HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

GUIDANCE FOR INDUSTRY

GUIDANCE ON PRISM APPLICATION FOR ACTIVE INGREDIENTS MANUFACTURER'S LICENCE AND GMP CERTIFICATE

HSA Health Sciences Authority

PREFACE

This document is intended to provide general guidance. Although we have tried to ensure that the information contained here is accurate, we do not, however, warrant its accuracy of completeness. The Health Science Authority (HSA) accepts no liability of any errors or omissions in this document, or for any actions / decision taken or not taken as a result of using this document. If you need specific legal or profession advice, you should consult your own legal or other relevant professional advisers.

In the event of any contradiction between the contents of this document and any written law, the latter shall take precedence.

REVISION HISTORY

Version 1.0 (18 December 2023) – First release

Contents

I. APPLICATION DETAILS FOR ACTIVE INGREDIENTS MANUFACTURER'S LICENCE 4

Part One – Company Particular 4

Part Two – Applicant Particulars 4

Part Three – Approved Manufacturing Operations 5

Part Four – Manufacturing Particulars (Manufacturing / Packaging Address) 11

Part Five – Warehouse Particulars 11

Part Six – Other Products Manufactured in Same Premises 12

Part Seven – Contract Testing Laboratories Particulars 13

Part Eight – Personnel Particulars 14

Part Nine – Licence Duration 15

Part Ten – Supporting Attachments 16

Part Eleven – Declaration 17

II. HOW TO RESPOND TO INPUT REQUEST 18

III. APPLICATION FOR GOOD MANUFACTURING PRACTICE (GMP) CERTIFICATE 21

1. Application For GMP Certificate For Licensed Manufacturers Of Active Ingredients 21

2. Application For Additional Copies of GMP Certificate 24

3. New Application for GMP Certificate 26

I. APPLICATION DETAILS FOR ACTIVE INGREDIENTS MANUFACTURER'S LICENCE

The following sections provides guidance on how to complete the PRISM application for the Manufacturer's Licence for Active Ingredients.

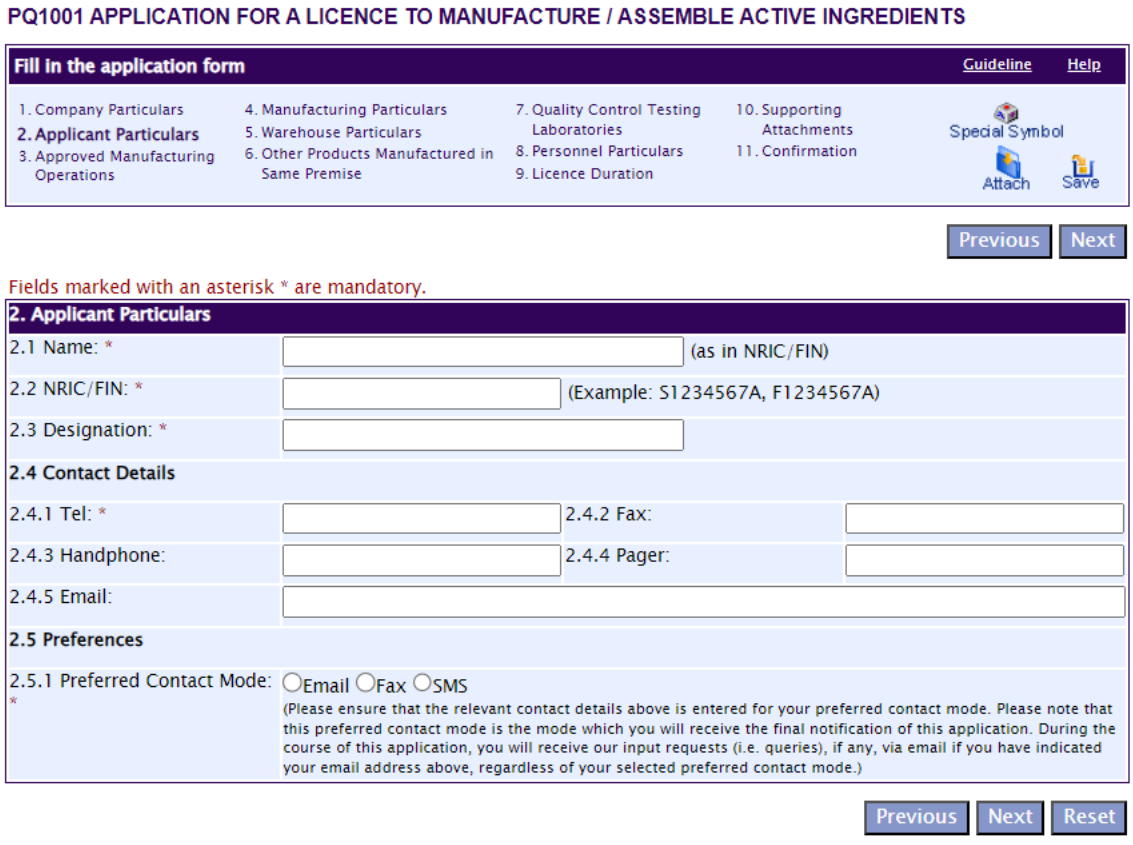
Part One – Company Particular

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

Please ensure that the company contact person details are correct and update in order to receive all the updates and correspondence related to the applications.

Click the Next button after checking the applicant particulars.



PQ1001 APPLICATION FOR A LICENCE TO MANUFACTURE / ASSEMBLE ACTIVE INGREDIENTS

Fill in the application form — Guideline Help

1. Company Particulars
2. Applicant Particulars
3. Approved Manufacturing Operations
4. Manufacturing Particulars
5. Warehouse Particulars
6. Other Products Manufactured in Same Premise
7. Quality Control Testing Laboratories
8. Personnel Particulars
9. Licence Duration
10. Supporting Attachments
11. Confirmation

Special Symbol | Attach | Save

Previous | Next

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.)		

Previous | Next | Reset

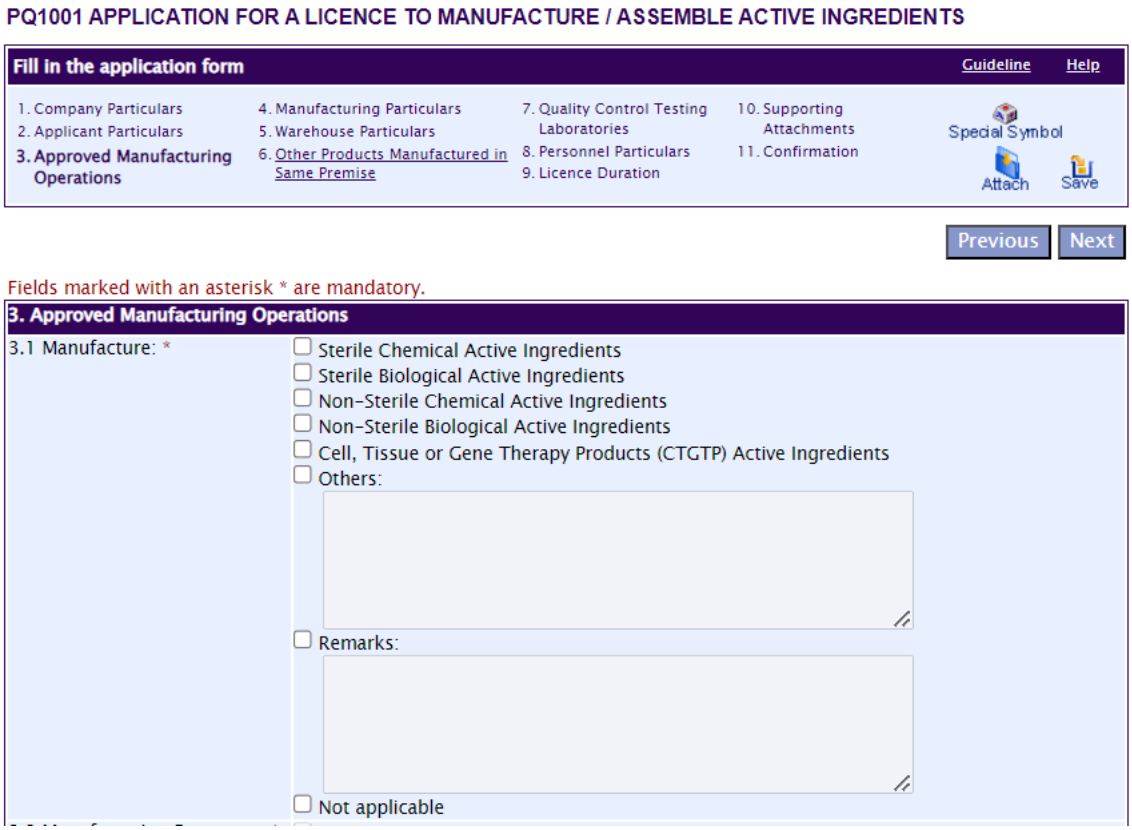
Part Three – Approved Manufacturing Operations

Section 3.1 - Type of Active Ingredients

The active ingredients are broadly classified as sterile or non-sterile and whether they are produced by chemical synthesis or biological processes.

If the type of active ingredients that the company is manufacturing does not fit in any of the selection, please select the option "Others", and enter the free-text description of the active ingredients.

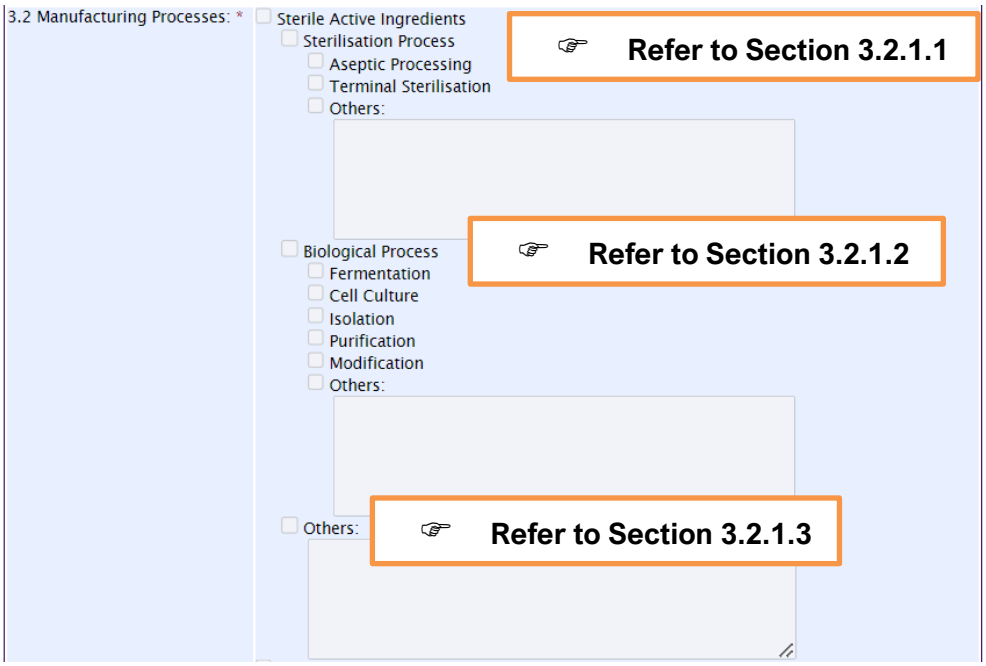
If the manufacturer is only conducting packaging, repacking or relabelling activities, please select 'Not applicable' for sections 3.1 and 3.2.



