NEW APPLICATION FOR A LICENCE TO MANUFACTURE/ASSEMBLE PREPARATIONS CONTAINING CONTROLLED DRUGS

Companies and its applicants must register with Client, Registration, and Identification Service (CRIS) with valid CRIS user rights in order to be able to submit applications on behalf of the company via apply@prism.

The applicant will also 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 is necessary for authentication and authorization 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 CRIS, please refer to

https://www.hsa.gov.sg/e-services/cris

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

1 . The online form may 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, 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. You may need the following information/item(s) to fill the form:

- Business profile registered with ACRA (formerly known as RCB)
- Site Master File (a mandatory requirement for a company involves in manufacturing and/or primary assembly)
- Certificate of Accreditation of the contract testing laboratory, if any
- Letter of approval issued by the agency / institution that approves the use of the warehouse(s) for the storage of health products, if applicable
- List of manufacturing equipment available and their function, if applicable. Please only provide a brief description of the information requested
- List of quality control equipment available and function of each equipment, if applicable. Please only provide a brief description of the information requested

- Details of the name and type (i.e. dosage forms) of products manufactured / assembled

3. Mode of payment

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

The modes of payment available are as follow:

- GIRO
- 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.

Application Form

Part 1. 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**, **Address**, **Telephone** and/or **Fax** will be pre-populated based on the registered CRIS records.

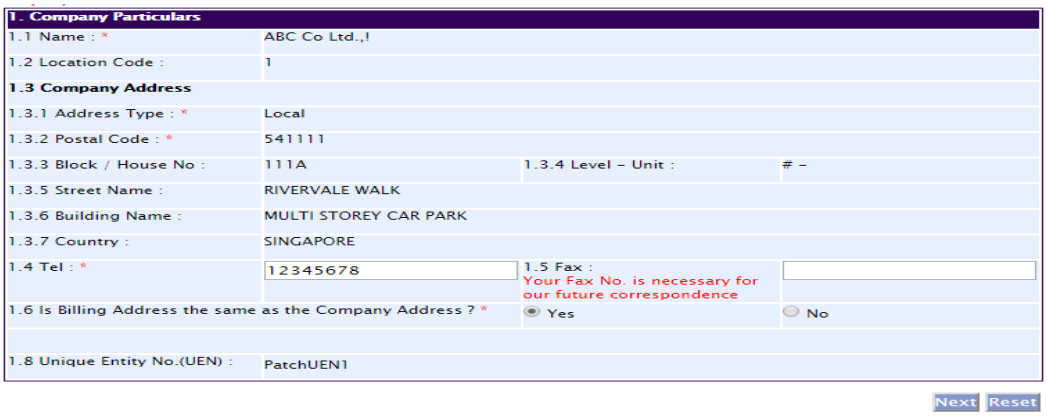
If you need to makes changes to this information, please submit the changes via the **"Amend Company Information"** module under the amend@prism on PRISM e-Service webpage.

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

(3) If the Billing Address is not the same as **Company Address**, please fill in the **'Postal Code'** field and click the **'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 2. Applicant Particulars** section.



Part 2. Applicant Particulars

This section requires the applicant to enter relevant information relating to the applicant particulars.

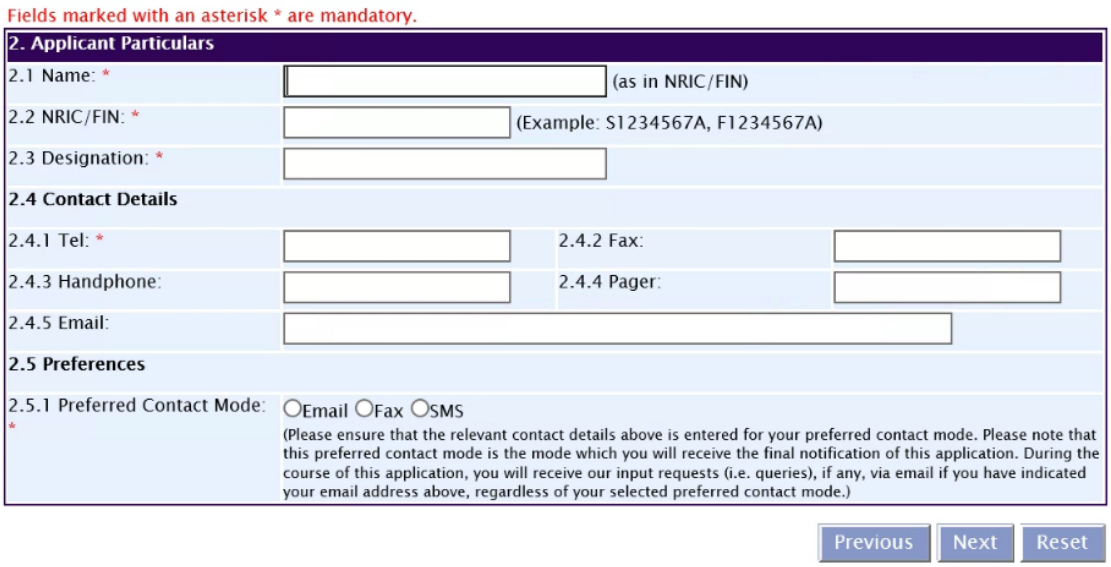
(1) Applicant details such as name, NRIC / FIN, designation, Telephone/Fax/Handphone number and e-mail address.

