NEW APPLICATION FOR A LICENCE TO MANUFACTURE/ASSEMBLE THERAPEUTIC PRODUCTS

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 20 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:
   - Site Master File (This is a mandatory requirement and scan 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 (i.e. name, strength and product licence number, if applicable) 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

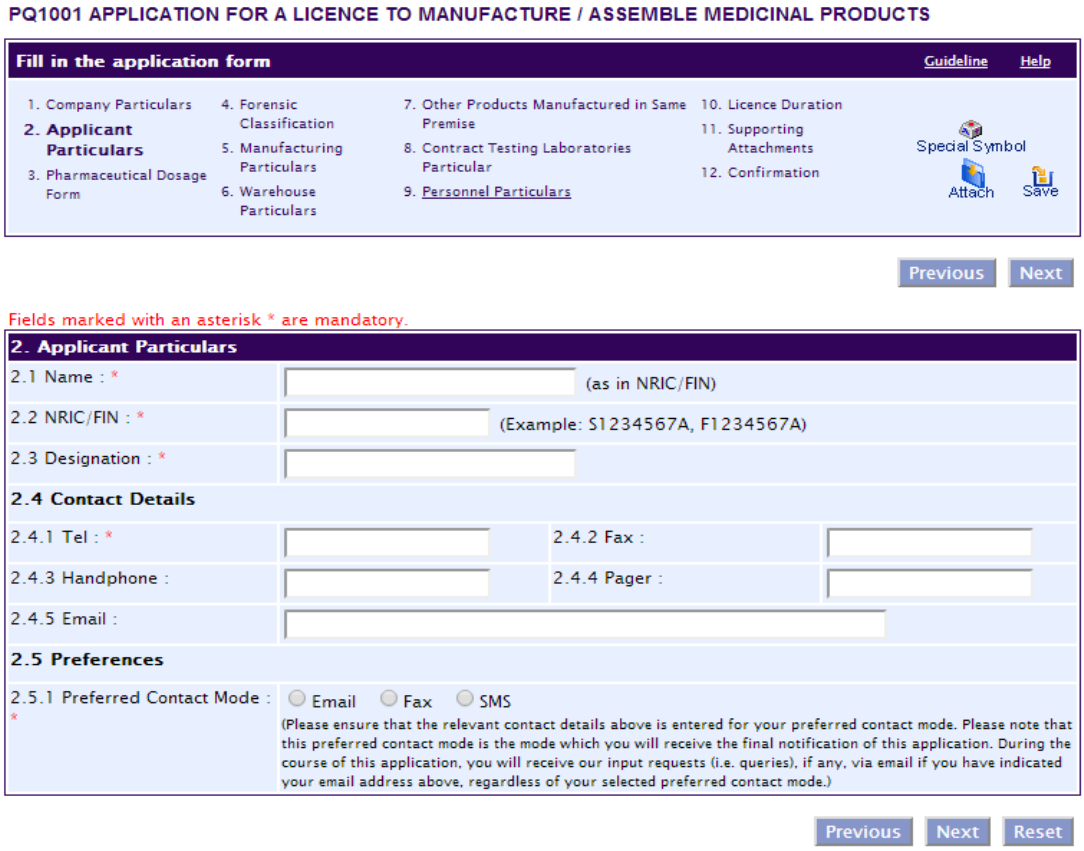
Part One - Company Particulars

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 amend@prism and select "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:

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 section 3.2.

