Protected B when completed

FRM-0455: Application form for an electronic good manufacturing practices certificate

For Health Canada use only:			
Record number:	Certificate number:		
The following sections are to be completed by the applicant.			
Section 1: Applicant details			
Company name:	Drug establishment licence (DEL) number:		
Address:	Suite:		
City:	Province:	Postal code:	
Country:			
Contact name:	Title:		
Telephone number:			
Email address where the completed certificate should be sent:			
Preferred language of communication: ○ English ○ French			

Section 2: Certificate information

Language you would like the certificate to be issued in: ◯ English ◯ French	
Total number of certificates requested (same dosage form, same country):	Importing country:
Dosage form:	Category: ◯ Pharmaceutical ◯ Biological ◯ Vaccine ◯ Radiopharmaceutical ◯ Active pharmaceutical ingredient

Section 2.1 Batched application information

If you require identical certificates with the exception of different importing countries, please complete this section for a batched application. Refer to Section 2, #6 of the instructions.

Language you would like the certificates to be issued in: ◯ English ◯ French

Total number of certificates requested:

Certificate number (for Health Canada use only):	Importing countries:	Number of certificates requested (same dosage form, same activities):

If necessary, attach separate sheets in the same format. Please indicate number of pages attached:

Dosage form:	Category: ◯ Pharmaceutical ◯ Biological ◯ Vaccine ◯ Radiopharmaceutical ◯ Active pharmaceutical ingredient

Section 3: Site(s) of production

Establishment name and address

Establishment name:	DEL number and building letter (if applicable):

Building name (if applicable):

Street number/PO box:	Street name:	Suite:

City:	Province:	Postal code:

Country:

Type of establishment (select all that apply):

☐ Fabricate ☐ Package ☐ Label ☐ Test

Establishment name and address

Establishment name:	DEL number and building letter (if applicable):

Building name (if applicable):

Street number/PO box:	Street name:	Suite:

City:	Province:	Postal code:

Country:

Type of establishment (select all that apply):

☐ Fabricate ☐ Package ☐ Label ☐ Test

Establishment name and address			
Establishment name:			DEL number and building letter (if applicable):
Building name (if applicable):			
Street number/PO box:	Street name:		Suite:
City:	Province:	Postal code:	
Country:			
Type of establishment (select all that apply): ☐ Fabricate ☐ Package ☐ Label ☐ Test			

Establishment name and address			
Establishment name:			DEL number and building letter (if applicable):
Building name (if applicable):			
Street number/PO box:	Street name:		Suite:
City:	Province:	Postal code:	
Country:			
Type of establishment (select all that apply): ☐ Fabricate ☐ Package ☐ Label ☐ Test			

Section 4: Health Canada attestations

Health Products Compliance Directorate
Health Canada

It is hereby certified that:

☐ 1. The above-mentioned dosage form(s) has (have) been fabricated in accordance with the currently approved master production document.

☐ 2. I have authorization from the above fabricator to apply for a certificate listing them as a site of production.

☐ 3. Product is fabricated in compliance with the Canadian good manufacturing practices (GMP) provisions (Division 2, Part C of the *Food and Drug Regulations*).

☐ 4. If the above-mentioned product is fabricated at a foreign site, I certify that I have evidence that it complies with Canadian GMP provisions (Division 2, Part C of the *Food and Drug Regulations*) and the foreign site appears on my drug establishment licence (DEL).

☐ 5. I will advise the Health Product Compliance Directorate (HPCD) of any quality defects or other hazards associated with the dosage form or shipment that may arise.

☐ 6. The manufacturer applies identical GMP standards to the production of all batches of pharmaceutical products manufactured within the facility, including those destined exclusively for export.

☐ 7. All above information is accurate and complete.

Name of authorized representative:	Title:
Signature:	Date (yyyy-mm-dd):

Privacy notice

The personal information you provide to Health Canada will be used by the Drug Establishment Licensing regimen, under the authority of the *Food and Drugs Act*, section 23(1)(c) and handled in accordance with the *Privacy Act.*

Why are we collecting your personal information? The personal information is used to support Health Canada's compliance and enforcement activities, including inspections and investigations related to human or veterinary drugs.

Will we use or share your personal information for any other reason? In limited and specific situations, your personal information may be shared internally or with other regulators through international agreements, without your consent in accordance with subsection 8(2) of the *Privacy Act.*

What are your rights? You have the right to access and request a correction and/or notation to your personal information. You also have a right to complain to the Privacy Commissioner of Canada if you feel your personal information has been handled improperly. For more information about these rights, or about how we handle your personal information, please contact Health Canada's Privacy Management Division at 613-948-1219 or privacy.vie.pricee@hc-sc.gc.ca.

For more information: The collection of your personal information is described in Info Source at infosource.gc.ca. Refer to the personal information bank (PIB) for these collections, which are described in HC PPU 407 Compliance and Enforcement Pharmaceutical Drugs and HC PPU 408 Compliance and Enforcement – Biologics & Radiopharmaceuticals.

Electronic good manufacturing practices (GMP) certificate application checklist

The electronic GMP certificate application checklist is provided to help you submit a complete electronic GMP certificate application. It will help minimize any delays in issuing your GMP certificate and avoid the rejection of your application. Cover letters are not necessary. If Section 2 or 2.1 of certificate information is not being used, you may delete or remove this section before submission.