(2) Select the type of **Preferred Contact Mode**.

(Note: Please ensure that the relevant contact details above are entered for your preferred contact mode. Please note that the 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 Request (i.e. queries), if any, via email if you have indicated your email address above, regardless of your selected preferred contact mode.)

(3) Click **'Next'** button to proceed to Error! Reference source not found.**Wholesale / Manufacture Licence** section.



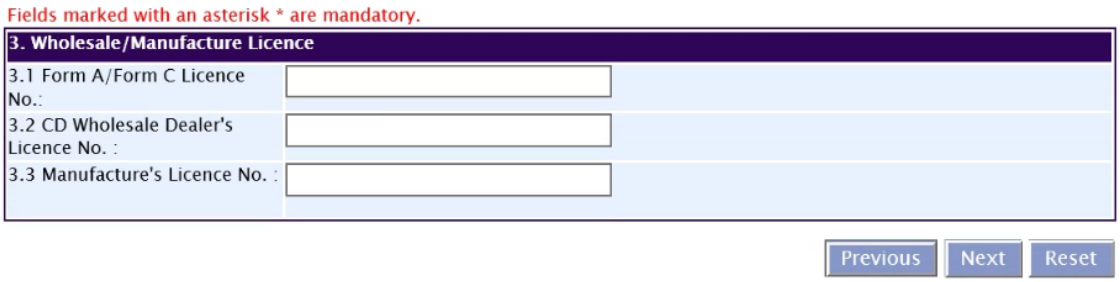
Part 3. Wholesale / Manufacture Licence

The section requires the applicant to furnish this information:

1) A valid Poisons Licence No. The Poisons Licence should be held by the applicant of the application for a Licence to Manufacture/Assemble Preparations Containing Controlled Drugs.

2) CD Wholesale Dealer's Licence No, if applicable. Dealers who wish to resell or re-supply the controlled drugs manufactured/assembled will be required to hold a valid CD Wholesale Dealer's Licence before the Licence to Manufacture/Assemble Preparations Containing Controlled Drugs will be issued. The CD Wholesale Dealer's Licence should be held by the applicant of the application for a Licence to Manufacture/Assemble Preparations Containing Controlled Drugs.

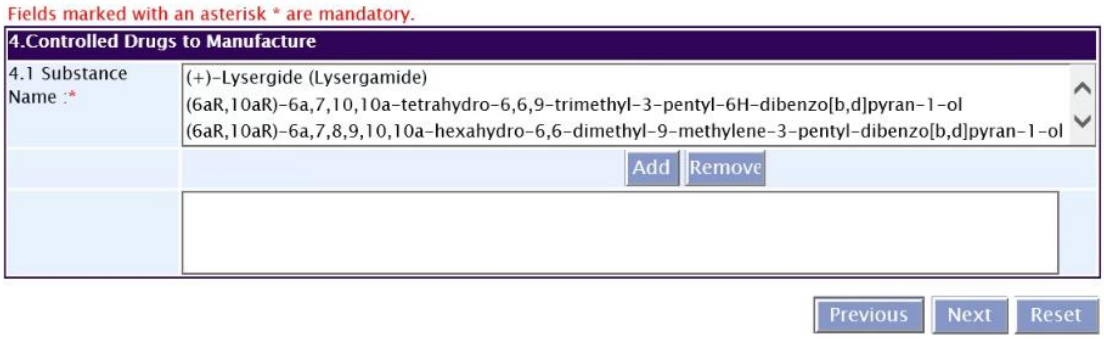
3) Therapeutic Products Manufacture's Licence No. If you are manufacturing/assembling a therapeutic product containing controlled drugs, your company will be required to hold a corresponding Therapeutic Products Manufacturer's Licence. The licence no, or the application no of a Therapeutic Products Manufacturer's Licence should be furnished.



Part 4. Controlled Drugs to Manufacture

The section requires the applicant to furnish this information:

1) Substance name. You can select the controlled drug(s) your company is dealing with from the list provided.