Section 3.2 - Manufacturing Activities Details

Please provide the details for the manufacturing process, packaging and quality control testing operations performed for the active ingredients manufactured at the site.

3.2.1 For Sterile Active Ingredients



3.2.1.1 Sterilization Process

This refers to those steps in the manufacturing process which render an active ingredient sterile.

3.2.1.2 Manufacture of Active Ingredients Produced by Biological Process

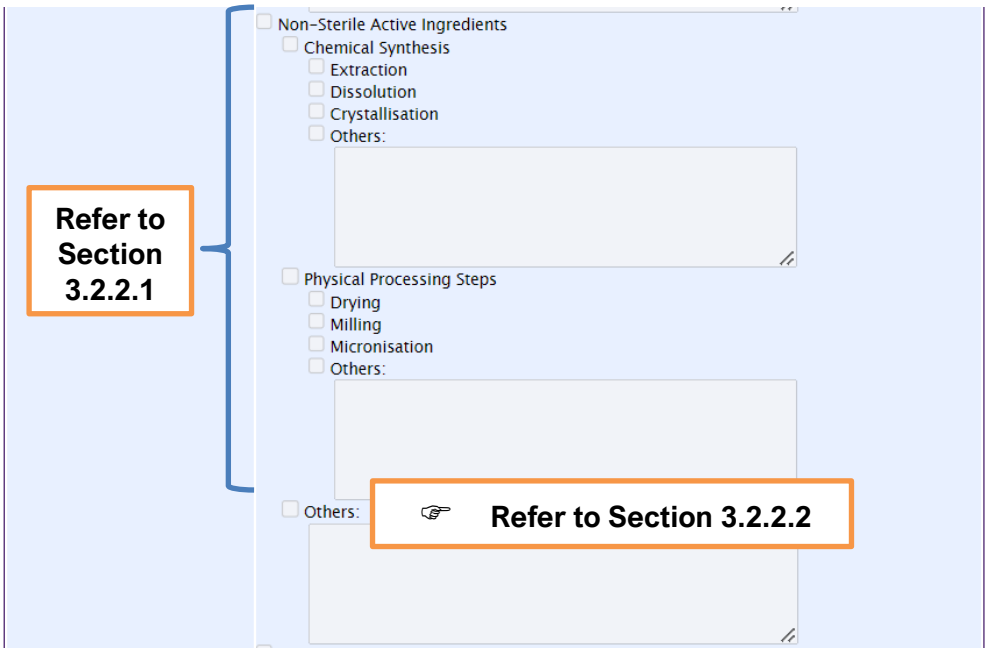
Please select 'Biological Process' and the applicable steps

3.2.1.3 Manufacture of Active Ingredients Produced by Chemical Synthesis or other processes.

Please select 'Others' (after Biological Process) and fill in the description of any steps from manufacture of the defined active ingredient starting materials until the step prior to manufacture of the crude active substance.

Please also see section 3.2.2.2 for more explanatory notes.

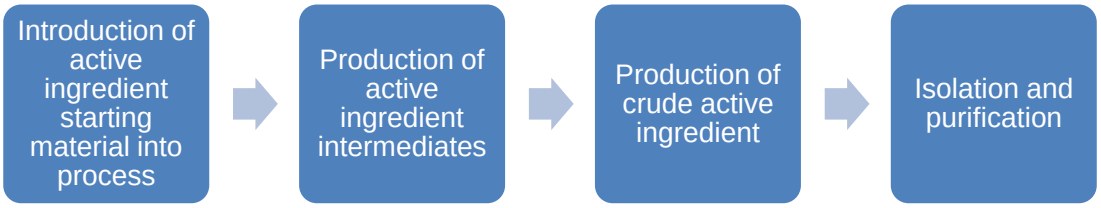
3.2.2 For Non-Sterile Active Ingredients:



3.2.2.1 Manufacture of Active Ingredients Produced by Chemical Synthesis

Please select 'Chemical Synthesis' and select any applicable steps.
You can also select 'others' and include free text description of any steps from manufacture of the defined active ingredient starting materials until the step prior to manufacture of the crude active substance.

The typical manufacturing process steps for active ingredients produced by chemical synthesis are described in PIC/S Guide to GMP Part II Scope and as shown below:



General Finishing Steps

Please select any applicable steps for physical processing of active ingredients such as granulation, coating or physical manipulation of the particle size (e.g. milling, micronizing) performed at the site.

3.2.2.2 Manufacture of Active Ingredients Produced by Biological Process

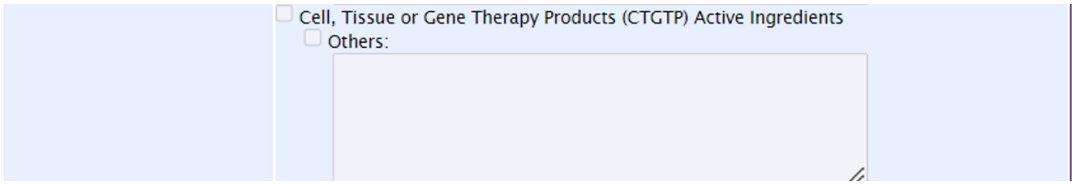
Please select 'Others' (after Physical Processing Steps) and fill in the description of any steps (e.g., microbial fermentation, cell culture, isolation, purification, modification) where the production of active ingredients begins.
The typical manufacturing process steps for active ingredients produced by biological processes are described in PIC/S Guide to GMP Annex 2B Scope as shown below:

Type and source of material	Example of products	Manufacturing Processes		
1. Animal or plant sources: non-transgenic	Heparins, insulin, enzymes, proteins, allergen extract, immunosera	Collection of plant, organ, animal material or fluid	Cutting, mixing, and / or initial processing	Isolation and purification
2. Virus or bacteria / fermentation / cell culture	Viral or bacterial vaccines; enzymes, proteins	Establishment & maintenance of MCB, WCB, MVS, WVS	Cell culture and/or fermentation	Inactivation when applicable, isolation and purification
3. Biotechnology fermentation/ cell culture	Recombinant products, MAb, allergens, vaccines	Establishment & maintenance of MCB and WCB, MSL, WSL	Cell culture and /or fermentation	Isolation, purification, modification

3.2.3 For Cell, Tissue and Gene Therapy Active Ingredients

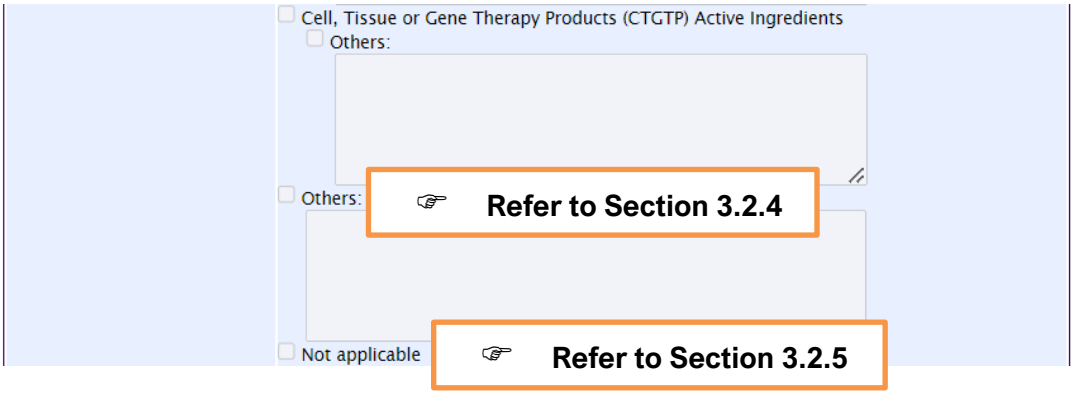
This category should be selected where there are processing operations carried out in relation to the manufacture of cell, tissue and gene therapy active ingredients.

Please select 'Others' and fill in the description of any steps (e.g. microbial fermentation, cell culture, purification) where the production of active ingredients begins.



3.2.4 For other types of manufacturing activities

Company may describe additional manufacturing processes by selecting 'Others' and provide the free-text description in the box as shown below.



3.2.5 For companies only performing packaging activities

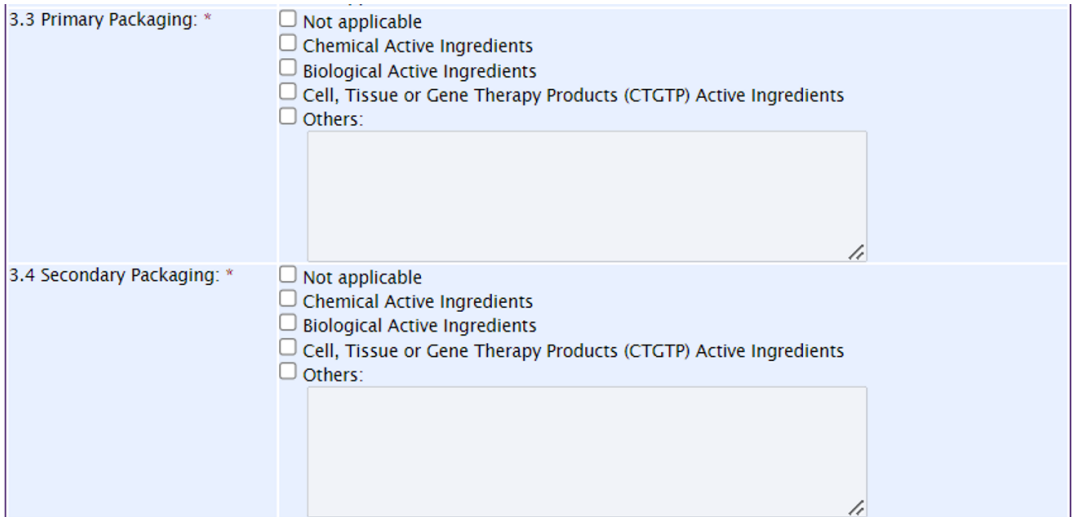
If the manufacturer is only conducting packaging, repacking or relabelling activities, please select 'Not applicable'.

Section 3.3 and 3.4 – Primary and Secondary Packaging

Please select the type of active ingredients company is conducting packaging, repacking, or relabelling activities

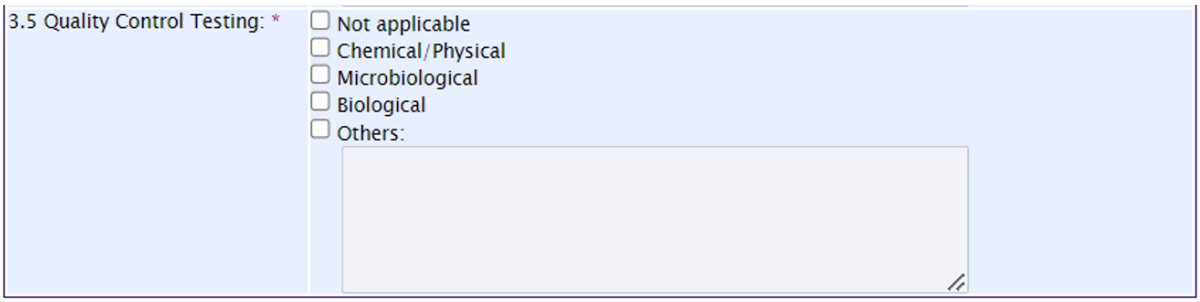
Primary Packaging	Refers to placing and sealing of the active ingredient within the packaging material, which is in direct contact with the active ingredient.
Secondary Packaging	Refers to placing the sealed primary package within an outer packaging material or container. This includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active ingredients.