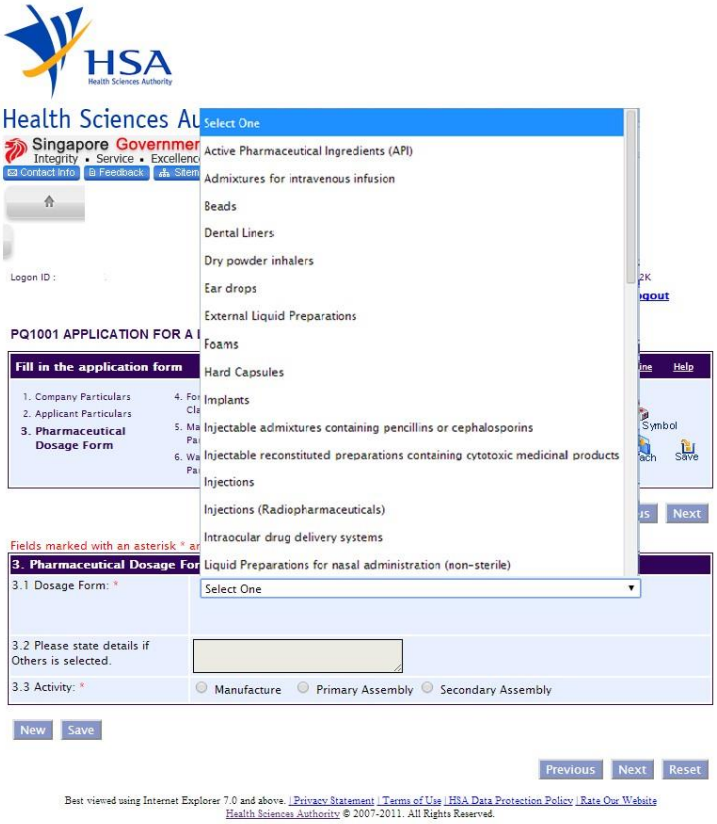
Dosage forms	
Active Pharmaceutical Ingredient (API)	Non-sterile semi-solid preparations
Admixtures for intravenous infusion	Oral Liquid Preparations
Beads	Oral powders and granules
Dental Liners	Pastilles
Dry powder inhalers	Pessaries
Ear drops	Pills
External Liquid Preparations	Powder Preparations for inhalation
Foams	Powders and granules for oral liquid preparations
Hard Capsules	Reconstituted cytotoxic preparations
Implants	Soft Capsules
Injectable admixtures containing pencillins or cephalosporins	Sterile non-injectable liquid preparations
Injectable reconstituted preparations containing cytotoxic medical products	Sterile powders for injection
Injections	Sterile powders for irrigations
Injections (Radiopharmaceuticals)	Sterile semi-solid preparations
Intracular drug delivery systems	Sterile strips
Liquid Preparations for nasal administration (non-sterile)	Suppositories
Liquid preparations for inhalation (non-sterile)	Tablets for external administration
Medicated Gums	Tablets for oral administration
Medicated Tampons	Total parenteral nutrition preparations
Medicated Soap bars	Transdermal patches
Medicinal Gases	Others
Non sterile powders for topical applications	

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)

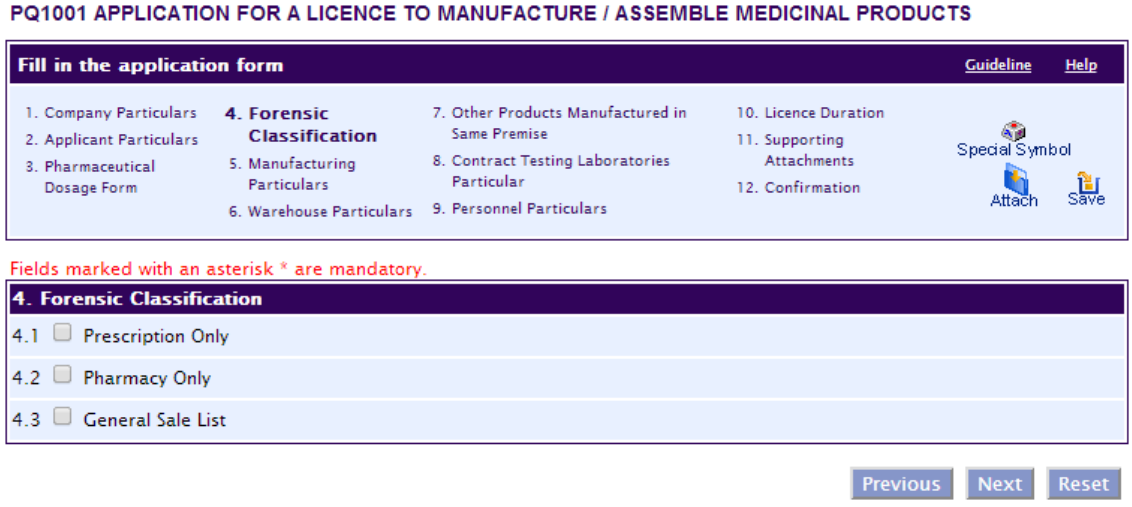
- Please note that product licence holders are also required to file/update corresponding product registration with the Therapeutic Products Branch of Pre-Marketing Division for each product in the dosage form selected, if applicable.