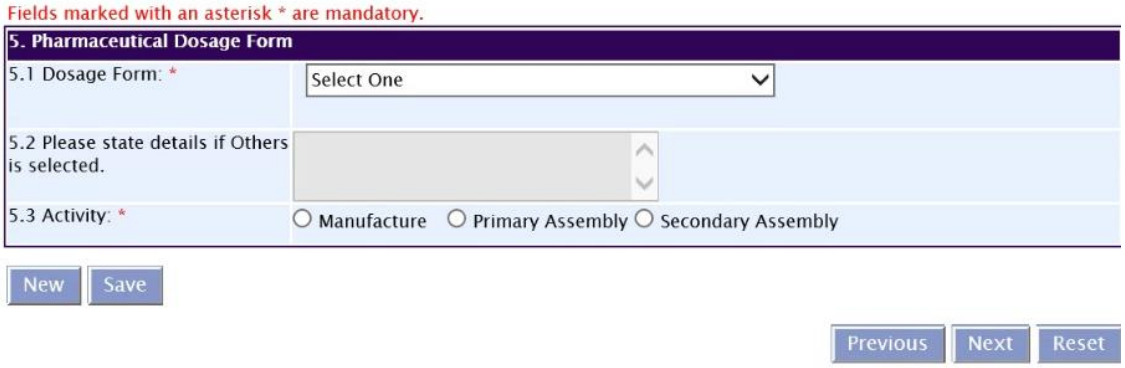


Part 5. Pharmaceutical Dosage Form

The section requires the applicant to furnish this 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 5.2.

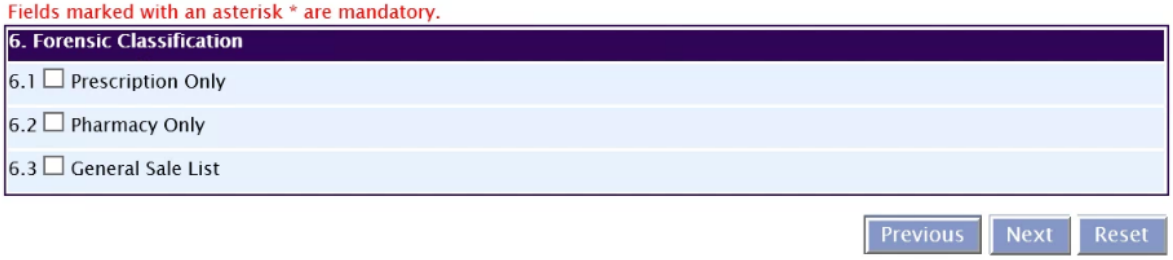
2) Activity. Please select the relevant activity for each dosage form you are dealing with, and save the entry. You will see the page refreshes, and the refreshed page will display the details of the dosage form with its associated activity you have added.



Part 6. Forensic Classification

The section requires the applicant to furnish this information:

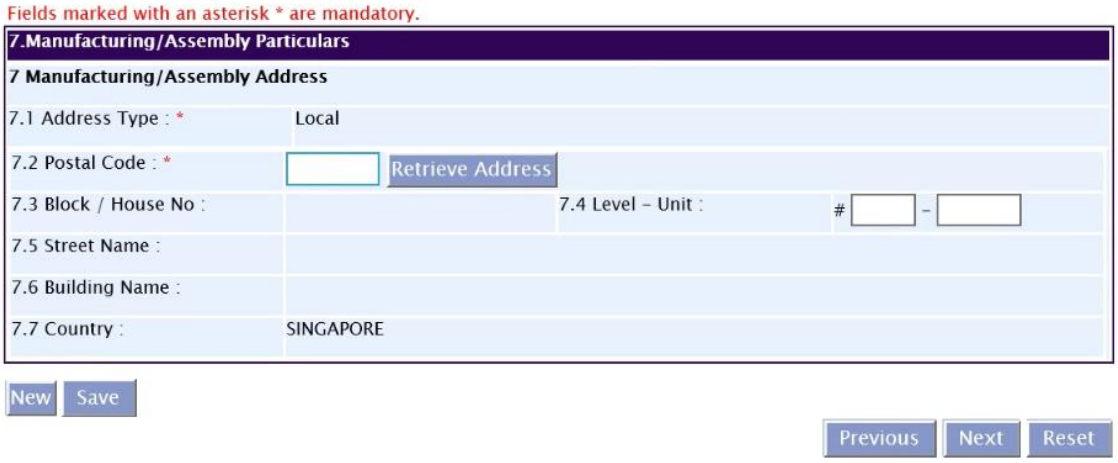
1) Forensic classification. Please select the relevant forensic classification(s) of the products you manufacture or assemble. You can select more than one option.



Part 7. Manufacturing / Assembly Addresses

The section requires the applicant to furnish this information:

1) Manufacturing/Assembly Addresses (addresses of all the sites where the therapeutic products would be manufactured or assembled). You will see the page refresh, and the refreshed page will display the details of the manufacturing/assembly addresses you have added after you click on the "Save" button.



