AMENDMENT 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.

   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:
   - Updated Site Master File, if applicable. 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 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 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/

For more information on HSA PIN, please refer to
https://www.hsa.gov.sg/e-services/hsa-pin

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 Zero – Licence/Permit/Certificate/Listing Summary

The applicable Licence No, the start and expiry dates of the existing licence will be displayed for your information.



The applicant would need to furnish the following information:

1) Amendment Details (Please provide in this entry the reason for the amendment)

The applicant has to make amendment(s) to the licence when the following changes occur:

A) Examples of changes which may require on-site audit:

- Addition or amendment of manufacturing site address
    - Please note that each Manufacturer's Licence is issued to each company with a specific manufacturing address and postal code. If your company is relocating the manufacturing premise to a different address (i.e. postal code), please submit a new application.
    - Your company may file for amendment application if there is addition or relocation of manufacturing activities within the approved building (e.g. addition of unit or floor) and/or postal code.
- Addition or amendment of warehouse address, including addition of third party logistic warehouse
- Addition or amendment of manufacturing activities (i.e. manufacture or primary assembly or secondary assembly) for approved dosage form(s) Addition of cold-chain activities.

B) Examples of changes which do not involve on-site audit. The appropriateness of such changes would be assessed in the next audit.
   - Amendment of company name or business address (Note: Such amendment has to be made via the "Change of Company Information" module)
   - Amendment of applicant
   - Deletion of approved manufacturing site address
   - Deletion of approved warehouse address
   - Deletion of approved manufacturing activities
   - Deletion of approved dosage form
   - Addition of new dosage forms for secondary assembly

If you are in doubt or encounter a situation which is not found in the above lists of examples, please contact us before submission.

