

## <u>NEW APPLICATION FOR A LICENCE TO</u> <u>MANUFACTURE/ASSEMBLE CHINESE PROPRIETARY MEDICINE</u> (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 <u>here</u>. For enquiry relating to CRIS, you can contact us at <u>HSA\_CRIS@hsa.gov.sg</u>.

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:
  - 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 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 <a href="http://www.Corppass.gov.sg/">http://www.Corppass.gov.sg/</a>

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



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 <u>GIRO application form</u> 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 listing or licence" and select the "<u>Amend Company Information</u>" 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 applicatio	n form			Guideline	<u>Help</u>
1. Company Particulars 2. Applicant Particulars 3. Pharmaceutical Dosage Form	<ol> <li>Manufacturing/Assembly Particulars</li> <li>Warehouse Particulars</li> <li>Other Products Manufactured in Same Premise</li> </ol>	7. Contract Testing Laboratories Particular 8. Personnel Particulars 9. Licence Duration	10. Supporting Attachments 11. Confirmation	Special Symu Attach	ool Save

#### Fields marked with an asterisk \* are mandatory.

2. Applicant Particulars			
2.1 Name: *		(as in NRIC/FIN)	
2.2 NRIC/FIN: *		(Example: \$1234567A, F123456	57A)
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: *	this preferred contact mode is the mo course of this application, you will rec	ct details above is entered for your pre ide which you will receive the final noti teive our input requests (i.e. queries), if of your selected preferred contact mod	fication of this application. During the f any, via email if you have indicated

Effective Date: August 2021

Previous Next Reset

Previous Next



#### 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.

Do	sage 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	Теа
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.

Health Sciences Au	Ithority	
Singapore Governmer	Select One	
Integrity • Service • Excellenc ☑ Contact Info B Feedback & Stem		
\$	Creams-乳膏剂	
	Ear Drops-適耳剂	
	Gels-雅陵剂	
Logon ID :	Granules (External Use)-冲剂 (外用)	
	Granules (Internal Use)-沖劑(内服)	Logout
	Liquid Preparations (External Use)-液体剂(外用)	
PQ1001 APPLICATION FOR A I MEDICINES	Liquid Preparations (Internal Use)-液体剂(内服)	TARY
Fill in the application form	Lozenges-口含片剂	Guideline Help
1. Company Particulars	Nose Drops-滴鼻剂	
2. Applicant Particulars	Ointments-软膏剂	Special Symbol
3. Pharmaceutical Dosage Form	Others	Attack Sav
Form	Others	Mitacin Gui
	Paste, with or without adhesive backing (External Use)-音帖劄 (外用)	Previous Nex
Fields marked with an asterisk * ar		
3. Pharmaceutical Dosage For		
3.1 Dosage Form: *	Select One	*
3.2 Please state details if		
Others is selected.		
3.3 Activity: * (	Manufacture O Primary Assembly O Secondary Assembly	



#### 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.

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anufacturing/Assembly articulars arehouse Particulars ther Products Manufactured in me Premise risk * are mandatory. Iy Particulars	<ol> <li>Contract Testing Laboratories Particular</li> <li>Personnel Particulars</li> <li>Licence Duration</li> </ol>	10. Supporting Attachments 11. Confirmation	Special Symbol Attach	Save
4			Previous	Next
4				
y Particulars				
ly Address				
al				
Retrieve	Address			
	4.4 Level - Unit :	#	-	
SINGAPORE				
	al Retrieve	Al Retrieve Address 4.4 Level – Unit :	Al Retrieve Address 4.4 Level – Unit : #	al Retrieve Address 4.4 Level – Unit : #

New Save



#### 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.

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

Fill in the application f	form	<u>Guideline</u> <u>Help</u>
2. Applicant Particulars 5.	Manufacturing/Assembly Particulars 7. Contract Testing Laboratories 10. Supporting Warehouse Particulars Particular Attachments Other Products Manufactured in 8. Personnel Particulars 11. Confirmation Same Premise 9. Licence Duration	Special Symbol
		Previous Next
Fields marked with an a		
5. Warehouse Particula		
5.1 Warehouse Address	5	
5.1.1 Address Type : *	Local	
5.1.2 Postal Code : *	Retrieve Address	
5.1.3 Block / House No	: 5.1.4 Level - Unit : #	-
5.1.5 Street Name :		
5.1.6 Building Name :		
5.1.7 Other Address De (To input specific identificat number for the warehouse w not reflected above, e.g. for of 1, AEC Road, #01-01, XY, Building, Annex A, SINGAPO 123455, 'Annex A' can be av the 'Other Address Details')	ion vhich /s addross Z RE	
5.1.8 Country :	SINGAPORE	
5.2 Storage Condition	of Warehouse	
5.2.1 Temperature: *	IS°C to 30°C (Room Temperature) S°C to 15°C (Cool) 2°C to 8°C (Refrigerate, Do not freeze) -10°C to -20°C (Freeze) Others	
5.2.2 Relative Humidity:	Min 96 - Max 96	
5.2.3 Approved By:	Select One 💙	
Add Warehouse		



#### 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	on form			Guideline	<u>Help</u>
	<ol> <li>Manufacturing/Assembly Particulars</li> <li>Warehouse Particulars</li> <li>Other Products Manufactured in Same Premise</li> </ol>	7. Contract Testing Laboratories Particular 8. Personnel Particulars 9. Licence Duration	10. Supporting Attachments 11. Confirmation	Special Symb Attach	ol Save
				Previous	Next