If the active ingredients were packed directly into a container for release and supply, please select both primary and secondary packaging.



Section 3.5 – Quality Control Testing

Where Quality Control testing is carried out at the site then authorised categories of testing should be identified in section 3.5.
If there are quality control testing performed by outsourced testing laboratories, please refer to part 7.



Please refer to the table below for examples of the 3 different testing categories.

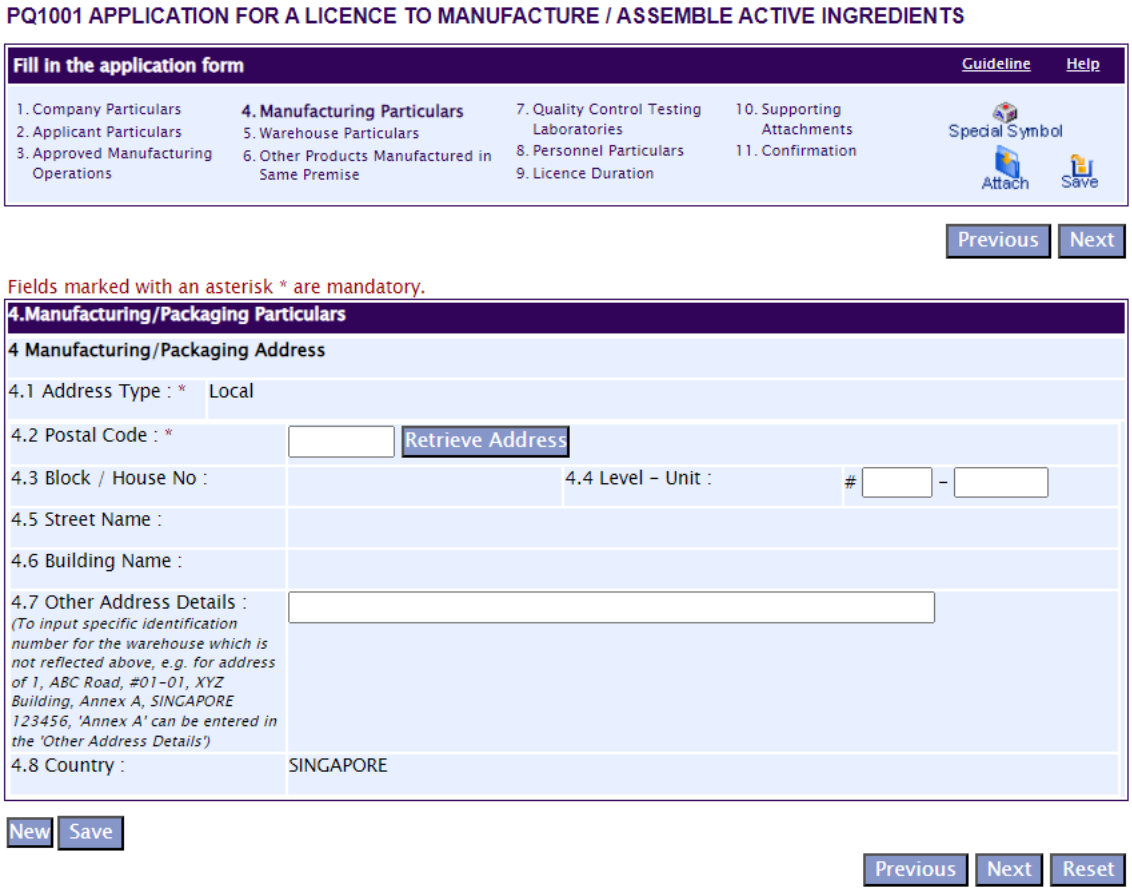
Testing Categories	Examples
Chemical / Physical	Testing of quality attributes by physical or chemical means e.g. Physical measurements, Wet Chemistry, Chromatographic techniques
Microbiological	Sterility Test, Testing involving culturing, enumeration and identification of micro-organisms, Preservative efficacy testing
Biological	Tests involving use of live cultured animal cells or animals and tests utilising materials of biological origin (e.g. antibodies, antigens). Examples of such tests would include, Rabbit Pyrogen, ELISA, Monocyte Activation Test & qPCR, Endotoxin testing (e.g. gel clot, turbidometric or chromogenic methods.)

Part Four – Manufacturing Particulars (Manufacturing / Packaging Address)

Please list all addresses where manufacturing operations will take place under this proposed manufacturer's licence.

If the manufacturing site consists of a number of separate units located in an industrial estate/building (i.e. same postal code) which are managed under the same pharmaceutical quality system and under the responsibility of the same key personnel named on this application, include the main contact address for the manufacturing site. Provide details of other 'units' which will operate under the scope of this authorisation below the main contact address.

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, followed by 'Save' button.

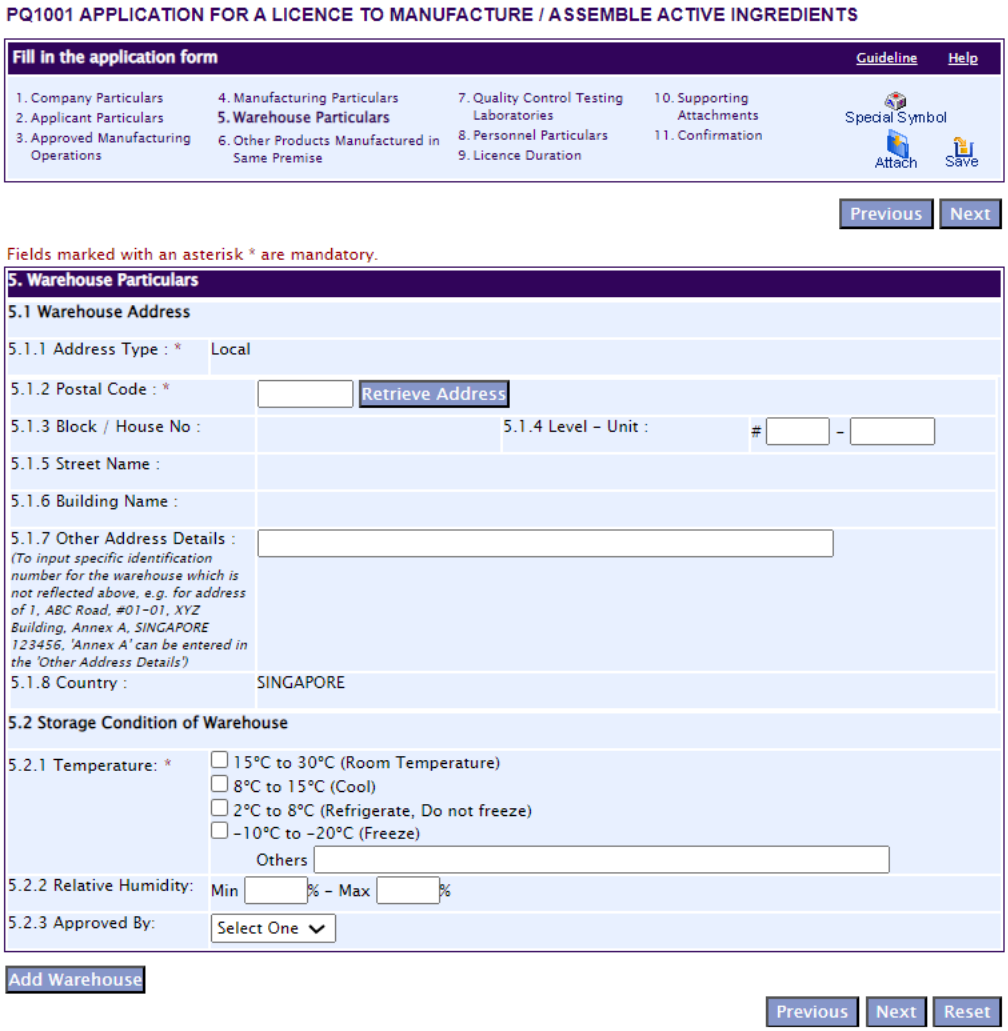


Part Five – Warehouse Particulars

The company is required to provide the details of the warehouse which are used to store the following:

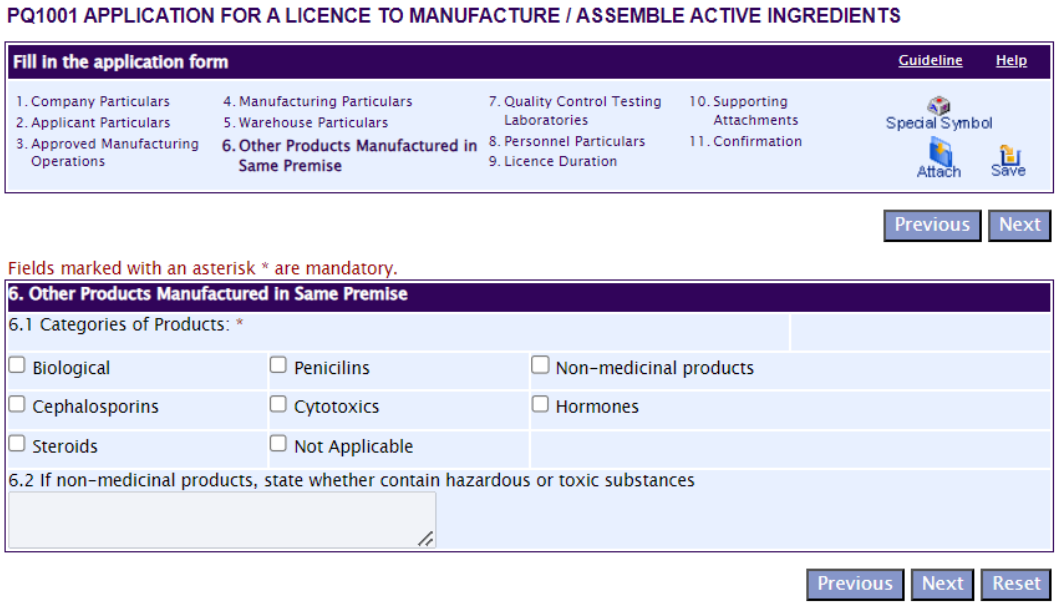
(a) Starting materials
(a) Intermediate products
(b) Reference samples
(c) Active Ingredients under quarantine / pending batch release
(d) Critical Process Consumables (i.e., Columns, Resins)
(e) Packaging materials which are in direct contact with the active ingredients

Please indicate the storage condition (temperature and relative humidity) of the warehouse. You can select more than one option for the warehouse temperature. Click on the "Add Warehouse" button to add a warehouse address.