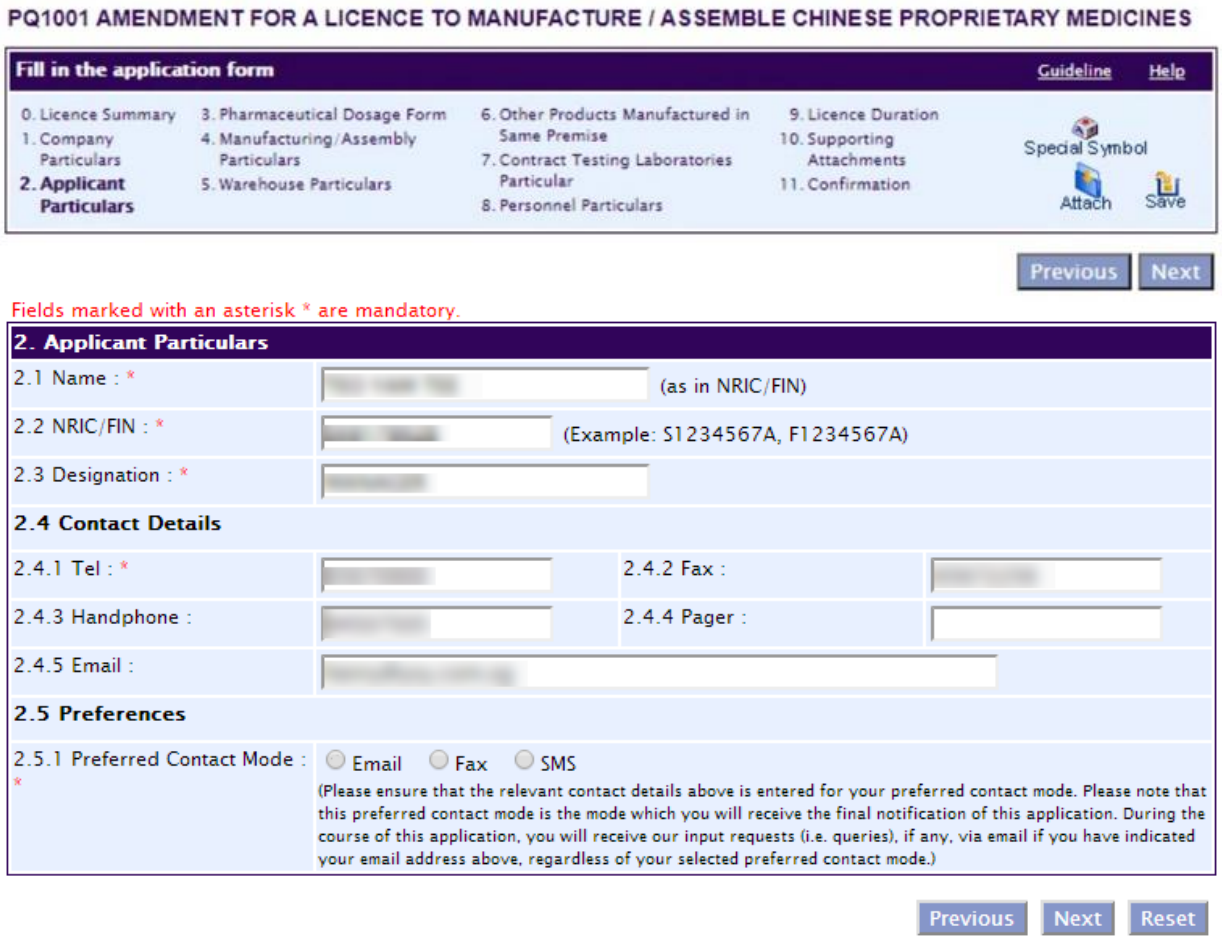
Part One - Company Particulars

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 via "amend listing or licence" and select 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.



Part Three – Pharmaceutical Dosage Form

The section requires the applicant to furnish the following information if there is an amendment to the details. **Otherwise, please do not amend any details at this section.**

To amend the dosage form, you will just have to click on the dosage form of interest, and the page will refresh to display the particulars of the dosage form. Click on "Update" to update any changes you have made. You may also choose to add or remove any of the previously applied dosage forms.

To add new dosage form(s):

1) **Dosage form**

   You can select the new dosage form(s) your company is going to deal with from the list provided. If a dosage form that your company is going to deal 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	