Part Four – Forensic Classification

The section requires the applicant to furnish the following information:

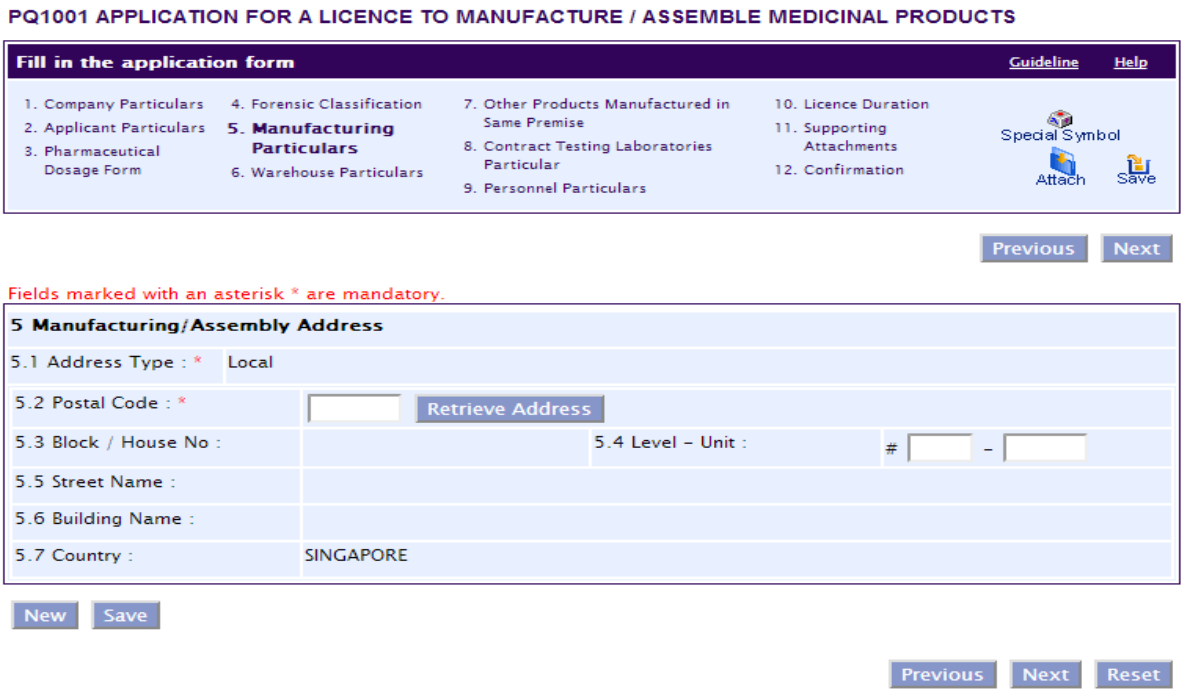
1) Forensic classification. Please select the relevant forensic classification(s) of the products you manufacture or assemble. You can select more than one option.



Part Five – 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.

