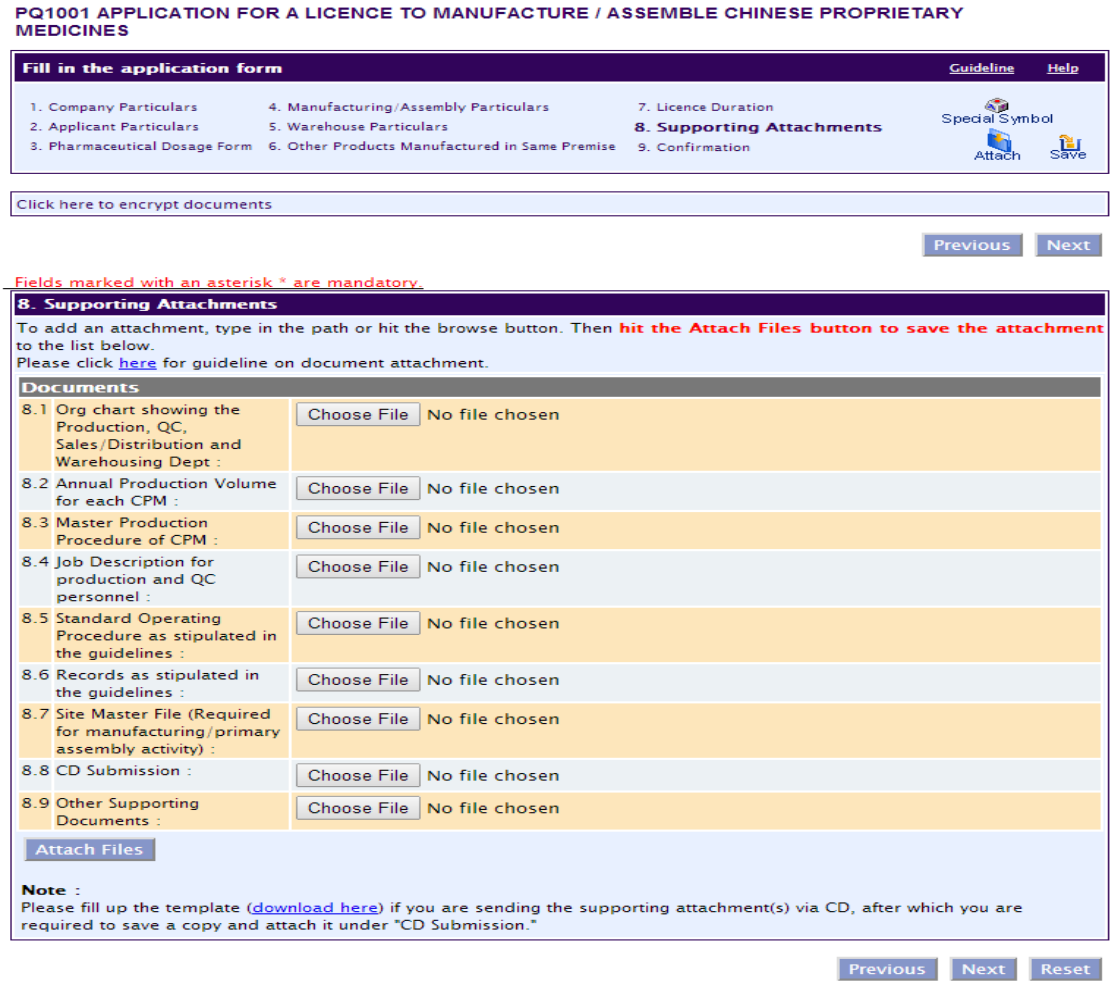
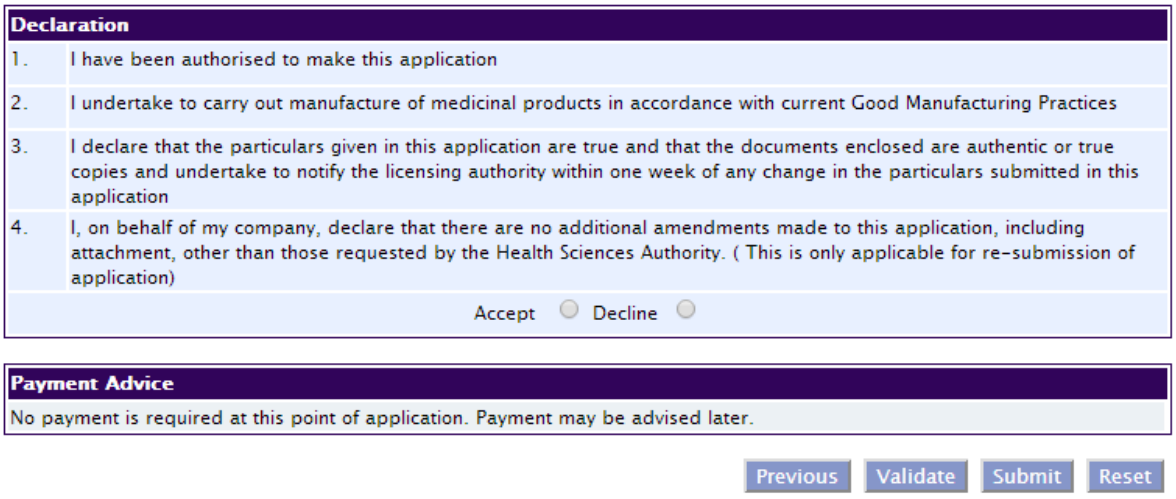
Part Seven – Licence Duration

The default licence duration is 1 year; this meant for information only and cannot be changed. Please click the “Next” button to proceed to the next section.

Part Eight – Supporting Attachments



Part Nine – Declaration



Declaration	
1.	I have been authorised to make this application
2.	I undertake to carry out manufacture of medicinal products in accordance with current Good Manufacturing Practices
3.	I declare that the particulars given in this application are true and that the documents enclosed are authentic or true copies and undertake to notify the licensing authority within one week of any change in the particulars submitted in this application
4.	I, on behalf of my company, declare that there are no additional amendments made to this application, including attachment, other than those requested by the Health Sciences Authority. (This is only applicable for re-submission of application)
	Accept ○ Decline ○

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

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Other useful information

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

2. Kindly contact HSA Helpdesk at the following contact details if you encounter any technical issues (IT problems) during the application submission or any enquiry relating to your CRIS account:

   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