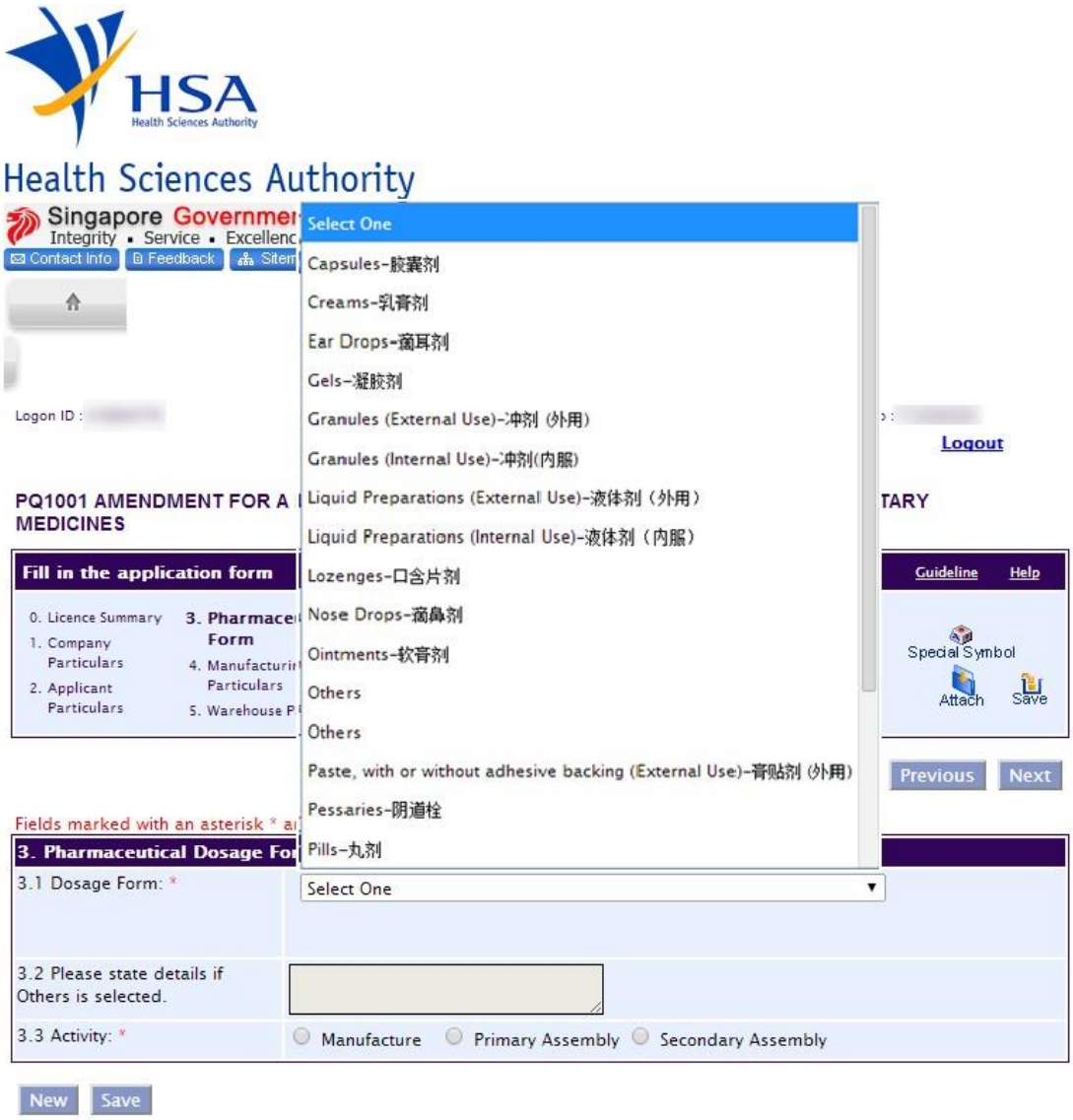
2) **Activity**

   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)

To remove the manufacturing activities for each dosage form(s), please select the correct dosage form and activity displayed in the list and click the 'Remove' button.

Please note that for addition of new dosage form, relevant 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.