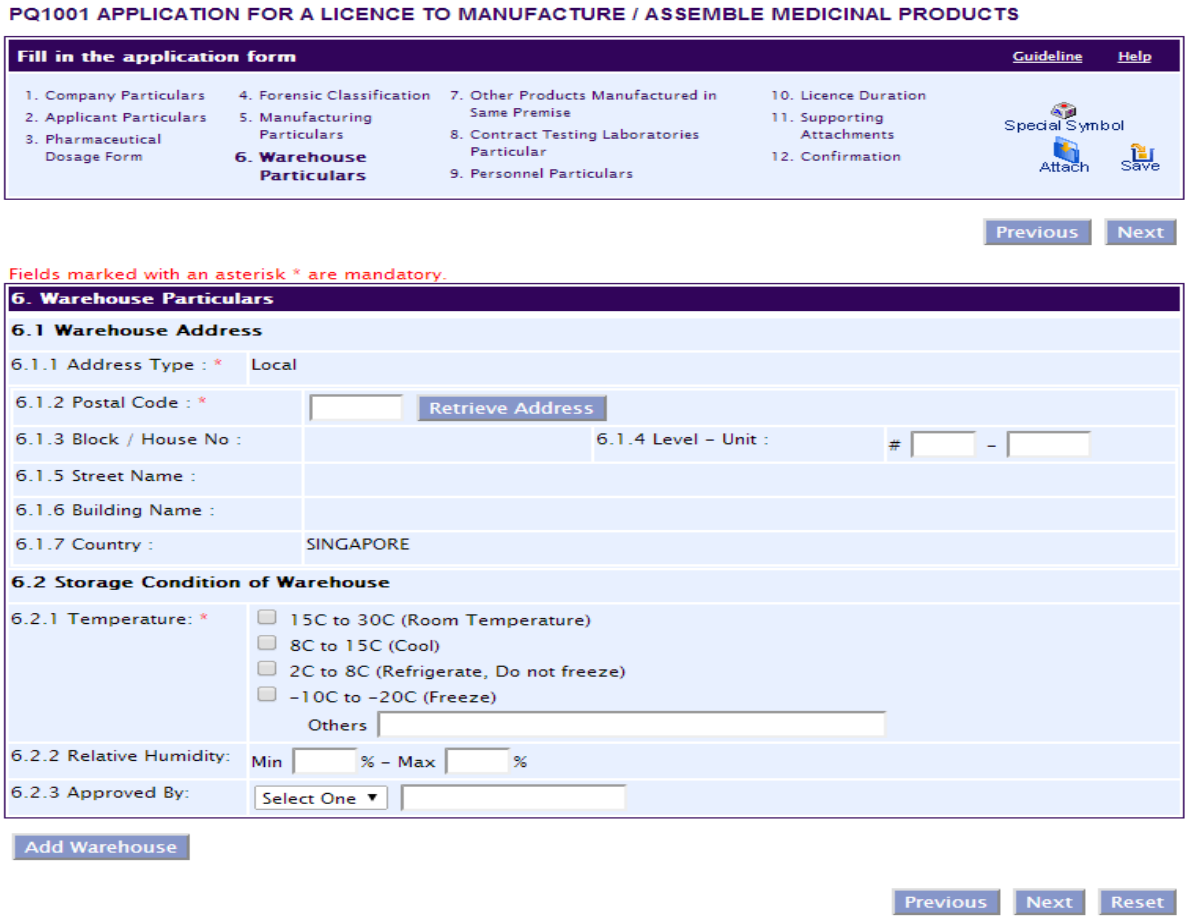


Part Six – Warehouse Particulars

All storage and handling address 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.