Part Six – Other Products Manufactured in Same Premises

Company should conduct assessment on potency, toxicity, and characteristics of materials (i.e., highly sensitising) for the materials handled at the manufacturing site. The company would need to declare the categories of the materials handled at the site. You can select more than one option. Specific restrictions may apply as licensing conditions in the licence.


PQ1001 APPLICATION FOR A LICENCE TO MANUFACTURE / ASSEMBLE ACTIVE INGREDIENTS

Fill in the application form — Guideline — Help

1. Company Particulars
2. Applicant Particulars
3. Approved Manufacturing Operations
4. Manufacturing Particulars
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11. Confirmation

Special Symbol — Attach — Save

Previous Next

Fields marked with an asterisk * are mandatory.

6. Other Products Manufactured in Same Premise

6.1 Categories of Products: *

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

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

Previous Next Reset

Part Seven – Contract Testing Laboratories Particulars

If the manufacturer outsourced the testing activities to local third party contract testing laboratories, these laboratories would need to be named in the licence.

Contract laboratories only need to be named if they are undertaking the following testing:

- Microbiological, biological and chemical/physical testing of active ingredients i.e., final testing for the purposes of batch release
- Stability testing of active ingredients
- In process control tests which are described in the product registration
- Environmental monitoring and/or process simulation work for sterile active ingredients

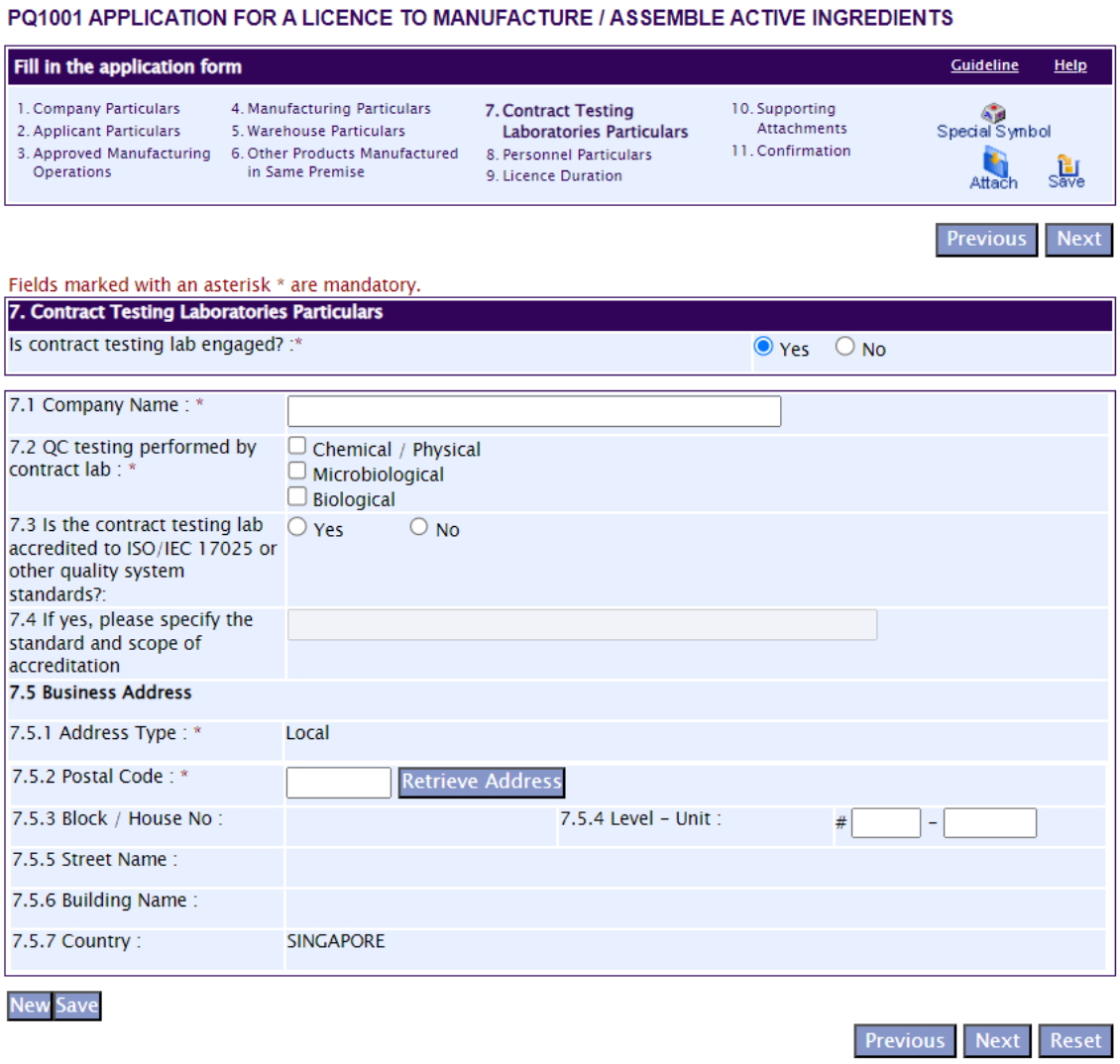
The manufacturer should ensure that the contract laboratory is accredited to perform the outsourced testing or performed qualification on the contract laboratory before approving the contract laboratory. If part of the quality control or product tests which are outsourced to the contract testing laboratory is subcontracted to a third-party testing laboratory, this subcontracted testing laboratory should also be named in the Manufacturer's Licence if it is involved in quality control testing of the active ingredients.

The manufacturer (i.e., contract givers) who wishes to use a contract laboratory (i.e., contract acceptor) must:

- ❑ Have a system in place to assess the suitability, competency and GMP compliance of proposed contract laboratories prior to their use.
- ❑ Ensure that the contract laboratories used are appropriately managed with their Pharmaceutical Quality System and listed in their site master file.
- ❑ The outsourced testing lab should agree and accept that the outsourced testing activities may be subject to inspection by the regulatory authority.
- ❑ Update their respective licences to name the contract laboratory if the contract laboratory meets the criteria and agree to be named in the licence.
- ❑ Ensure that a written contract or Quality Agreement which describes the GMP responsibilities of each party, including the scope of testing and type of tests covered by the agreement has been put in place.

- ❑ Have a system of ongoing risk-based supervision for the contract laboratories, including arrangements for periodic formal reassessment of compliance.

Add the contract testing laboratory by clicking on the "Save" button. The refreshed page will display the details of the contract testing laboratory which was added.



Part Eight – Personnel Particulars

The *HP(AI) Regulation 29* requires at least one responsible person for production and quality operations to be named in the Manufacturer's Licence.

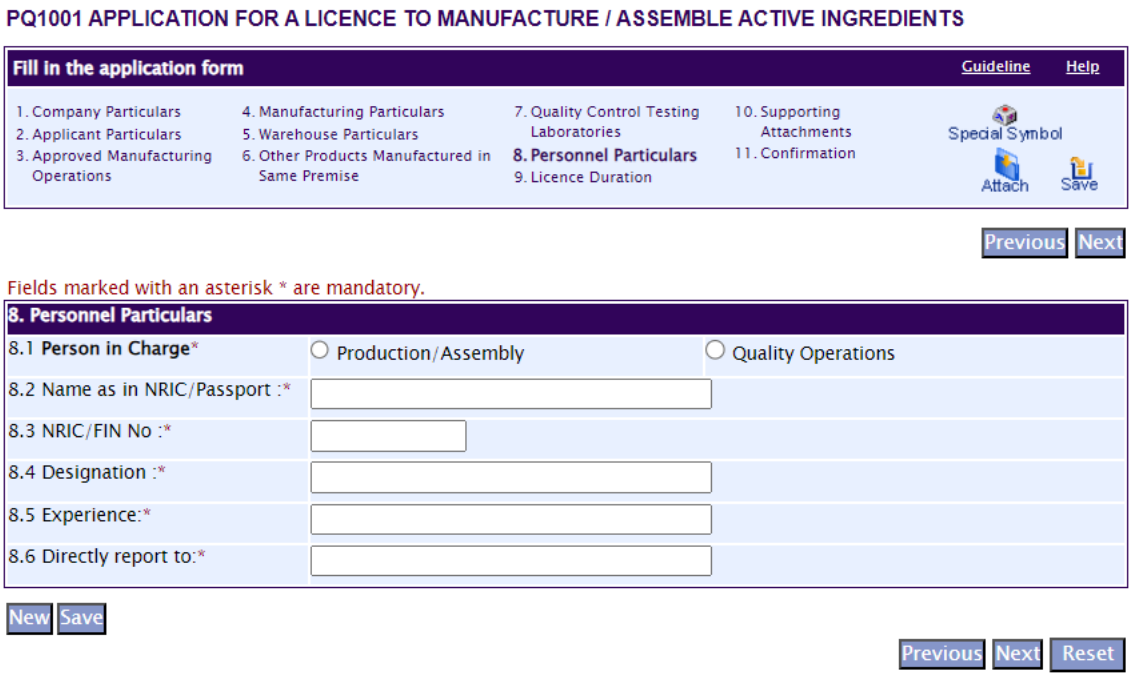
- ❑ Responsible person for Production should be someone who has adequate knowledge of the production activities and capable of supervising the production operations.
- ❑ Responsible person for Quality should be someone who has adequate knowledge of quality operations and competent to supervise all the quality control activities.

Typically, the responsible person for Production and Quality are expected to perform his or her role as the Head of Production and Head of Quality and comply with the guidelines of GMP described in PIC/S Guide to GMP Chapter 2. The heads of Production and Quality Control **must be independent from each other**, such that the quality department is able to perform its roles and responsibilities **without any controlling influence** from the production department.

The roles and responsibilities of the responsible persons should be defined in their job description. The relevant education qualification and work experience of the responsible persons should also be described in their curriculum vitae include past and present role and responsibilities at the specific site, a summary of training and competency programme completed to demonstrate that they are able to fulfil their responsibilities.

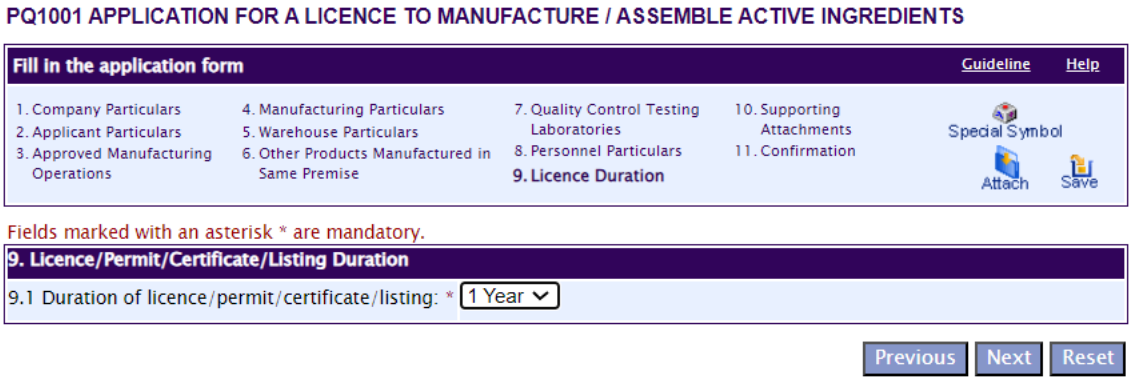
The responsible persons for production and quality operations should have practical experience in production supervision or in quality control activities at the manufacturing site. Hence, these two positions should be occupied by full-time personnel & normally have been working in the company for some time. The suitability of the responsible persons and competency in executing their responsibilities would be assessed during the on-site inspection

Please provide the particulars of the persons in-charge of production/assembly and quality operations. Add the record by clicking on the "Save" button. The refreshed page will display the details of the personnel which was added. The company can nominate more than one person for each role.