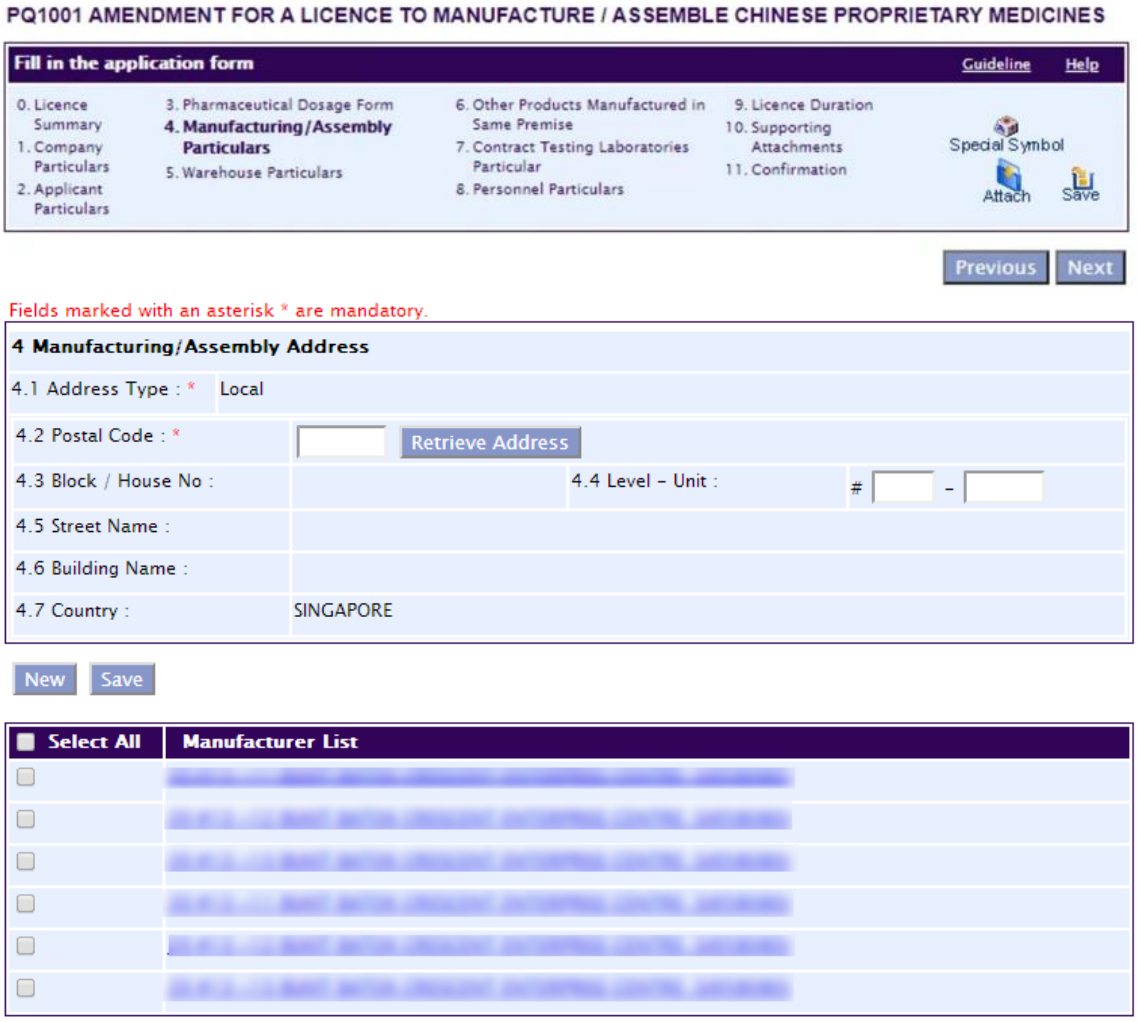


Part Four – Manufacturing / Assembly Particulars

The section requires the applicant to furnish the following information if there is an amendment to the manufacturing site particulars. **Otherwise, please do not amend any details at this section.**

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. To amend the manufacturing site address, click on the manufacturing site of interest, and the page will refresh to display the details of the manufacturing/assembly address. After you have amended the address, Click on the "Save" button.

To add new Manufacturing/Assembly Address, click on the "New" button. Please remember to click the 'Save' button after updating the address. To remove manufacturing address, please select the address of interest from the Manufacturer List and click the 'Remove' button.