Part 8. Warehouse Particulars

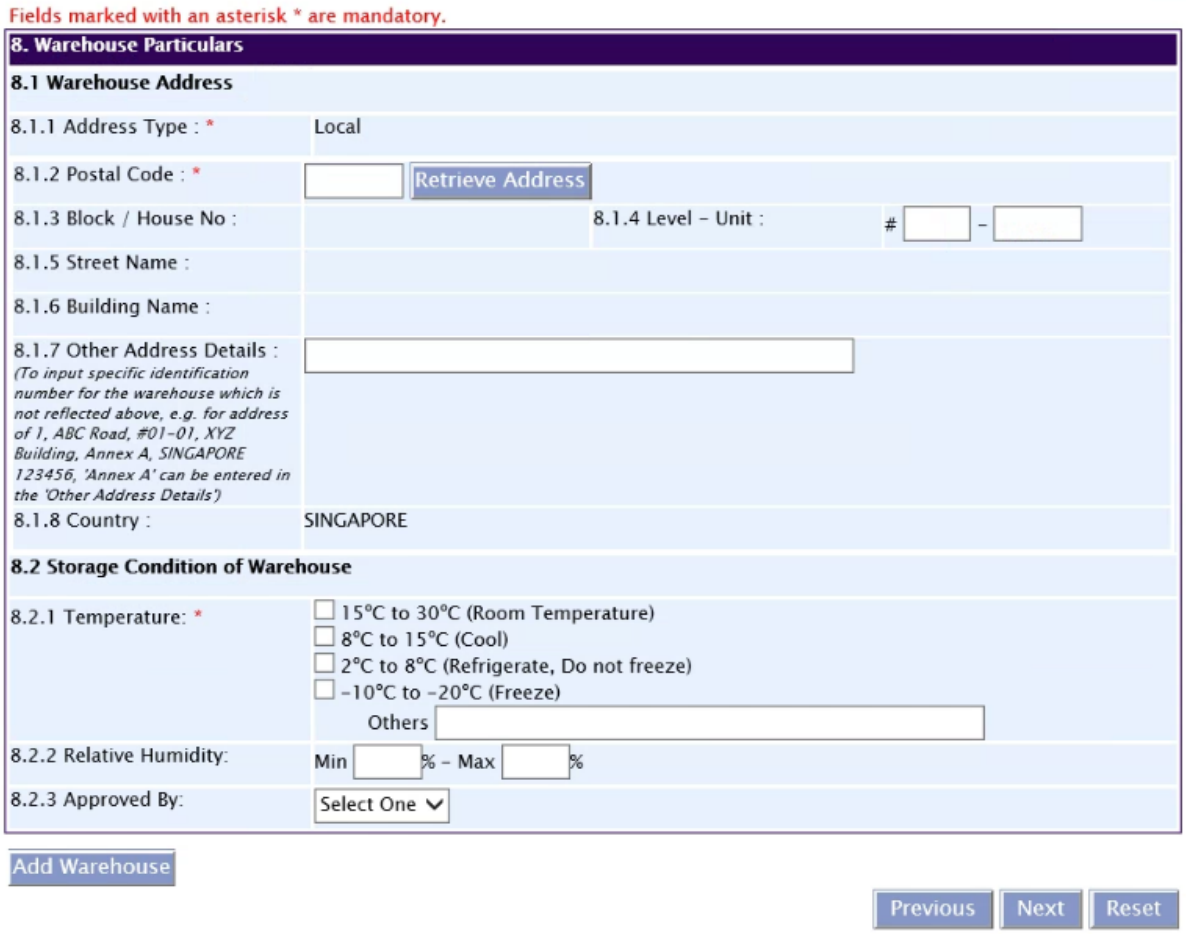
The section requires the applicant to furnish this information:

1) Warehouse Addresses (addresses of all the sites where the therapeutic products would be stored). You will see that the page refreshes, and the refreshed page will display the details of the warehouse addresses you have added

2) 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

3) Warehouse approved by. Please give details of the agency/institution that approves the use of the warehouse(s) for the storage of health products

4) Add the warehouse address by clicking on the "Add Warehouse" button. You will see the page refresh, and the refreshed page will display the details of the warehouse particulars you have added


Fields marked with an asterisk * are mandatory.