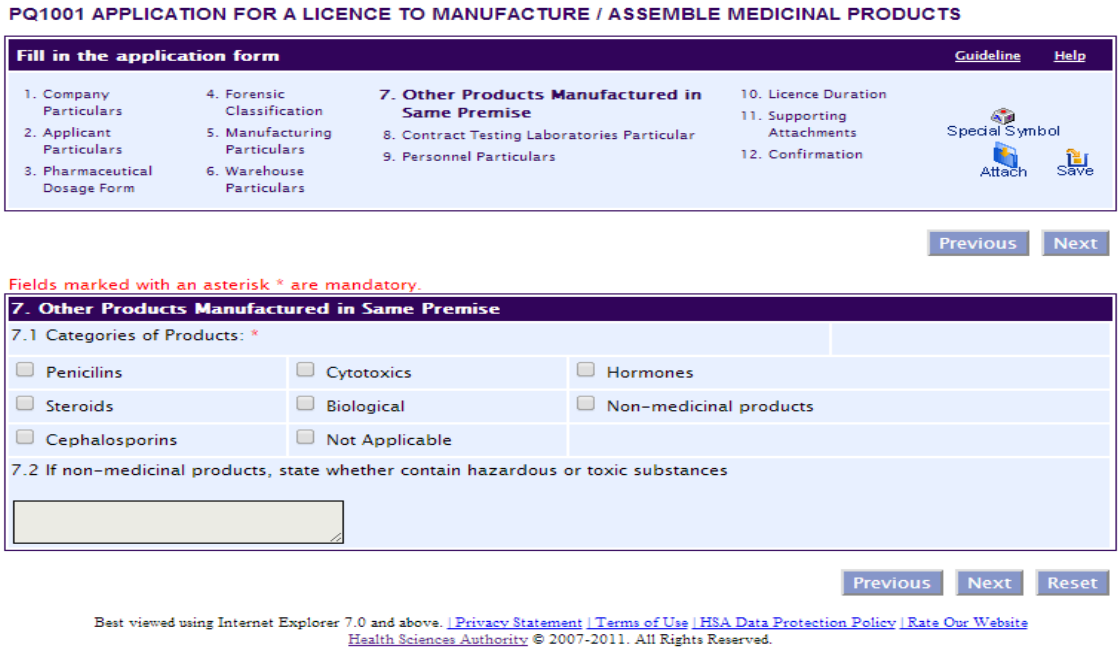
1) Note: Storage condition of the warehouse. You will have to provide the optimized warehouse temperature and relative humidity. You can select more than one option for the warehouse temperature
2) Approval of warehouse: Please give details of the agency/institution that approves the use of the warehouse(s)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



Part Seven – 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.



Part Eight – Contract Testing Laboratories Particulars

The section requires applicant to furnish the following information:

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.

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Fill in the application form Guideline Help

1. Company Particulars
2. Applicant Particulars
3. Pharmaceutical Dosage Form
4. Forensic Classification
5. Manufacturing Particulars
6. Warehouse Particulars
7. Other Products Manufactured in Same Premise
8. **Contract Testing Laboratories Particular**
9. Personnel Particulars
10. Licence Duration
11. Supporting Attachments
12. Confirmation

Special Symbol Attach Save

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Fields marked with an asterisk * are mandatory.

8. Contract Testing Laboratories Particulars

Is a contract testing lab engaged? :*	(•) Yes ( ) No

8.1 Company Name : *	
8.2 Type of analytical test performed : *	
8.3 Are the contract testing laboratories accredited to ISO/IEC 17025 or other quality system standards?:	( ) Yes ( ) No
8.4 If yes, please specify the standard and scope of accreditation	
8.5 Business Address	
8.5.1 Address Type : *	(•) Local ( ) Overseas

8.5.2 Postal Code : *		Retrieve Address	
8.5.3 Block / House No :		8.5.4 Level – Unit :	# –
8.5.5 Street Name :			
8.5.6 Building Name :			
8.5.7 Country :	SINGAPORE		