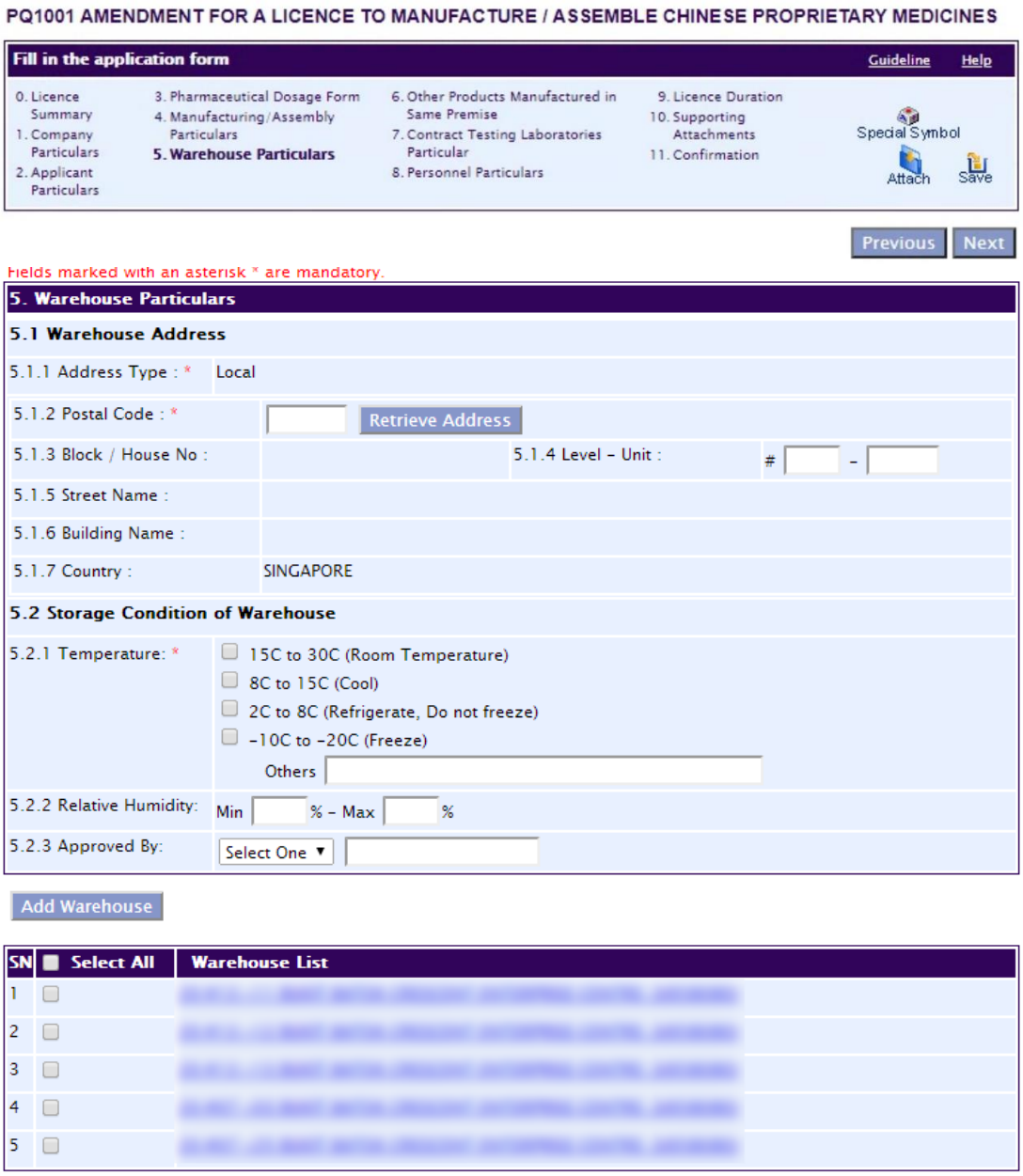
Part Five – Warehouse Particulars

The section requires the applicant to furnish the following information if there is an amendment to the warehouse particulars. **Otherwise, please do not amend any details at this section.**

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 amend the warehouse address, click on the warehouse of interest, and the page will refresh to display the details of the warehouse address. After you have amended the address, Click on the "Reset" button.

To add new warehouse address, update the detail and click on the "Add Warehouse" button.

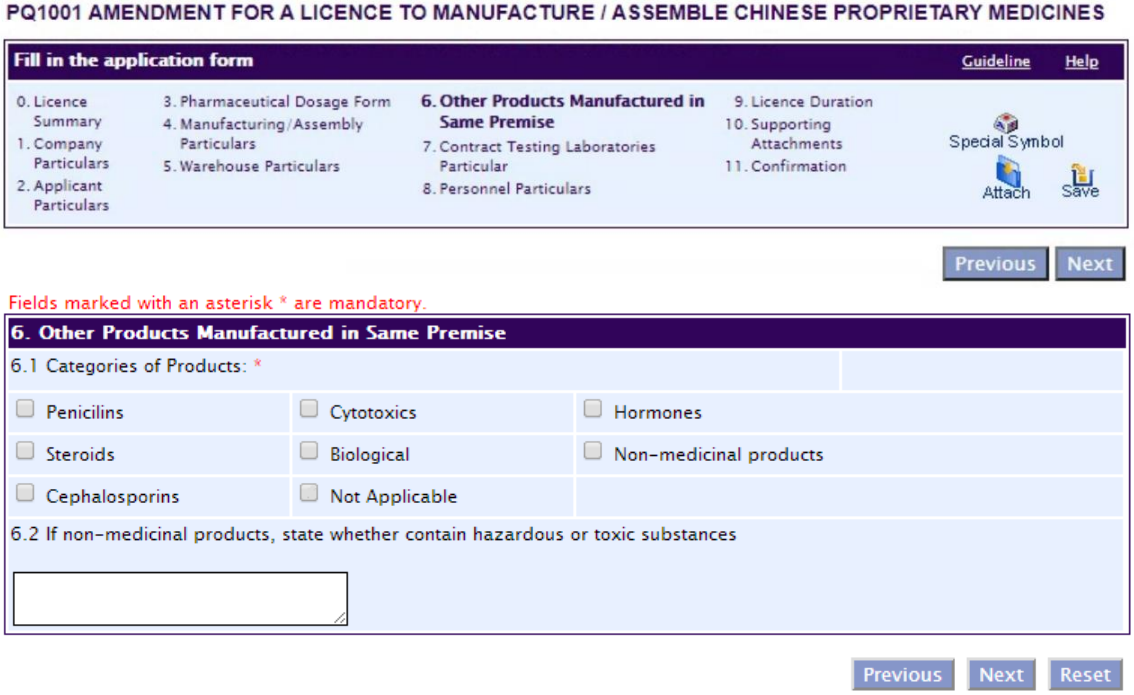
To remove warehouse address, please select the warehouse of interest and click the 'Remove' button.