8. Warehouse Particulars

8.1 Warehouse Address

8.1.1 Address Type : * Local

8.1.2 Postal Code : * Retrieve Address

8.1.3 Block / House No :

8.1.4 Level - Unit : # -

8.1.5 Street Name :

8.1.6 Building Name :

8.1.7 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')*

8.1.8 Country : SINGAPORE

8.2 Storage Condition of Warehouse

8.2.1 Temperature: *
- ☐ 15°C to 30°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

8.2.2 Relative Humidity: Min % - Max %

8.2.3 Approved By: Select One

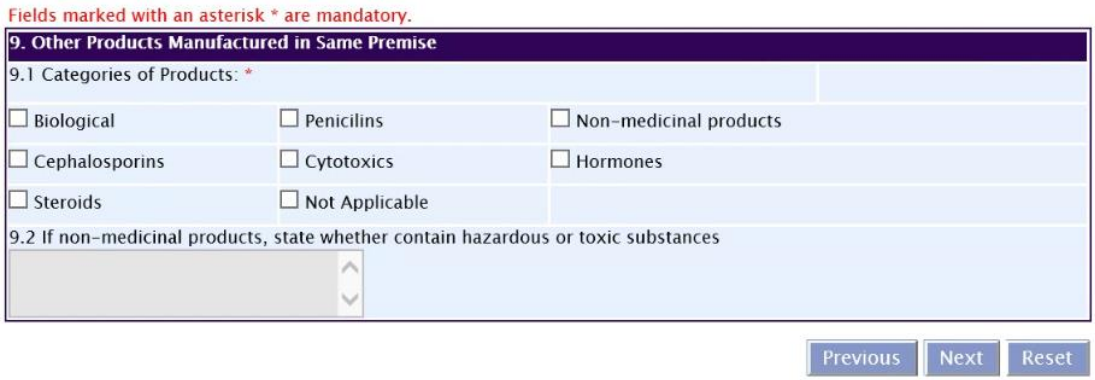
Add Warehouse

Previous Next Reset

Part 9. Other Products Manufactured in Same Premise

The section requires applicant to furnish this 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.


Fields marked with an asterisk * are mandatory.

9. Other Products Manufactured in Same Premise

9.1 Categories of Products: *

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

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

Previous Next Reset

Part 10. Contract Testing Laboratories Particulars

The section requires applicant to furnish this information:

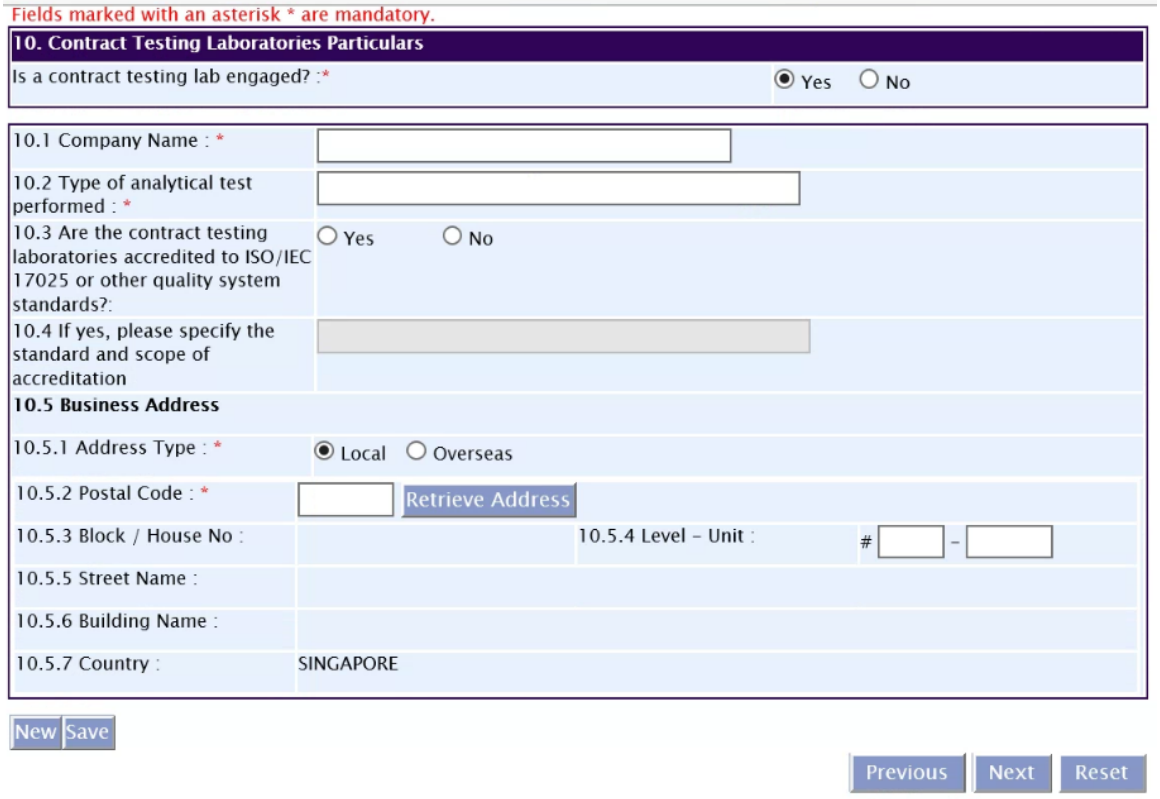
1) Is a contract testing laboratory engaged to conduct laboratory tests for your company? If your answer to the question is “No”, you can proceed to the next Part. If your answer is “Yes”, you will be required to give details of the contract testing laboratory in the following sections.

