

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 <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 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 <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@prism and select "<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 MEDICINAL PRODUCTS

Fill in the application	ı form			<u>Guideline</u>	<u>Help</u>
 Company Particulars Applicant Particulars Pharmaceutical Dosage Form 	 Forensic Classification Manufacturing Particulars Warehouse Particulars 	 Other Products Manufactured in Same Premise Contract Testing Laboratories Particular <u>Personnel Particulars</u> 	 Licence Duration Supporting Attachments Confirmation 	Special Symb Attach	ool Save

Fields marked with an asterisk *	are mandatory.				
2. Applicant Particulars					
2.1 Name : *			(as in NRIC/FIN)		
2.2 NRIC/FIN : *		(Exan	nple: \$1234567A, 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 : *	de : 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.)				
				Previo	us Next Res

Best viewed using Internet Explorer 7.0 and above. |<u>Privacy Statement</u> | <u>Terms of Use</u> |<u>HSA Data Protection Policy</u> |<u>Rate Our Website</u> <u>Health Sciences Authority</u> © 2007-2011. All Rights Reserved.

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 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	Sterile non-injectable liquid preparations				
cephalosporins					
Injectable reconstituted preparations containing	Sterile powders for injection				
cytotoxic medical products					
Injections	Sterile powders for irrigations				
Injections (Radiopharmaceuticals)	Sterile semi-solid preparations				
Intracular drug delivery systems	Sterile strips				
Liquid Preparations for nasal administration	Suppositories				
(non-sterile)					
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.

ealth Sciences	AL Select One	
Singapore Governr Integrity • Service • Excel	ner Active Pharmaceutical Ingredients (API)	
Contact Info	Sitem Admixtures for intravenous infusion	
^	Beads	
	Dental Liners	
	Dry powder inhalers	1
ogon ID :	Ear drops	2K
	External Liquid Preparations	-qour
Q1001 APPLICATION FOR	R A I Foams	
Fill in the application form	Hard Capsules	ine <u>He</u>
1. Company Particulars	4. For Implants	
2. Applicant Particulars	Cla 5. Ma Injectable admixtures containing pencillins or cephalosporins	Symbol
Dosage Form	Pa	
	Pa	
	Injections (Radionharmaceuticals)	
	Intraquilar drug delivery systems	IS N
ields marked with an asterisk	* ar	-
.1 Dosage Form: *	Select One	•
	Sector one	_
2 Plana dan karib it		
thers is selected.		
3.3 Activity: *	Manufacture Primary Assembly Secondary Assembly	

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.

PQ1001 APPLICATION FOR A LICENCE TO MANUFACTURE / ASSEMBLE MEDICINAL PRODUCTS

Fill in the application	on form			Guideline	<u>Help</u>
 Company Particulars Applicant Particulars Pharmaceutical Dosage Form 	 Forensic Classification Manufacturing Particulars Warehouse Particulars 	 Other Products Manufactured in Same Premise Contract Testing Laboratories Particular Personnel Particulars 	 Licence Duration Supporting Attachments Confirmation 	Special Sym Attach	bol Save
ields marked with an a 4. Forensic Classific	isterisk * are mandatory ation				
4.1 🔲 Prescription On	ly				
4.2 🔲 Pharmacy Only					
4.3 🔲 General Sale Li	st				
			Previous	Next	Reset

st viewed using Internet Explorer 7.0 and above. <u>| Privacy Statement | Terms of Use | HSA Data Protection Policy | Rate Our Website</u> <u>Health Sciences Authority</u> © 2007-2011. All Rights Reserved.



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.

PQ1001 APPLICATION FOR A LICENCE TO MANUFACTURE / ASSEMBLE MEDICINAL PRODUCTS

Fill in the application	on form				Guideline	<u>Help</u>
 Company Particulars Applicant Particulars Pharmaceutical Dosage Form 	 Forensic Classification Manufacturing Particulars Warehouse Particulars 	 Other Product: Same Premise Contract Testin Particular Personnel Part 	s Manufactured in ng Laboratories iculars	 10. Licence Duration 11. Supporting Attachments 12. Confirmation 	Special Symi Attach	bol Save
					Previous	Next
Fields marked with an a	sterisk * are mandator	у.				
5 Manufacturing/Ass	sembly Address					
5.1 Address Type : *	Local					
5.2 Postal Code : *		Retrieve Address				
5.3 Block / House No :			5.4 Level – Unit :	#	-	
5.5 Street Name :						
5.6 Building Name :						
5.7 Country :	SINGAPORE					
New Save						

Best viewed using Internet Explorer 7.0 and above. <u>|Privacy Statement | Terms of Use | HSA Data Protection Policy | Rate Our Website</u> <u>Health Sciences Authority</u> © 2007-2011. Atl Rights Reserved.