Part Six – Other Products Manufactured in Same Premise

The section requires applicant to furnish the following information if there is an amendment to the details. **Otherwise, please do not amend any details at this section.**

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



Part Seven – Contract Testing Laboratories Particular

The section requires applicant to furnish the following information if there is an amendment to the details. **Otherwise, please do not amend any details at this section:**

1) Is a contract testing laboratory engaged to conduct laboratory tests for your company? If your answer to the question is “No”, you can proceed to the next Part. If your answer is “Yes”, you will be required to give details of the contract testing laboratory in the following sections.
2) Name and address of the contract testing laboratory.
3) Type of analytical test performed by the laboratory based on your contract. You will only need to give a brief description of the test(s) performed.
4) If the contract testing laboratory is accredited to any international quality system standards, and the scope of accreditation. You will only need to give a brief description of the scope of accreditation.
5) Add the contract testing laboratory by clicking on the “Save” button. You will see the page refreshes, and the refreshed page will display the details of the contract testing laboratory you have added.

To remove Contract Testing Laboratories, select the laboratory and click on the ‘Remove’ button.



Part Eight – Personnel Particulars

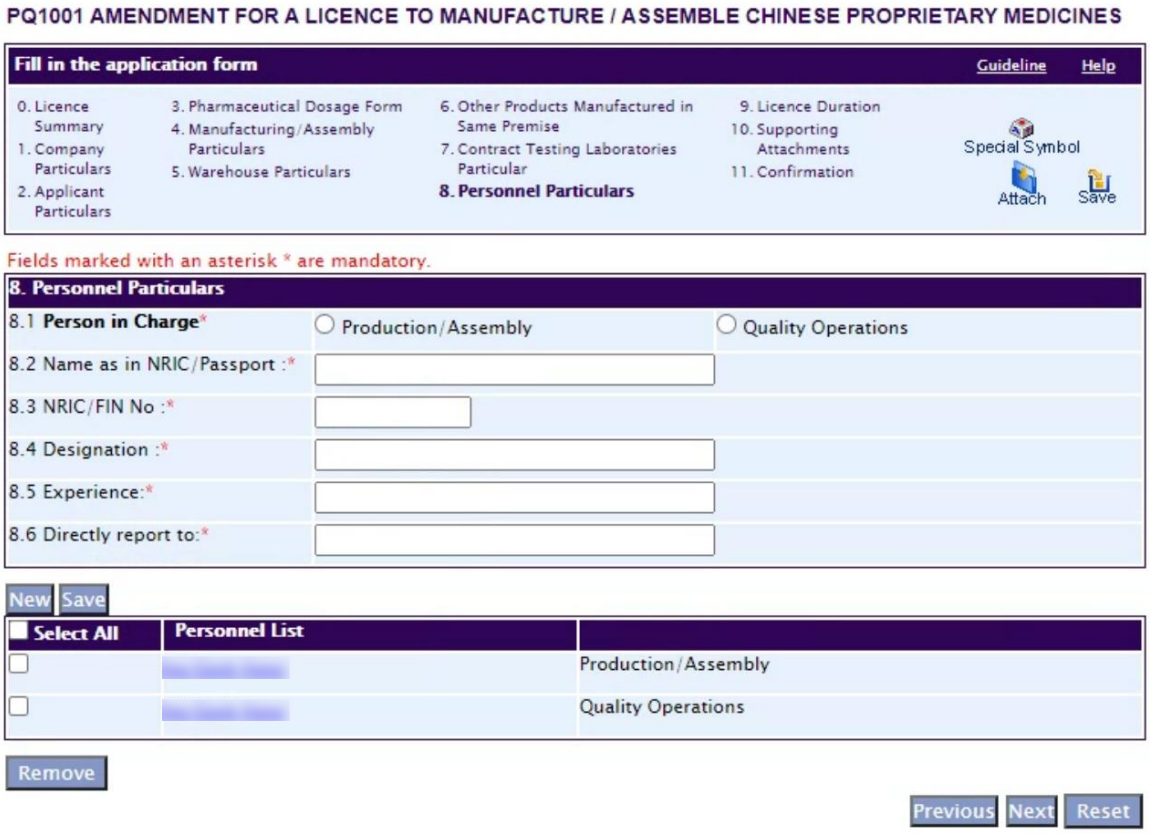
The section requires the applicant to furnish the following information if there is an amendment to the personnel. **Otherwise, please do not amend any details at this section.**