Part Nine – Licence Duration

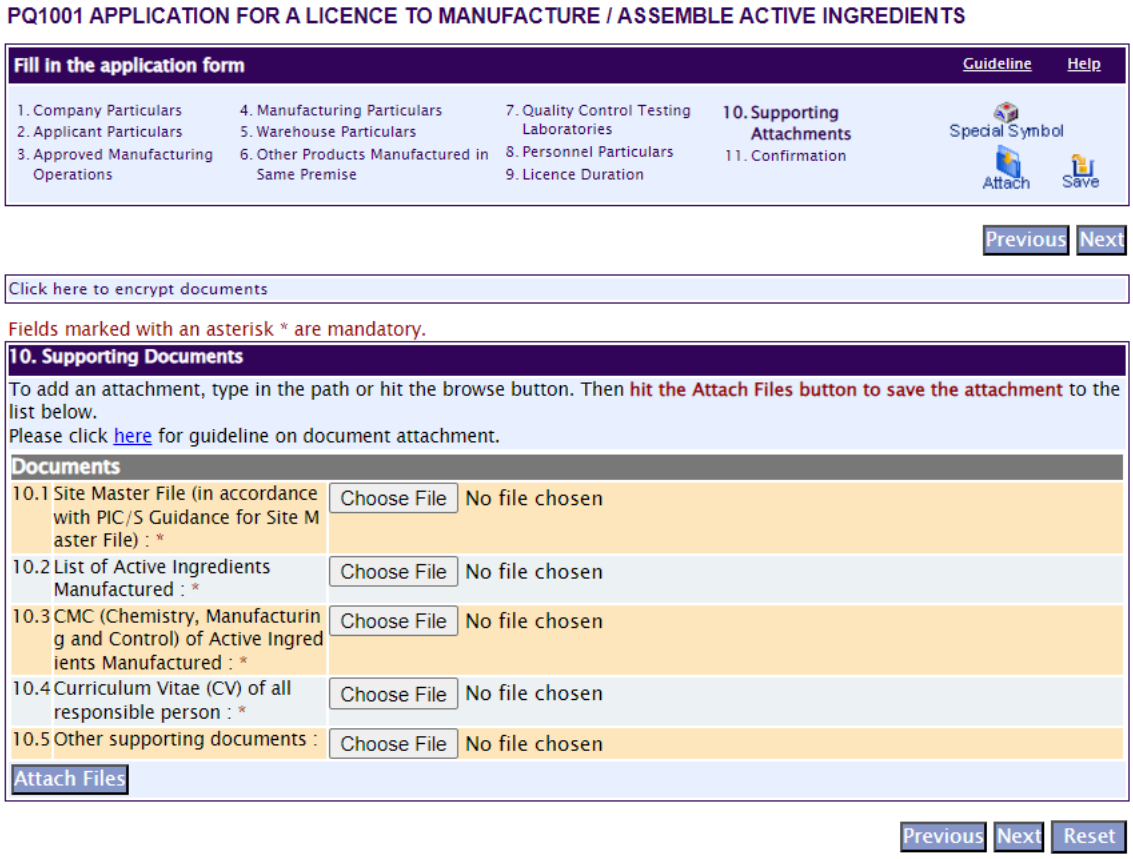
The default licence duration is 1 year. This page is for information only and cannot be changed. Please click the "Next" button to proceed to the next section.



Part Ten – Supporting Attachments

For new application of Manufacturer's Licence, please attach the relevant documents for submission:

1) Latest Site Master File of the manufacturing site including all appendices as per PIC/S explanatory notes for pharmaceutical manufacturers (accessible at https://www.picscheme.org). Please provide information (e.g., layout plans showing the material, personnel, equipment flow and pressure cascade) on the specific building, facilities, production line or equipment.
2) List of ALL active ingredients manufactured at the site, including any Investigational Medicinal Products, research drugs and non-medicinal products. Please include the description (or name if available) of the active substance(s), reference of the process line used for manufacturing of different product if done in dedicated / shared facility.
3) Curriculum Vitae, job description, training of all responsible persons.
4) Any other supporting documents.



Part Eleven – Declaration

Please complete the declaration. The fee chargeable for the application are reflected on the payment advice.

All applicants under the Health Product Act (HPA) must comply with HPA and their regulations. This is to ensure that all active ingredients in Singapore meet the required standards. Applicants must also comply with all other applicable laws and their regulations.

Declaration

1. I, on behalf of my company, confirm that the information submitted in this application is true and accurate.

(•) Accept ( ) Decline

Payment Advice

Sn	Description	Amount (SGD)	GST
1	App: API Manufacturer's Lic		N

The total payment for your application is SGD

Progressive Payment: (•) Full payment ( ) Progressive Payment

The amount of SGD will be deducted from your Giro Account.

Previous | Validate | Submit | Reset

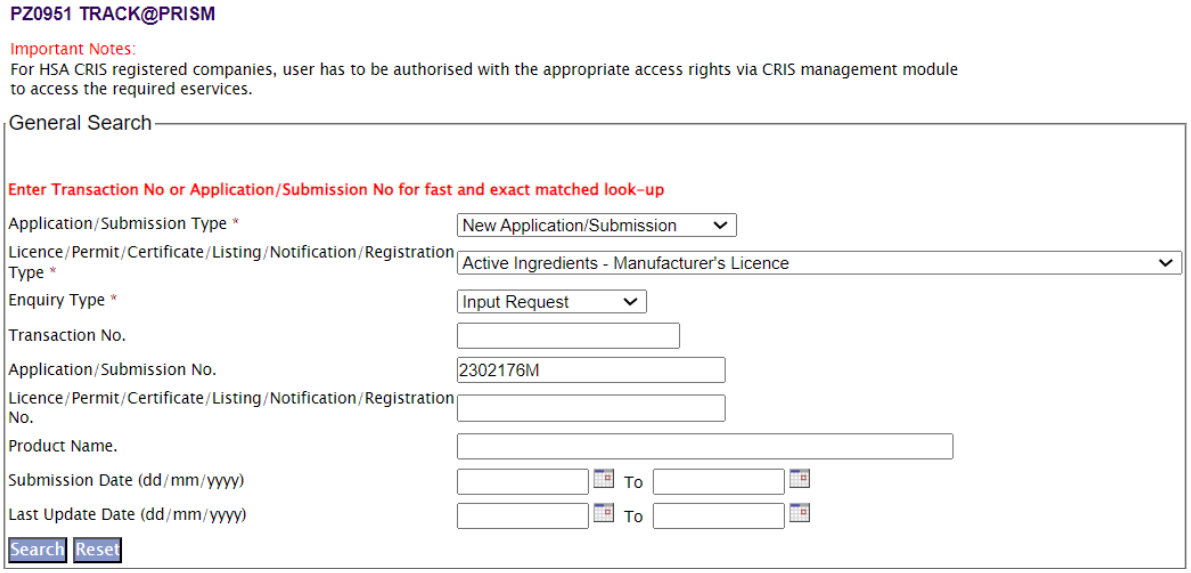
II. HOW TO RESPOND TO INPUT REQUEST

Input Requests arise when the reviewing HSA officer requires further clarification from the applicant regarding the application. This section illustrates how applicants can respond to the Input Request. A notification will be sent to the applicant to inform the applicant to log in to track@prism to make the necessary changes.

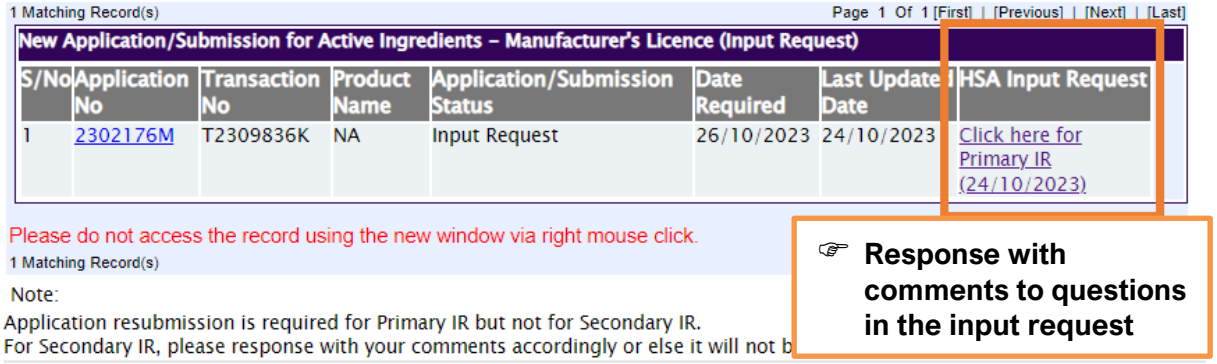
Input requests can be classified as Primary or Secondary. Primary Input Request requires changes to be made directly on the application form. Secondary Input Request requires applicant's explanation to certain matters pertaining to the application form submitted.

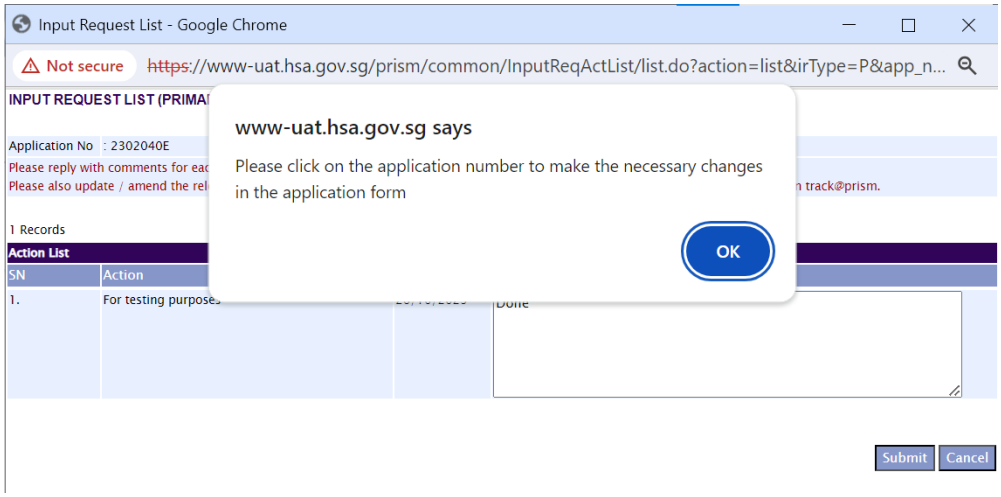
1. Responding to Primary Input Request

(1) In track@prism enter the Application Number to retrieve the application that requires clarification.