Previous Next Reset



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.

- 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 MEDICINAL PRODUCTS

Fill in the applicatio	n form					Guideline	<u>Help</u>
 Company Particulars Applicant Particulars Pharmaceutical Dosage Form 	 4. Forensic Classification 5. Manufacturing Particulars 6. Warehouse Particulars 	 Other Products Ma Same Premise Contract Testing Li Particular Personnel Particula 	nufactured in aboratories ars	 Licence Dur Supporting Attachment Confirmation 	ation s on	Special Sym Attach	bol Save
Fields marked with an a	sterisk * are mandator	у.				Previous	Next
6. Warehouse Partice	ilars						
6.1.1 Address Type : *	Local						
6.1.2 Postal Code : *		Retrieve Address					
6.1.3 Block / House No	-	6.	1.4 Level – Unit	:	#	-	
6.1.5 Street Name :						,	
6.1.6 Building Name :							
6.1.7 Country :	SINGAPORE						
6.2 Storage Conditio	n of Warehouse						
6.2.1 Temperature: *	 15C to 30C (Ro 8C to 15C (Coo 2C to 8C (Refrig -10C to -20C (Others 	om Temperature)) gerate, Do not freeze Freeze)	=)				
6.2.2 Relative Humidity:	Min 🛛 % – Max	« 🦳 %					
6.2.3 Approved By:	Select One 🔻						
Add Warehouse							

Best viewed using Internet Explorer 7.0 and above. | <u>Privacy Statement</u> | <u>Terms of Use</u> | <u>HSA Data Protection Policy</u> | <u>Rate Our Website</u> <u>Health Sciences Authority</u> © 2007-2011. All Rights Reserved.

Previous Next Reset



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.

PQ1001 APPLICATION FOR A LICENCE TO MANUFACTURE / ASSEMBLE MEDICINAL PRODUCTS

Fill in the applica	tion form					Guideline	<u>Help</u>
 Company Particulars Applicant Particulars Pharmaceutical Dosage Form 	 Forensic Classification Manufacturing Particulars Warehouse Particulars 	7. Other Products M Same Premise 8. Contract Testing Labo 9. Personnel Particulars	anufactured in ratories Particular	 Licence D Supportin Attachme Confirma 	uration 19 nts tion	Special Sym Attach	bol Save
					F	Previous	Next
Fields marked with a	n asterisk * are man	datory.					
7. Other Products	Manufactured in	Same Premise					
7.1 Categories of Pro	oducts: *						
Penicilins	Cyte	otoxics	Hormones				
Steroids	Biole	ogical	Non-medicinal products				
Cephalosporins	Not	Applicable	ble				
7.2 If non-medicinal	products, state whe	ther contain hazardous	or toxic substances	;			
					Previous	Next	Reset
Best viewed using Internet Explorer 7.0 and above. <u> Privacy Statement Terms of Use HSA Data Protection Policy Rate Our Website</u> Health Sciences Authority © 2007-2011, All Rights Reserved.							

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.
- 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.



PQ1001 APPLICATION FOR A LICENCE TO MANUFACTURE / ASSEMBLE MEDICINAL PRODUCTS

Fill in the applicati	on form			Guideline	<u>Help</u>
 Company Particulars Applicant Particulars Pharmaceutical Dosage Form 	 Forensic Classification Manufacturing Particulars Warehouse Particulars 	 Other Products Manufactured in Same Premise Contract Testing Laboratories Particular Personnel Particulars 	 Licence Duration Supporting Attachments Confirmation 	Special Syml	ool Save
				Previous	Next

Fields marked with an asterisk * are mandatory.							
8. Contract Testing Laboratories Particulars							
Is a contract testing lab engage	d? :*			Yes	No		
8.1 Company Name : *							
8.2 Type of analytical test perfe	ormed : *						
8.3 Are the contract testing lab accredited to ISO/IEC 17025 or system standards?:	oratories r other quality	Yes	○ No				
8.4 If yes, please specify the st scope of accreditation	andard and						
8.5 Business Address							
8.5.1 Address Type : *		Eocal	Overseas				
8.5.2 Postal Code : *	F	Retrieve Ad	dress				
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

Previous Next Reset

Best viewed using Internet Explorer 7.0 and above. <u>Privacy Statement</u> | <u>Terms of Use</u> | <u>HSA Data Protection Policy</u> | <u>Rate Our Website</u> <u>Health Sciences Authority</u> © 2007-2011. All Rights Reserved.