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 and the scope of accreditation. You will only need to give a brief description of the scope of accreditation.

4) If the contract testing laboratory is accredited to any international quality system standards.

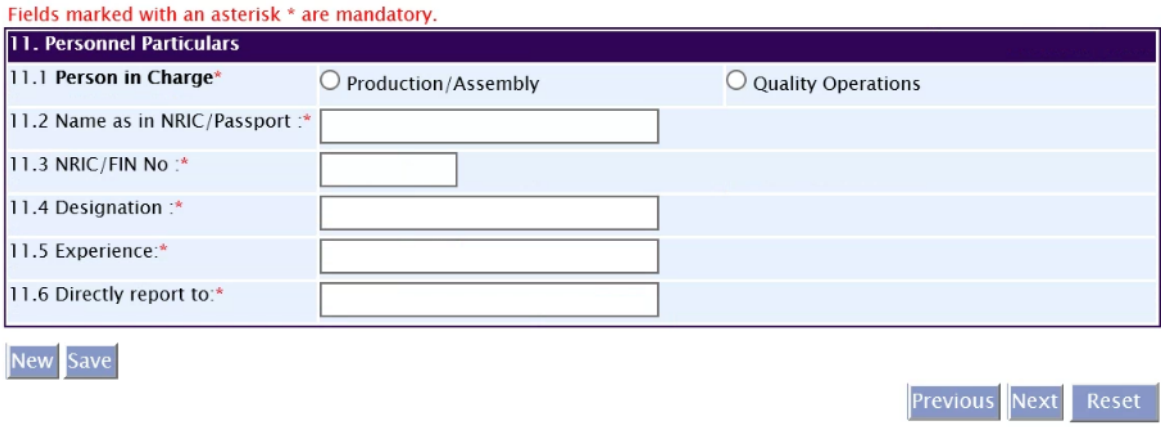
5) Add the contract testing laboratory by clicking on the “Save” button. You will see the page refresh, and the refreshed page will display the details of the contract testing laboratory you have added.



Part 11. Personnel Particulars

The section requires applicant to furnish this information:

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



Part 12. Licence Duration

These details should be automatically displayed for your confirmation:

1) Licence duration which is set to one year as a default duration.



Part 13. Attachment of supporting documents:

This section allows the attachment of any supporting documents for the application, such as the company's Site Master File, and lists of manufacturing and quality control equipment.

Fields marked with an asterisk * are mandatory.

13. 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		
13.1	Site Master File (Required for manufacturing/primary assembly activity) :	Browse...
13.2	Certificate of Accreditation :	Browse...
13.3	Letter of approval for the usage of store :	Browse...
13.4	List of Manufacturing Equipment available and their function : *	Browse...
13.5	List of Quality Control equipment available and function of each equipment : *	Browse...
13.6	Details of Products Manufactured :	Browse...
13.7	CD Submission :	Browse...
13.8	Other Supporting Documents :	Browse...

Attach Files

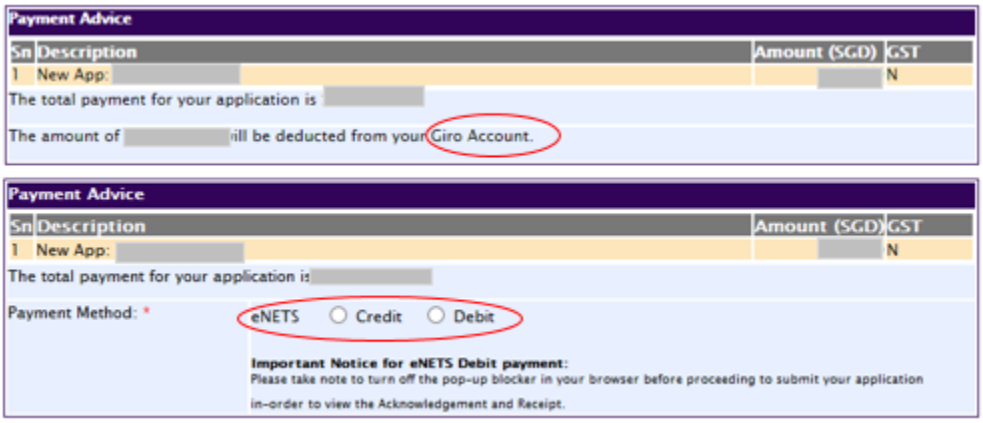
Note :
Please fill up the template (download here) if you are sending the supporting attachment(s) via CD, after which you are required to save a copy and attach it under "CD Submission."