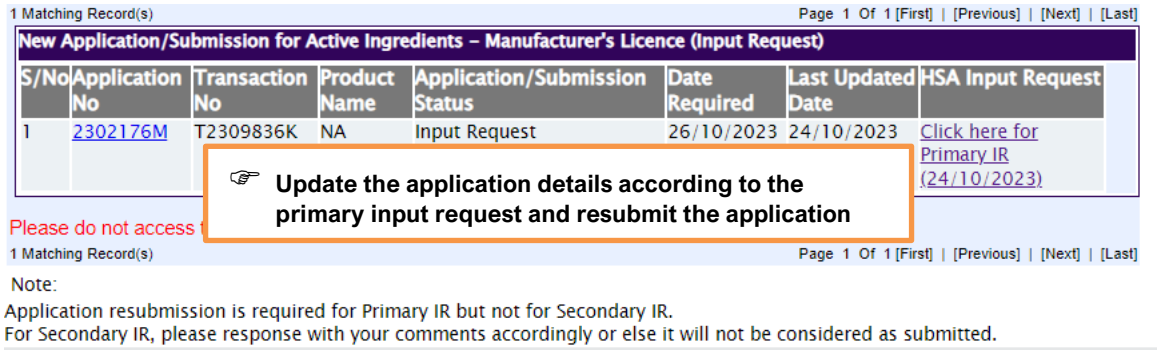


(2) Click on the 'HSA Input Request' to view if any reply is required from the applicant. Click the 'Submit' button and an alert message will pop up to prompt you to make the necessary changes in the application form.





(3) Click on the **'Application No.'** to open the application.

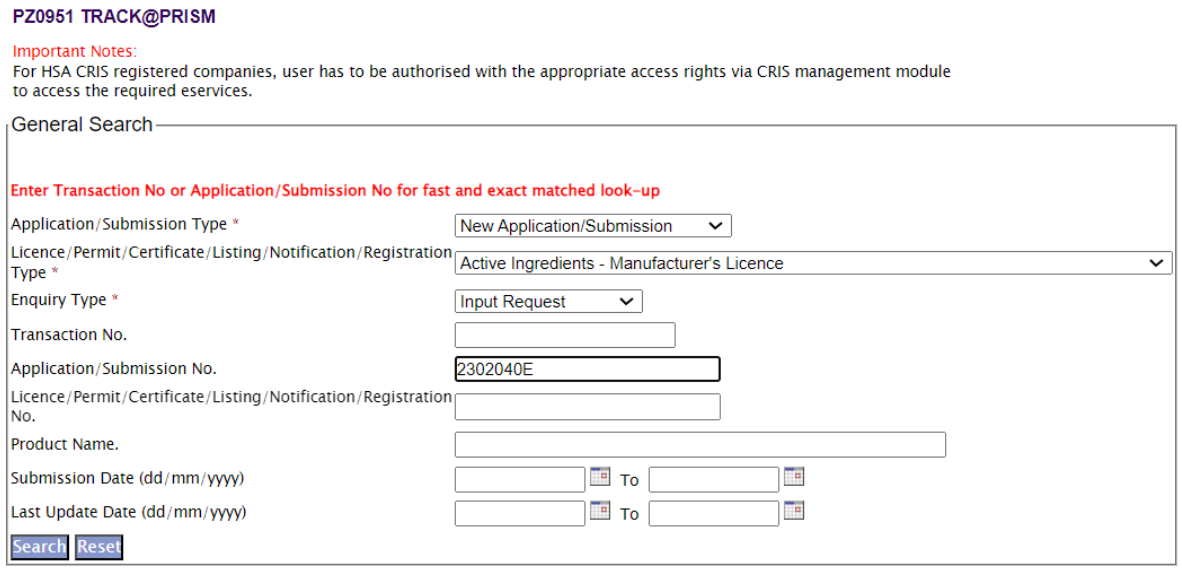


Note:
Application resubmission is required for Primary IR but not for Secondary IR.
For Secondary IR, please response with your comments accordingly or else it will not be considered as submitted.

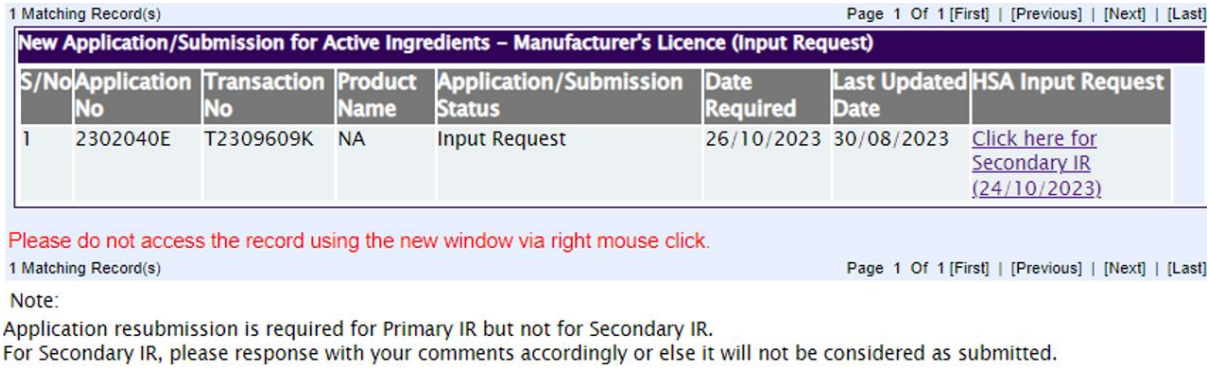
(4) The webpage will display the application form as per previously submitted.
(5) Proceed to make the necessary changes for the section(s) that require clarification and submit the revised application form.

2. Responding to Secondary Input Request

(1) In track@prism enter the Application Number to retrieve the application that requires clarification.

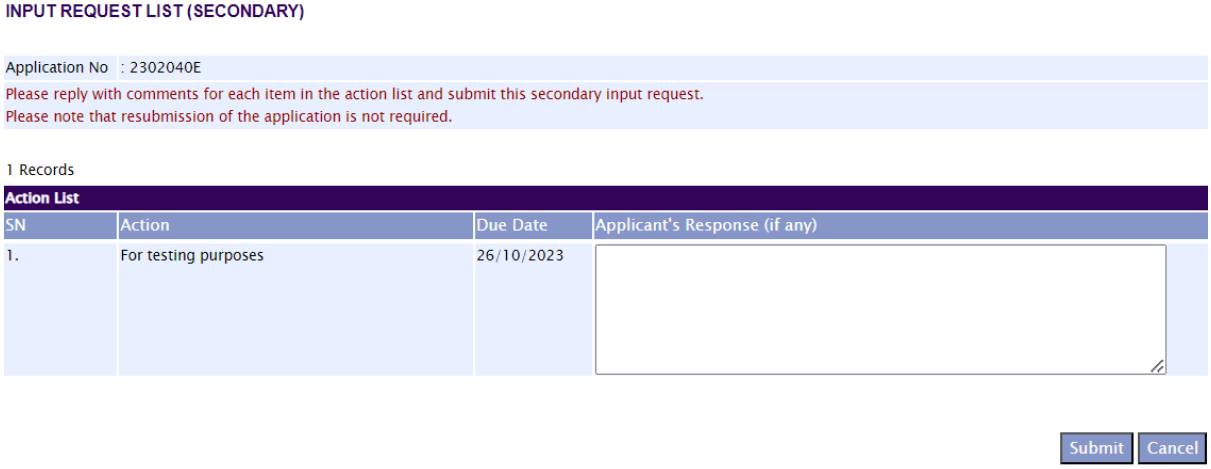


(2) Click on the 'HSA Input Request' to view the comments left by the HSA officer and the necessary action to be taken with regards to the application.



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 for response to Secondary Input Request and click the **'Submit'** button.



III. APPLICATION FOR GOOD MANUFACTURING PRACTICE (GMP) CERTIFICATE

The following sections provides guidance on how to complete the PRISM application for Active Ingredients GMP Certificate.

The GMP Certificate is a hard-copy certificate issued by the HSA which confirms that the manufacturer carried out the manufacturing activities in conformity with the applicable GMP standards following an inspection conducted by HSA. Company can request for GMP Certificates through the following applications:

1. A copy of GMP Certificate for licensed active ingredients manufacturers
2. Request for additional copy of GMP Certificate
3. New application for GMP Certificate[1]

Note:
[1]This is applicable for

(a) Investigational active ingredients which are used as Clinical Research Materials.
(b) If active ingredients are used to manufacture of therapeutic product, cell tissue gene therapy products or medical device but are not specified in the Schedule of Regulated Active Ingredients published in the Health Products (Active Ingredients) Regulations 2023.

1. Application For GMP Certificate For Licensed Manufacturers Of Active Ingredients

Section 1.1
Licensed manufacturers who require a copy of the GMP Certificate for their site should

- Select 'Without Technical Assessment' for 'Existing Active Ingredients Manufacturer's Licence'.
- Enter the Manufacturer's Licence number.

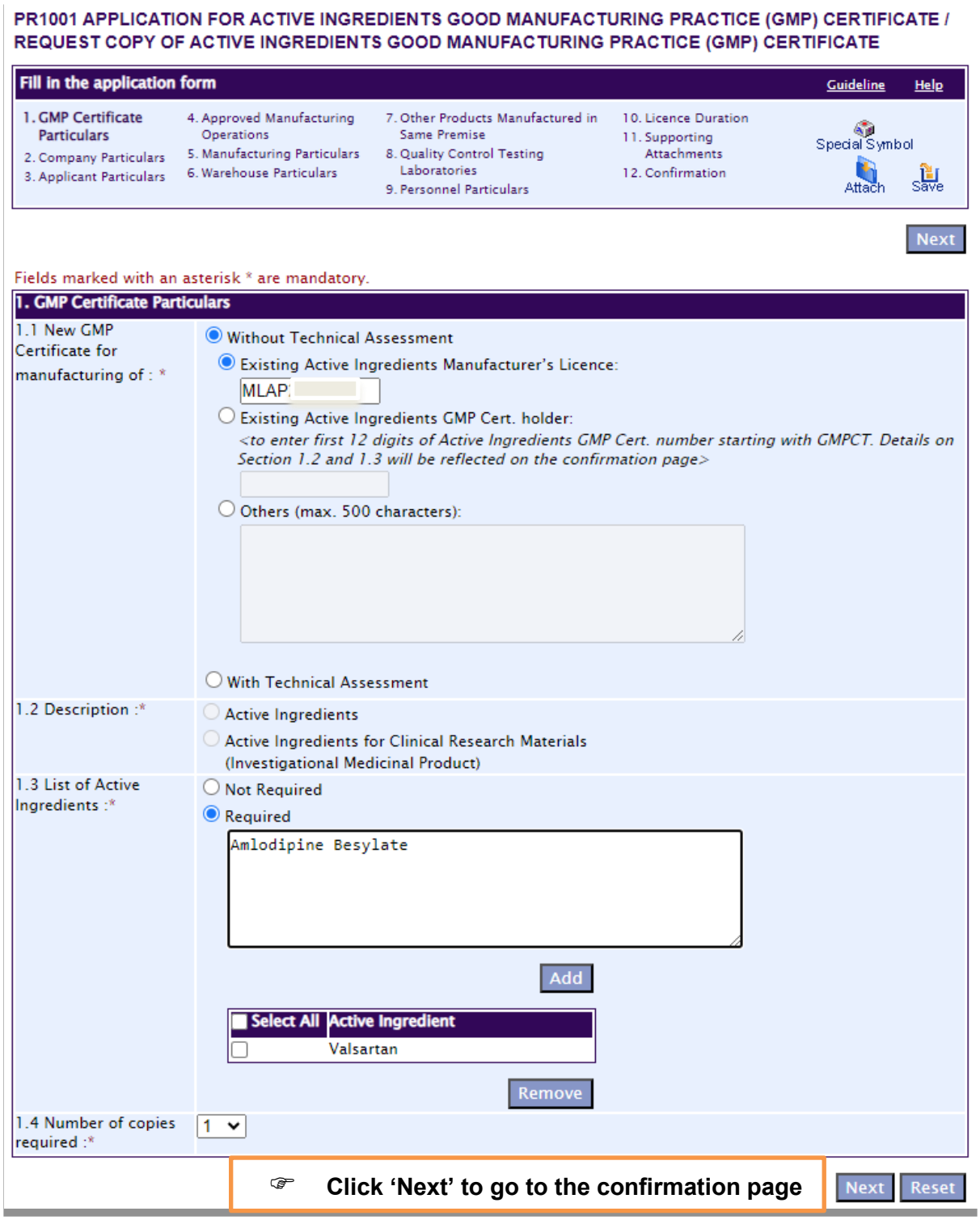
Section 1.2
Section 1.2 would be auto populated and reflected on the confirmation page.