Application type	Sections to be completed
☐ **Electronic GMP certificate application**	☐ Electronic GMP certificate application form (FRM-0455) ☐ Fee form for an electronic CPP and electronic GMP certificate application (FRM-0456) ☐ Letter of authorization (only if a consultant is applying on behalf of a company) ☐ All forms required for submission are complete, unlocked, legible (typed or printed in capital letters), in PDF format, signed and dated, and all attestation statements are confirmed

FRM-0455: Application form for an electronic good manufacturing practices (GMP) certificate

When to use this form

Canadian applicants only may use this form when applying for an electronic good manufacturing practices (GMP) certificate.

A GMP certificate attests to the GMP compliance of a manufacturing site as per the drug establishment licence (DEL). It can be used where GMP compliance information is requested by importers, exporters, procurement agencies and regulatory authorities. The GMP certificate issued under Guidance on obtaining electronic certificates of pharmaceutical product and good manufacturing practices (GUI-0024) is not part of the 55th Report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations (section 9.2)

How to complete this form

This section explains how to fill out an electronic CPP application form.

Section 1: Applicant details

1. Enter the full company name, DEL number, company address, contact name, title, telephone number and email address where the completed certificate should be sent.
2. If you're a third party consultant applying on behalf of a company, you'll require a letter of authorization. It should include the name of the company that's authorizing you to apply on their behalf and should be dated within the current calendar year.
    - If you are the DEL holder, ensure that the information is the same as the information on the:
        - DEL or
        - Drug and Health Products Inspection Database (DHPID)

If the company name or address are different, please contact the Drug Establishment Licensing Unit (DELU) at (del.questions-leppp@hc-sc.gc.ca) about how to notify Health Canada of DEL holder amendments.

3. Choose the official language in which you would like us to communicate with you.

Section 2: Certificate information

4. Certificates are issued in English or French. Select the official language you would like the certificate to be issued in. If no selection is made, the certificate will be issued in English.

5. Enter the number of certificates you would like Health Canada to issue. Supplemental certificates will only be issued for the same dosage form(s), same activities, same sites and same country (that is, identical to the original requested certificate).

6. **Batched certificate applications**: If submitting multiple **identical** certificates in the same language for **different** importing countries, submit only 1 form using section 2.1 of the application form with the batching table.

   Example of a completed batching table:

Total number of certificates requested: 3	
Importing countries:	Number of certificates requested per country (same dosage form and activities)
Egypt	1
Mexico	2

7. Enter the official full name of the importing country (for example, Nigeria or Thailand) or the official name of a state. For a list of country names, refer to the World Health Organization (WHO) countries list. Health Canada does not issue certificates to countries that:

   - have mutual recognition agreements (MRAs) with Canada
     - for a list of MRA countries, please refer to the Mutual Recognition Agreement Regulatory Authorities website
   - are stringent regulatory authorities (SRAs) as defined by the 55th Report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations
   - are WHO-listed authorities (WLAs) maturity level 4, according to the 55th Report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations

8. List the dosage forms (for example, tablet or capsule) and select the correct category from the list provided. Enter only 1 category per application.

   - If you are listing more than 1 building in Section 3, the dosage forms must be the same for all buildings listed. For example, if the dosage form is fabricated in a foreign building, the same dosage form would be packaged, labelled or tested at the other listed sites.

Section 3: Sites of production

9. If any activities are performed in a foreign building (outside of Canada) and you're a third-party consultant applying on behalf of a company, a Canadian importer should be listed in this section.

10. Clearly indicate the name(s) and address(es) of the sites of production of the final dosage form(s). If you are listing more than 1 establishment, use the additional boxes provided. The additional establishments must be linked to the dosage form being certified. This information will allow the Health Product Compliance Directorate (HPCD) to make statements about the GMP compliance status of third parties at the site(s).
    - Please ensure the company information listed in this section is identical to the information found on the DEL or DHPID. In the case of the foreign fabricator(s), ensure it is **listed on the applicant or Canadian importer's DEL**. If a foreign fabricator is not listed on the applicant or Canadian importer's DEL, the certificate will be rejected.
11. Clearly indicate the types of activities performed at the building (fabricate, package, label, test).

Section 4: Health Canada Attestations

You must attest to all statements (except #4 if not applicable) in order for a certificate application to be accepted. The application will be rejected if not all statements are attested to.

12. #1 - Check this box to certify that the dosage forms in question have been fabricated in accordance with the currently approved master production document. Failure to certify will result in rejection of the application.
13. #2 - Check this box to certify that you have authorization from the above fabricator to apply for a certificate listing them as a site of production.
14. #3 - Check this box to certify that the product in question is fabricated in compliance with Canadian GMP provisions (Division 2, Part C of the *Food and Drug Regulations*).
15. #4 - If the product is fabricated in a foreign site, check this box to certify that you have evidence that the product in question is fabricated in compliance with Canadian GMP provisions (Division 2, Part C of the *Food and Drug Regulations*) and the foreign site appears on your DEL.
16. #5 - Check this box to certify that the manufacturer will advise the Health Product Compliance Directorate (HPCD) of any quality defects or other hazards associated with the dosage form or shipment that arise.
17. #6 - Check this box to certify that the manufacturer applies identical GMP standards to the production of all batches of pharmaceutical products manufactured within the facility, including those destined exclusively for export.
18. #7 - Check this box to certify that all the information contained in the application is accurate and complete.
19. Sign, date and enter your name and title. Signing and dating the application certifies that all information is true, accurate and complete.

How to submit your form

Email your electronic GMP certificate application package to the Certificate of Pharmaceutical Product (CCP) group to: cpp_questions@hc-sc.gc.ca.

For more information

For information or help with your electronic GMP certificate application, email cpp_questions@hc-sc.gc.ca.