Payment Advice

This section shows the application fee for the licence applied.

There are 2 modes of payment available:

- GIRO
- eNETS



For GIRO, the amount payable will be deducted from the relevant bank account. This mode of payment is a recurring deduction.

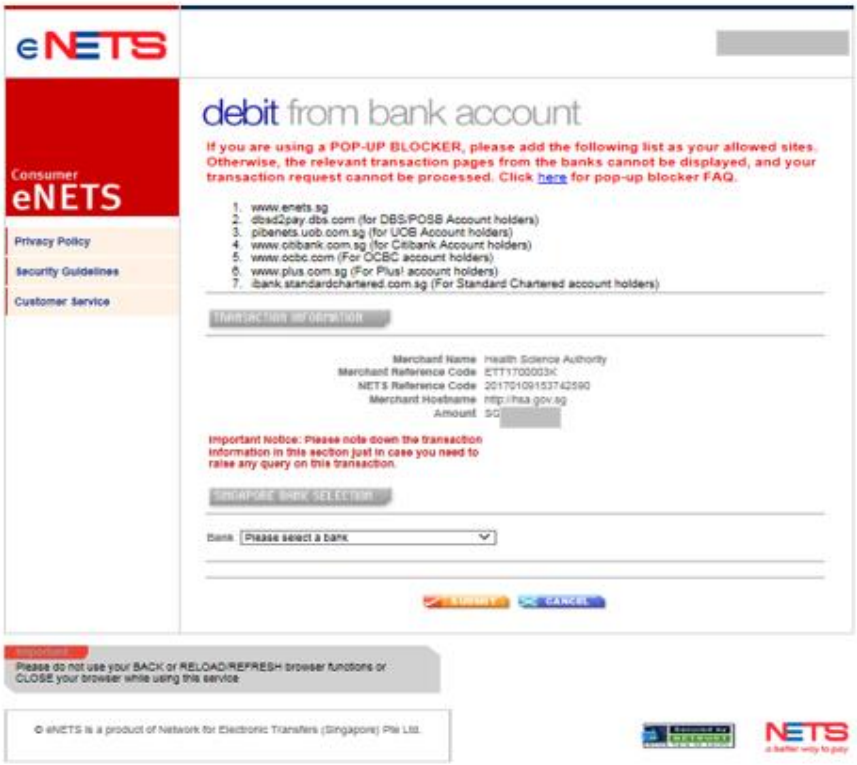
For eNETS, the payment choice is either Credit Card or Debit Card.

This is applicable for applicants with Non-GIRO Payment Method.

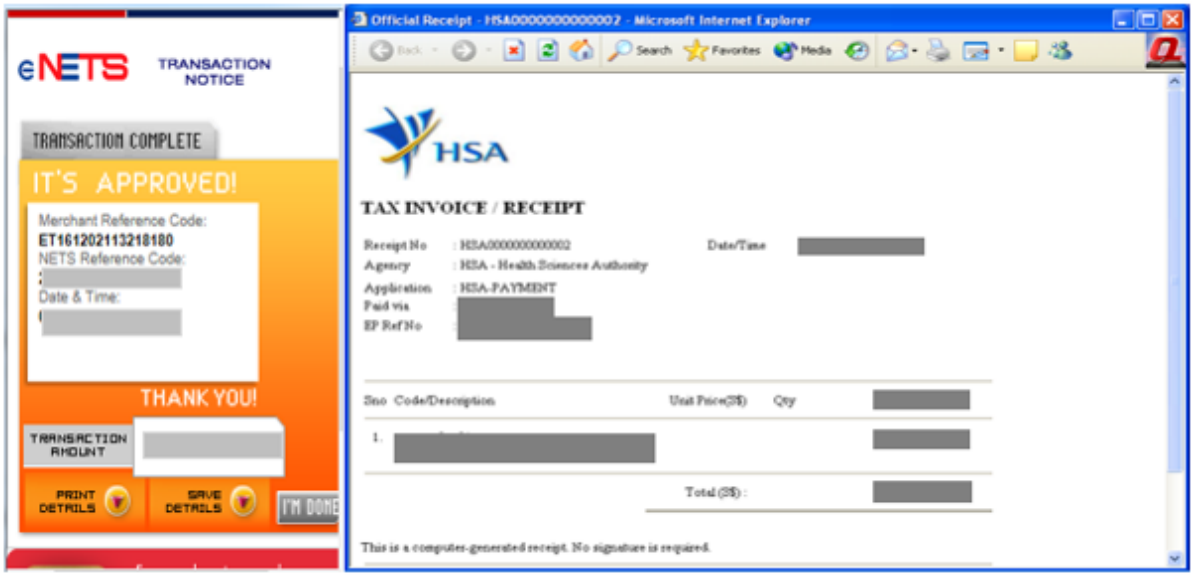
If the Credit option is selected, the page will be re-directed to the relevant screen for the applicant to input the credit card details.