Section 1.3

- Click 'Required' and enter the name of the Active Ingredient to be listed.
- Click 'Add' to continue adding the next Active Ingredient.

Section 1.4

- Select the number of copies required from the drop-down list.



PR1001 APPLICATION FOR ACTIVE INGREDIENTS GOOD MANUFACTURING PRACTICE (GMP) CERTIFICATE / REQUEST COPY OF ACTIVE INGREDIENTS GOOD MANUFACTURING PRACTICE (GMP) CERTIFICATE

Fill in the application form — Guideline — Help

1. GMP Certificate Particulars
2. Company Particulars
3. Applicant Particulars
4. Approved Manufacturing Operations
5. Manufacturing Particulars
6. Warehouse Particulars
7. Other Products Manufactured in Same Premise
8. Quality Control Testing Laboratories
9. Personnel Particulars
10. Licence Duration
11. Supporting Attachments
12. Confirmation

Special Symbol — Attach — Save

Next

Fields marked with an asterisk * are mandatory.

1. GMP Certificate Particulars

1.1 New GMP Certificate for manufacturing of : *

- (•) Without Technical Assessment
  - (•) Existing Active Ingredients Manufacturer's Licence: MLAP
  - ( ) Existing Active Ingredients GMP Cert. holder:
    <to enter first 12 digits of Active Ingredients GMP Cert. number starting with GMPCT. Details on Section 1.2 and 1.3 will be reflected on the confirmation page>
  - ( ) Others (max. 500 characters):
- ( ) With Technical Assessment

1.2 Description :*

- ( ) Active Ingredients
- ( ) Active Ingredients for Clinical Research Materials (Investigational Medicinal Product)

1.3 List of Active Ingredients :*

- ( ) Not Required
- (•) Required

Amlodipine Besylate

Add

Select All	Active Ingredient
[ ]	Valsartan

Remove

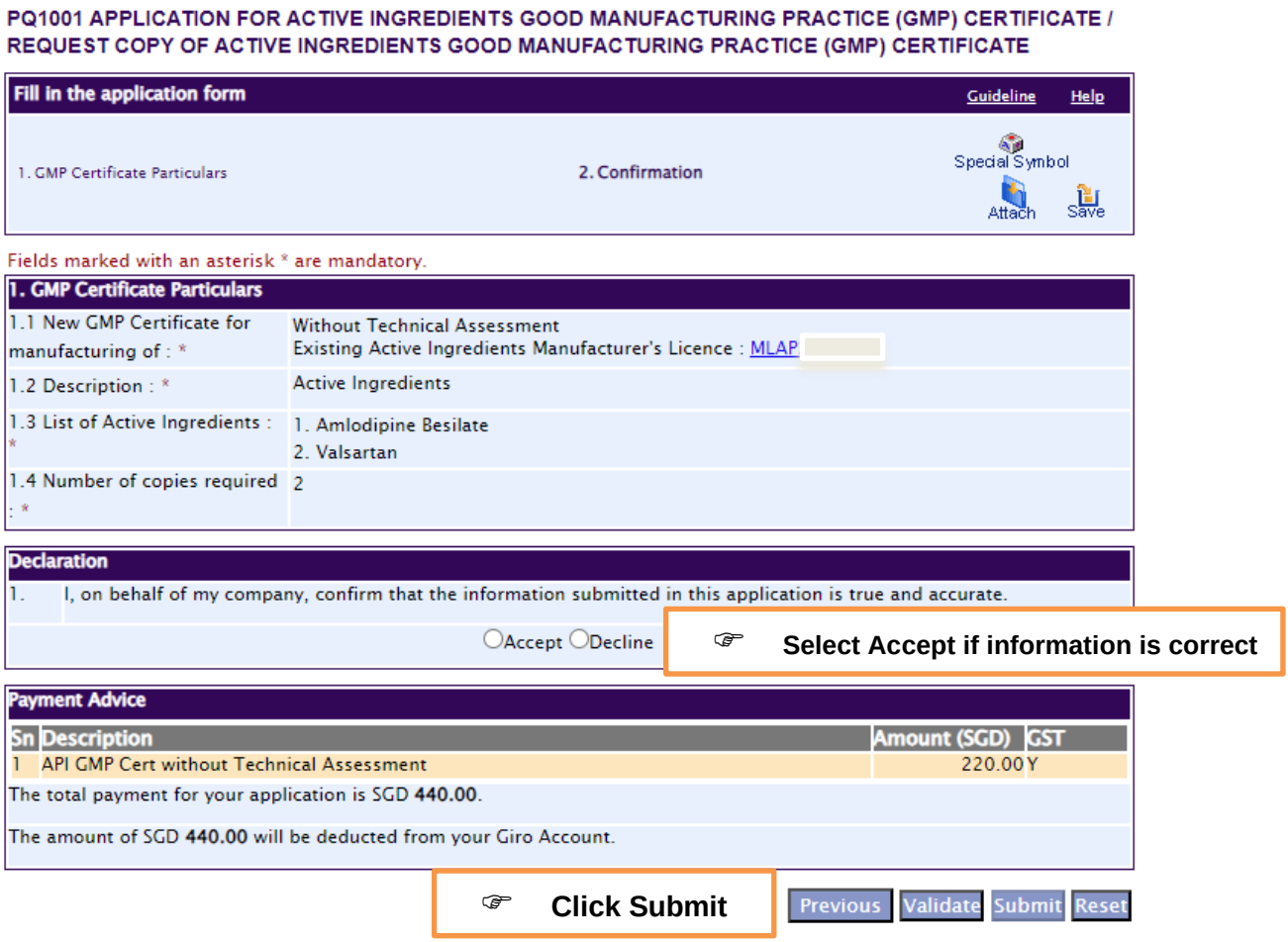
1.4 Number of copies required :* 1

☞ Click 'Next' to go to the confirmation page

Next Reset

Confirmation Page

- Click on the manufacturer's licence to preview the company's current licence.
- Review the information and select 'Accept'.
- The total payment is reflected under payment advice in **bold** (depending on the number of copies requested)
- Click 'Submit'



PQ1001 APPLICATION FOR ACTIVE INGREDIENTS GOOD MANUFACTURING PRACTICE (GMP) CERTIFICATE / REQUEST COPY OF ACTIVE INGREDIENTS GOOD MANUFACTURING PRACTICE (GMP) CERTIFICATE

Fill in the application form — Guideline — Help

1. GMP Certificate Particulars — 2. Confirmation — Special Symbol — Attach — Save

Fields marked with an asterisk * are mandatory.

1. GMP Certificate Particulars

1.1 New GMP Certificate for manufacturing of : *	Without Technical Assessment Existing Active Ingredients Manufacturer's Licence : MLAP
1.2 Description : *	Active Ingredients
1.3 List of Active Ingredients : *	1. Amlodipine Besilate 2. Valsartan
1.4 Number of copies required : *	2

Declaration

1. I, on behalf of my company, confirm that the information submitted in this application is true and accurate.

◯Accept ◯Decline

☞ **Select Accept if information is correct**

Payment Advice

Sn	Description	Amount (SGD)	GST
1	API GMP Cert without Technical Assessment	220.00	Y

The total payment for your application is SGD **440.00**.

The amount of SGD **440.00** will be deducted from your Giro Account.

☞ **Click Submit**

Previous | Validate | Submit | Reset

2. Application For Additional Copies of GMP Certificate

Section 1.1

- Select 'Without Technical Assessment' for 'Existing Active Ingredients GMP Cert. holder.
- Enter the GMP Certificate number starting with **GMPCT**.

Note:

Please do not enter the GMP Cert. number starting with GMPAP.

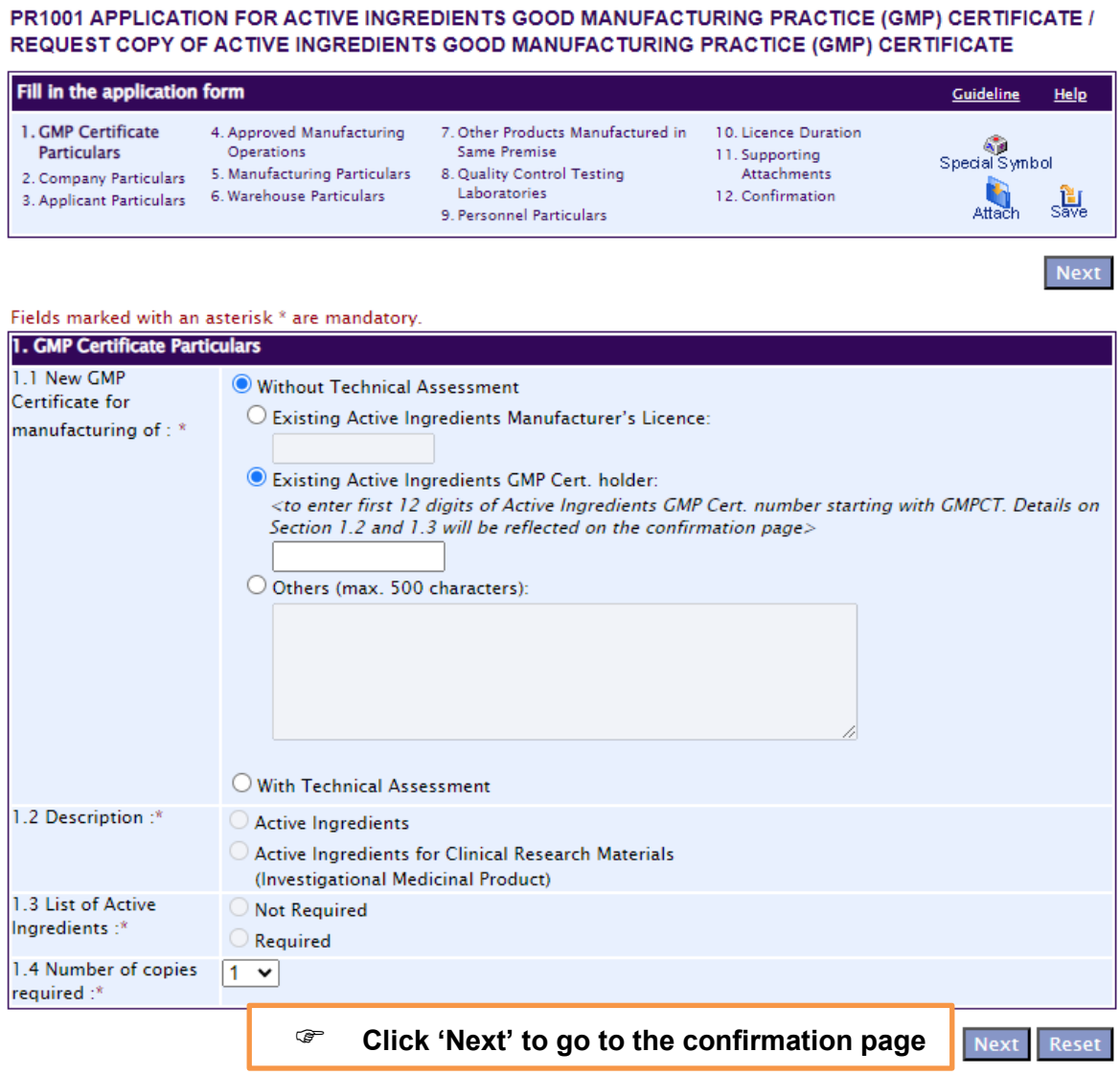
Please refer to Application For GMP Certificate For Licensed Manufacturers of Active Ingredients section 1.4 if the licenced manufacturer requires additional copies of the GMP Certificate.