New Save

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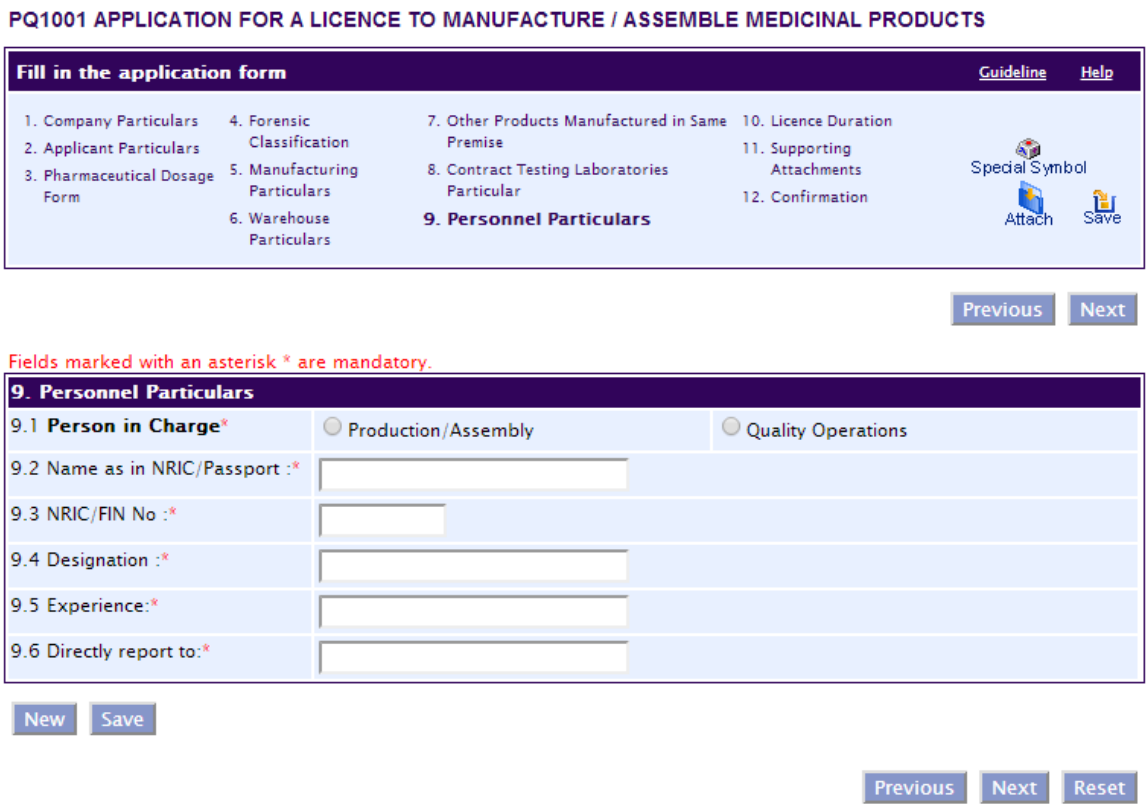
Part Nine – Personnel Particulars

The section requires applicant to furnish the following information:

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.



Part Ten – 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.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Fill in the application form — Guideline — Help

1. Company Particulars
2. Applicant Particulars
3. Pharmaceutical Dosage Form
4. Forensic Classification
5. Manufacturing Particulars
6. Warehouse Particulars
7. Other Products Manufactured in Same Premise
8. Contract Testing Laboratories Particular
9. Personnel Particulars
10. **Licence Duration**
11. Supporting Attachments
12. Confirmation

Special Symbol — Attach — Save

Fields marked with an asterisk * are mandatory.

10. Licence/Permit/Certificate/Listing Duration

10.1 Duration of licence/permit/certificate/listing: * 1 Year

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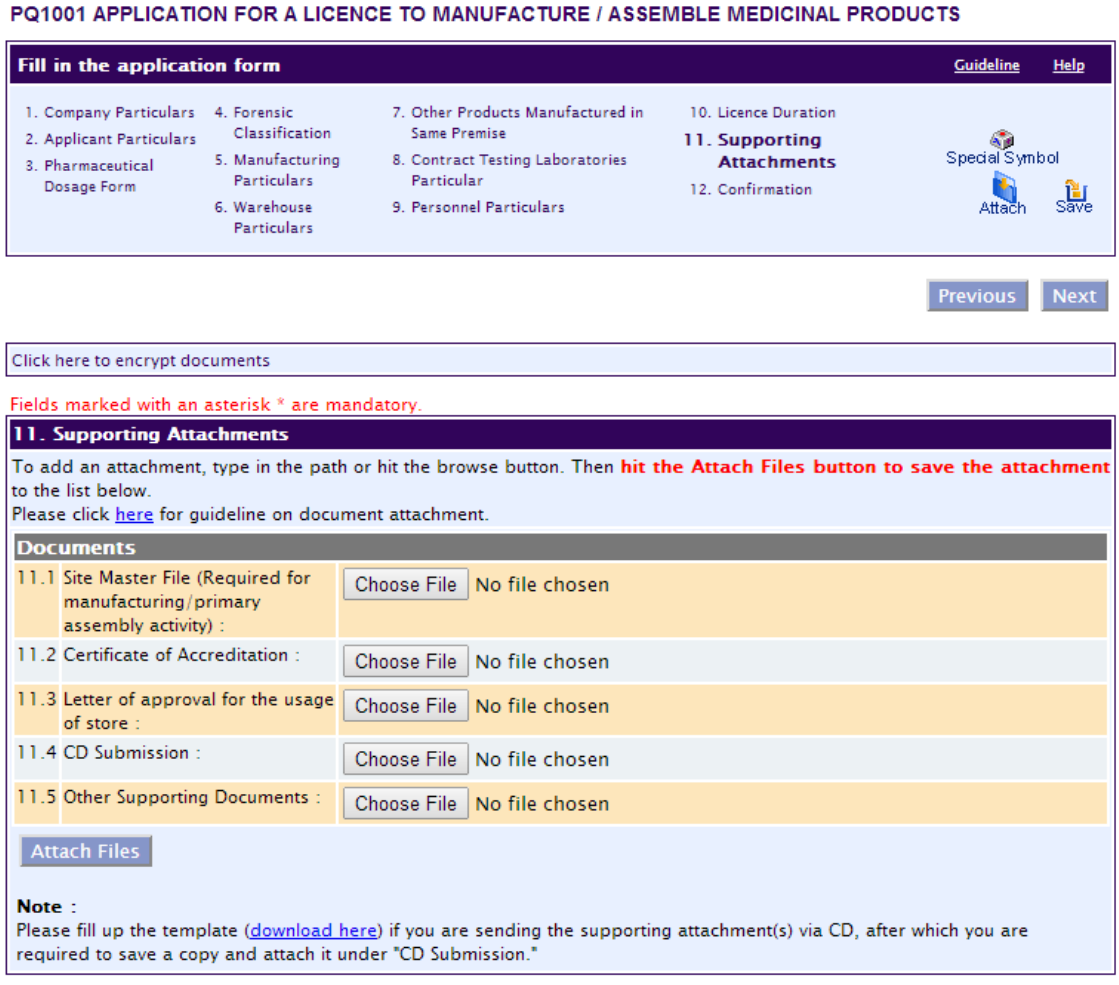
Part Eleven – Supporting Attachments