Fields marked with an asteris	k * are mandatory.				
6. Other Products Manufactu	red in Same Premise				
6.1 Categories of Products: *					
Biological	Penicilins	Steroids			
Non-medicinal products	Cephalosporins	Cytotoxics			
Hormones	Not Applicable				
6.2 If non-medicinal products	s, state whether contain hazardou	is or toxic substances			
	1				
			Previous	Next R	eset



#### Part Seven – Contract Testing Laboratories Particular

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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Fields marked with an 7. Contract Testing L					
ls a contract testing la				• Yes O No	
7.1 Company Name :	*				
7.2 Type of analytical	test performed : *	P			
7.3 Are the contract to accredited to ISO/IEC quality system standa	17025 or other	O Yes	O No		_
7.4 If yes, please spec and scope of accredit	Contraction of the second s				
7.5 Business Address	5				
7.5.1 Address Type :	*	O Local (	Overseas		
7.5.2 Postal Code : *		Retrie	eve Address		
7.5.3 Block / House N	No :		7.5.4 Level - Un	it : #	]-[]
7.5.5 Street Name :					
7.5.6 Building Name	:				
7.5.7 Country :	SINGAP	ORE			



#### Part Eight – Personnel Particulars

The section requires applicant to furnish the following information:

 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.

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Fill in the applicatio	n form				Guideline	<u>Help</u>
1. Company Particulars 2. Applicant Particulars 3. Pharmaceutical Dosage Form	Particulars 5. Warehouse	ucts Manufactured in	<ol> <li>Contract Testing Laborate Particular</li> <li>Personnel Particulars</li> <li>Licence Duration</li> </ol>	ories 10. Supporting Attachments 11. Confirmation	Special Symk Attach	ool Save
Fields marked with an	n asterisk * a	re mandatory.				
8. Personnel Particul	ars					
8.1 Person in Charge	*	O Production/Asse	embly	O Quality Operations		
8.2 Name as in NRIC/	Passport :*			]		
8.3 NRIC/FIN No :*						
8.4 Designation :*						
8.5 Experience:*						
8.6 Directly report to:	×			]		
New Save						

#### 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.

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Fill in the applicatio	n form			<u>Guideline</u>	<u>Help</u>
<ol> <li>Company Particulars</li> <li>Applicant Particulars</li> <li>Pharmaceutical Dosage Form</li> </ol>	<ol> <li>Manufacturing/Assembly Particulars</li> <li>Warehouse Particulars</li> <li>Other Products Manufactured in Same Premise</li> </ol>	7. Contract Testing Laboratories Particular 8. Personnel Particulars <b>9. Licence Duration</b>	10. Supporting Attachments 11. Confirmation	Special Symb Attach	ol Save
	n asterisk * are mandatory.				
9. Licence/Permit/Ce	ertificate/Listing Duration				
9.1 Duration of licence	e/permit/certificate/listing: *	1 Year 🗸			
			Prev	vious Next	Reset



#### Part Ten – Supporting Attachments

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

Company Particulars Applicant Particulars	4. Manufacturing/Assembly Particulars	7. Contract Testing Laboratories Particular	10. Supporting Attachments	Special Symb	ol
2. Pharmaceutical Dosage Form	5. Warehouse Particulars 6. Other Products Manufactured in Same Premise	8.Personnel Particulars 9.Licence Duration	11.Confirmation	Attach	save



#### Fields marked with an asterisk \* are mandatory.

10. Supporting Documents						
To add an attachment, type in the path or hit the browse button. Then <b>hit the Attach Files button to save the attachment</b> to the list below. Please click <u>here</u> for guideline on document attachment.						
Documents						
10.1 Org chart showing the Prod uction, QC, Sales/Distributi on and Warehousing Dept :	Choose File No file chosen					
10.2 Annual Production Volume for each CPM :	Choose File No file chosen					
10.3 Master Production Procedur e of CPM :	Choose File No file chosen					
10.4 Job Description for production and QC personnel :	Choose File No file chosen					
10.5 Standard Operating Proced ure as stipulated in the gui delines :	Choose File No file chosen					
10.6 Records as stipulated in the guidelines :	Choose File No file chosen					
10.7 Site Master File :	Choose File No file chosen					
10.8 CD Submission :	Choose File No file chosen					
10.9 Other Supporting Documen ts :	Choose File No file chosen					
Attach Files						
Note : Please fill up the template ( <u>downl</u> required to save a copy and attac	oad here) if you are sending the supporting attachment(s) via CD, after which you are h it under "CD Submission."					



### Part Eleven – Confirmation

Declaration					
I. I, on behalf of my	company, confirm that the informa	tion submitted in th	is application is tr	ue and accurate.	
	<ul> <li>Acceleration</li> </ul>	cept ODecline			
Payment Advice					
Sn Description				Amount (SGD) G	ST
1 New App:				N	
The total payment for yo	ur application is SGD				
The amount of SGD	will be deducted from your Gi	ro Account.			
			Previou	us Validate Subr	nit Rese

#### Other useful information

- 1. You may check on the status of your application upon submission at <u>track@prism</u>.
- 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 : <u>helpdesk@hsahelp.gov.sg</u>
- 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 <a href="https://crm.hsa.gov.sg/event/feedback.aspx">https://crm.hsa.gov.sg/event/feedback.aspx</a>