Sections 1.2 and 1.3

Section 1.2 and 1.3 would be auto populated and reflected on the confirmation page.

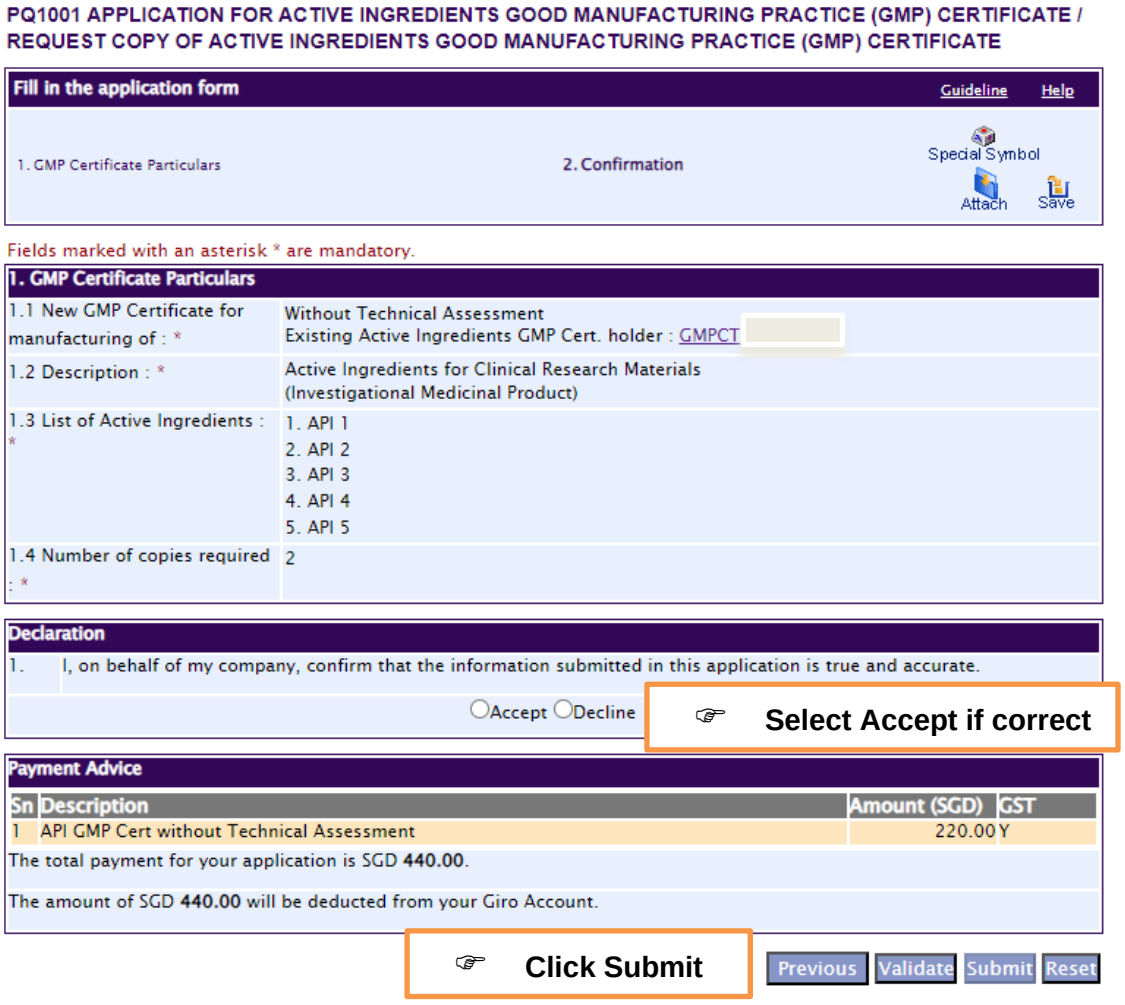
Section 1.4

- Select the number of copies required from the drop-down list.



Confirmation Page

- Click on the GMP Certificate to preview the certificate.
- Review the information and select 'Accept'.
- The total payment is reflected under payment advice in **bold** (depending on the number of copies requested)
- Click 'Submit'



PQ1001 APPLICATION FOR ACTIVE INGREDIENTS GOOD MANUFACTURING PRACTICE (GMP) CERTIFICATE / REQUEST COPY OF ACTIVE INGREDIENTS GOOD MANUFACTURING PRACTICE (GMP) CERTIFICATE

Fill in the application form — Guideline — Help

1. GMP Certificate Particulars — 2. Confirmation — Special Symbol — Attach — Save

Fields marked with an asterisk * are mandatory.

1. GMP Certificate Particulars

1.1 New GMP Certificate for manufacturing of : *	Without Technical Assessment Existing Active Ingredients GMP Cert. holder : GMPCT
1.2 Description : *	Active Ingredients for Clinical Research Materials (Investigational Medicinal Product)
1.3 List of Active Ingredients : *	1. API 1 2. API 2 3. API 3 4. API 4 5. API 5
1.4 Number of copies required : *	2

Declaration

1. I, on behalf of my company, confirm that the information submitted in this application is true and accurate.

○Accept ○Decline

☞ **Select Accept if correct**

Payment Advice

Sn	Description	Amount (SGD)	GST
1	API GMP Cert without Technical Assessment	220.00	Y

The total payment for your application is SGD **440.00**.

The amount of SGD **440.00** will be deducted from your Giro Account.

☞ **Click Submit**

Previous | Validate | Submit | Reset

3. New Application for GMP Certificate

Section 1.1

- Select 'With Technical Assessment'

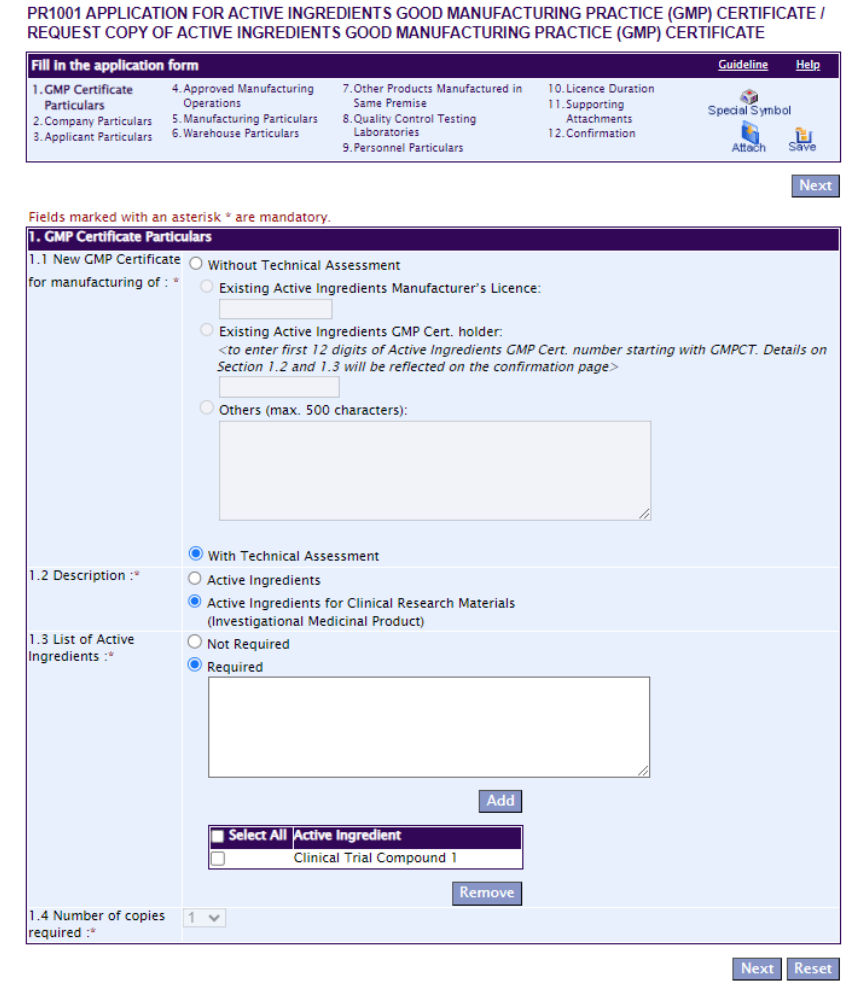
Section 1.2

- Select the description of the Active Ingredients:
  (a) Select '**Active Ingredients**' if the active ingredients are used to manufacture of therapeutic product, cell tissue gene therapy products or medical device but are not specified in the Schedule of Regulated Active Ingredients published in the Health Products (Active Ingredients) Regulations 2023

  (b) Select '**Active Ingredients for Clinical Research Materials'**

Section 1.3

- Click 'Required' and enter the name of the Active Ingredient to be listed.
- Click 'Add' to continue adding the next Active Ingredient
- Click 'Next'



Note:
Section 1.4 is not applicable as only 1 copy of GMP Certificate will be issued for new applications.

Complete Sections 2 to 12

- For explanatory notes on application details required, please refer to the **Application Details for Active Ingredients Manufacturer's Licence**. The application details for this GMP Certificate application are similar to the Manufacturer's Licence (note that the numbering of the section may be different).

HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

Contact:

GMP Unit
Audit and Licensing Division
Health Products Regulation Group
Health Sciences Authority

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HSA Health Sciences Authority