APPLICATION FOR A CERTIFICATE OF A PHARMACEUTICAL PRODUCT FOR A CELL, TISSUE OR GENE THERAPY PRODUCT (CTGTP)

NOTES:

1. Your company must have a CRIS account with HSA and obtain a client code in order to submit this application.

2. This form should be completed by the applicant who is authorised by the company. The applicant will be the point of contact for all matters related to this application.

3. This form may take you 20 minutes to fill in. You will need the following information to fill in the form:
   a. Company and applicant details
   b. Details of CTGTP and its manufacturers
   c. Supporting documents

4. All entries shall be made in English. All the information required in the form should be supplied as far as they are applicable.

5. If the space provided in any section of this form is insufficient, the information pertaining to the affected section(s) may be submitted as an attachment together with this completed form as a PDF document. Please indicate the section numbers clearly in the attachment for ease of reference.

6. This completed form with its relevant supporting documents should be submitted as an attachment in the online FormSG - CTGTP Dealer's Submission. CorpPass is required to access this FormSG. For more information, please visit the CorpPass website.

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Section 1 - Company Particulars	
1.1 Name of Company:	
1.2 UEN and Client Code:	
1.3 Company Address	
1.3.1 Postal Code:	
1.3.2 Block/House No.:	
1.3.3 Level – Unit:	
1.3.4 Street Name:	
1.4.5 Building Name:	
1.4 Billing Address *(if different from Company Address)*	
1.4.1 Postal Code:	
1.4.2 Block/House No.:	
1.4.3 Level – Unit:	
1.4.4 Street Name:	
1.4.5 Building Name:	
Section 2 - Applicant Particulars	
2.1 Name (as in NRIC/FIN):	
2.2 Designation:	
2.3 Contact number:	
2.4 Email address:	
Section 3 - Application information	
3.1 Name of importing country:	
3.2 Remarks:	
Section 4 - Particulars of the CTGTP	
4.1 Name and dosage form of the product:	
4.2 Details on the quantitative composition of the product (preferably the complete composition with both active substances and excipients) *(Please provide this information in the Schedule as follows)*	

THE SCHEDULE

Certificate No.

NAME OF PRODUCT	ALL INGREDIENT(S)	STRENGTH PER UNIT DOSE	REMARKS

……..……

LICENSING AUTHORITY

4.3 Is this product actually on the market in Singapore? ☐ Yes ☐ No	
4.4 Product registration number and date of issue:	
4.5 Name and address of Product registrant:	
4.6 Does the product registrant also conduct the following activity on the CTGTP? ☐ Manufacture ☐ Package ☐ Label	
Section 5 – Particulars of Manufacturer(s)	
(Please attach additional sheets of this section if there is more than one manufacturer to be included in the CPP)	
5.1 Name of Manufacturer:	
5.2 Address of Manufacturer	
5.2.1 Postal Code:	
5.2.2 Block/House No:	
5.2.3 Level – Unit:	
5.2.4 Street Name:	
5.2.5 Building Name:	
5.2.6 Country:	
5.3 Is the manufacturer licensed in Singapore? ☐ Yes ☐ No	
If YES, please state Manufacturer's Licence Number:	
If NO, please state GMP Certificate Number:	
5.4 Manufacturing activity: ☐ Manufacture ☐ Package ☐ Label	

Section 6 - Supporting Documents	
☐ The Schedule with details on the quantitative composition of the product (preferably the complete composition with both active substances and excipients) ☐ Product information leaflet (optional) ☐ Other supporting documents	
Section 7 - Declaration	
☐ I, on behalf of my company, confirm that the information submitted in this application is true and accurate. ☐ I, on behalf of my company, confirm that there are no additional amendments made to this application or to the attachments thereof.	
Name of applicant:	Signature and Date:

Application Fee

Certificate of a Pharmaceutical Product for CTGTP	$116

An invoice for the applicable fee will be sent to the company. For companies on the GIRO scheme, the fee will be deducted from the GIRO-linked bank account. For companies not on the GIRO scheme, the fee can be made by bank transfer. More information will be provided on the invoice.