Part Nine – 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.

PQ1001 APPLICATION FOR A LICENCE TO MANUFACTURE / ASSEMBLE MEDICINAL PRODUCTS

Fill in the applicatio	n form			Guideline	Help
 Company Particulars Applicant Particulars Pharmaceutical Dosage Form 	 Forensic Classification Manufacturing Particulars Warehouse Particulars 	 Other Products Manufactured in Same Premise Contract Testing Laboratories Particular Personnel Particulars 	 Licence Duration Supporting Attachments Confirmation 	Special Symbo Attach	l Save
				Previous	Next

Fields marked with an asterisk * are mandatory.

9. Personnel Particulars		
9.1 Person in Charge*	Production/Assembly	Quality Operations
9.2 Name as in NRIC/Passport :*		
9.3 NRIC/FIN No :*		
9.4 Designation :*		
9.5 Experience:*		
9.6 Directly report to:*		

New Save

Previous	Next	Reset	
----------	------	-------	--

Best viewed using Internet Explorer 7.0 and above. <u>Privacy Statement | Terms of Use | HSA Data Protection Policy | Rate Our Website</u> <u>Health Sciences Authority</u> © 2007-2011. All Rights Reserved.



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.

PQ1001 APPLICATION FOR A LICENCE TO MANUFACTURE / ASSEMBLE MEDICINAL PRODUCTS

Fill in the applicatio	n form			Guideline	<u>Help</u>
 Company Particulars Applicant Particulars Pharmaceutical Dosage Form 	 Forensic Classification Manufacturing Particulars Warehouse Particulars 	 Other Products Manufactured in Same Premise Contract Testing Laboratories Particular Personnel Particulars 	 Licence Duration Supporting Attachments Confirmation 	Special Sym Attach	bol La Save
Fields marked with an a	sterisk * are manda	atory.			
10. Licence/Permit/0	Certificate/Listin	g Duration			
10.1 Duration of licence	/permit/certificate	/listing: * 1 Year 🔻			
			Previo	us Next	Reset

Best viewed using Internet Explorer 7.0 and above. | <u>Privacy Statement</u> | <u>Terms of Use</u> | <u>HSA Data Protection Policy</u> |<u>Rate Our Website</u> <u>Health Sciences Authority</u> © 2007-2011. All Rights Reserved.

Part Eleven – Supporting Attachments

PQ1001 APPLICATION FOR A LICENCE TO MANUFACTURE / ASSEMBLE MEDICINAL PRODUCTS

Fill in the applicati	on form			<u>Guideline</u> <u>Help</u>
 Company Particulars Applicant Particulars Pharmaceutical Dosage Form 	 Forensic Classification Manufacturing Particulars Warehouse Particulars 	 Other Products Manufactured in Same Premise Contract Testing Laboratories Particular Personnel Particulars 	 10. Licence Duration 11. Supporting Attachments 12. Confirmation 	Special Symbol Attach Save

Click	here to encrypt documents	
Field	s marked with an asterisk * are m	andatory.
11.	Supporting Attachments	
To a	dd an attachment, type in the path	or hit the browse button. Then hit the Attach Files button to save the attachm
to the	e list below. se click here for quideline on docu	nent attachment.
Dor	iments	
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

Please fill up the template (<u>download here</u>) 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."





Part Twelve – Confirmation

Declaration					
1. I, on behalf of my c	ompany, confirm that the info	ormation submitted in	this application is tr	ue and accurate.	
	(Accept ODecline			
Paumont Advice					
rayment Advice					
Sn Description				Amount (SGD)) GST
1 New App:					N
The total payment for you	ir application is SGD				
The amount of SGD	will be deducted from you	ir Giro Account.			
			Previou	us Validate Su	ıbmit Reset

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 https://crm.hsa.gov.sg/event/feedback.aspx