To amend the personnel, you will just have to click on the personnel of interest, and the page will refresh to display the particulars of the personnel. Click on "Update" to update any changes you have made. You may also choose to add or remove any of the previously approved personnel.

To add personnel:

1) Particulars of the persons in-charge of production/assembly AND quality operations. The name, identity number, designation, experience, and the designation of the supervisor to whom they directly report to should be furnished. Add the record by clicking on the "Save" button. You will see the page refreshes, and the refreshed page will display the details of the personnel you have added. You can add more than one record.

To remove Personnel, select the personnel and click on the 'Remove' button.



Part Nine – Licence Duration

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

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

Fill in the application form Guideline Help

0. Licence Summary
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. Contract Testing Laboratories Particular
8. Personnel Particulars
9. Licence Duration
10. Supporting Attachments
11. Confirmation

Special Symbol Attach Save

7. Licence Duration

7.1 Duration of licence: *	1 Year

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Part Ten – Supporting Attachments

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Special Symbol Attach Save

Previous Next

Click here to encrypt documents

Fields marked with an asterisk * are mandatory.

8. Supporting Documents

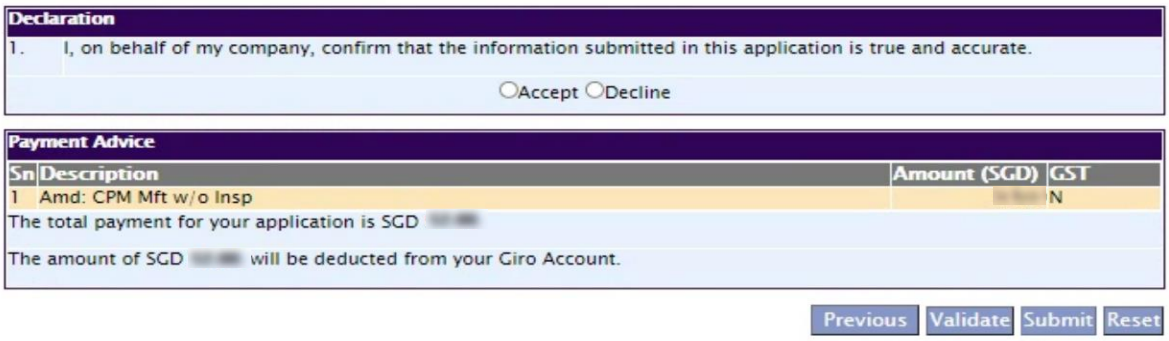
To add an attachment, type in the path or hit the browse button. Then **hit the Attach Files button to save the attachment** to the list below.
Please click here for guideline on document attachment.

Documents		
8.1	Choose File	No file chosen
8.2	Choose File	No file chosen
8.3	Choose File	No file chosen
8.4	Choose File	No file chosen
8.5	Choose File	No file chosen
8.6	Choose File	No file chosen
8.7	Choose File	No file chosen
8.8	Choose File	No file chosen

Attach Files

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Part Eleven – Confirmation



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)
   Email : helpdesk@hsahelp.gov.sg

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