PQ1001 APPLICATION FOR A LICENCE TO MANUFACTURE / ASSEMBLE MEDICINAL PRODUCTS

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1. Company Particulars
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12. Confirmation

Special Symbol — Attach — Save

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Click here to encrypt documents

Fields marked with an asterisk * are mandatory.

11. Supporting Attachments

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		
11.1	Site Master File (Required for manufacturing/primary assembly activity) :	Choose File No file chosen
11.2	Certificate of Accreditation :	Choose File No file chosen
11.3	Letter of approval for the usage of store :	Choose File No file chosen
11.4	CD Submission :	Choose File No file chosen
11.5	Other Supporting Documents :	Choose File No file chosen

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."

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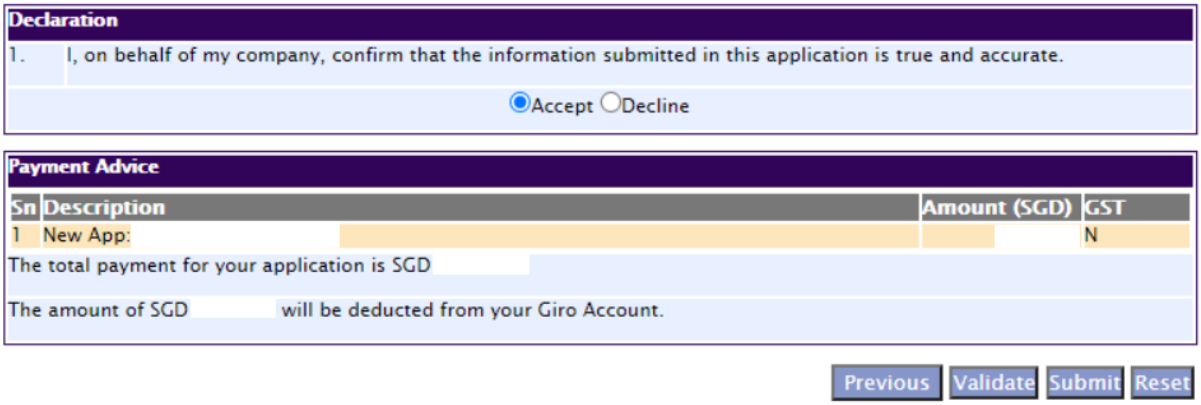
Part Twelve – Confirmation



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

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