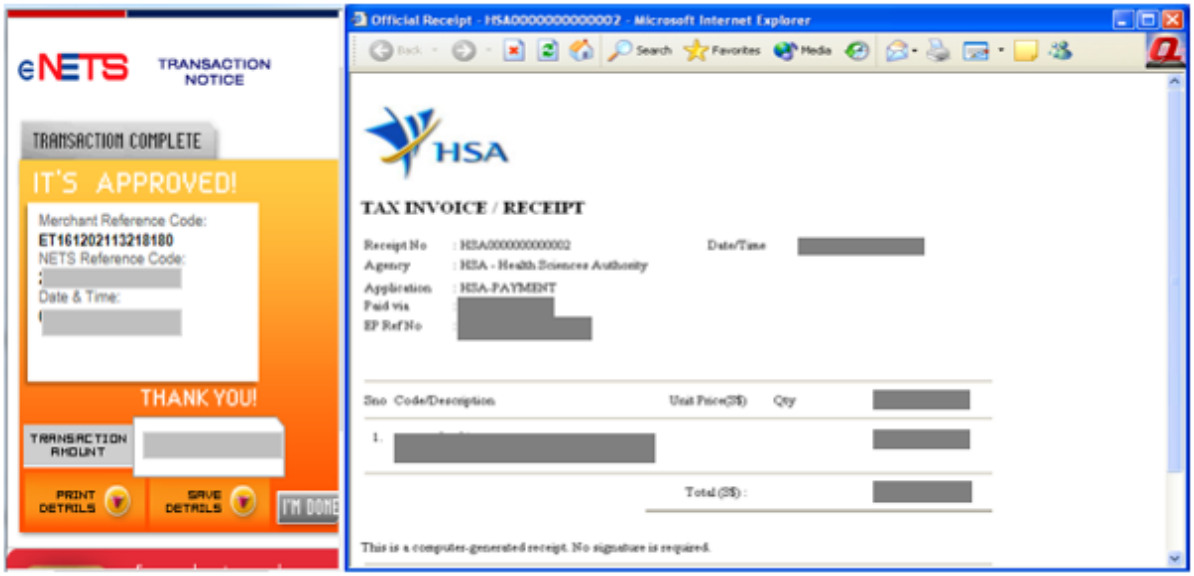
If the Debit option is selected, the page will be re-directed to the relevant screen for the applicant to select the bank first before being re-directed to input the debit card details. This mode of payment is a one-time deduction only.



Upon successful transaction, an eNETS official receipt and a HSA tax invoice will be generated.



If the payment was made via eNETS and was not completed successfully, the system will prevent retrieval of the draft application and the applicant will need to contact HSA HelpDesk for assistance.

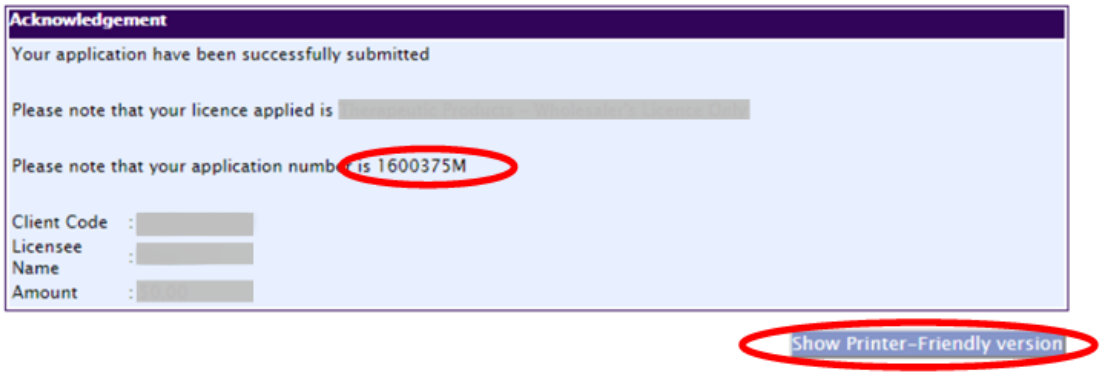


To submit the completed application, click the **'Submit'** button. Applicant will be prompt to confirm the submission. The application will then be submitted to HSA for the relevant personnel's processing.

Acknowledgement

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

Applicants may wish to print a copy of this acknowledgement page or take note of the **Application Number** for ease of reference. Applicants may provide the application number if they wish to communicate with HSA.



Note: The show Printer Friendly version allows applicant to print or view the application.

Other Useful Information

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

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

   HSA HelpDesk
   Tel : 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