Protected B when completed

FRM-0454: Application form for an electronic certificate of a pharmaceutical product

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

Canada

Section 2: Certificate information

Language you would like the certificate to be issued in:	○ English ○ French
Number of certificates requested (same drug identification number (DIN), same country):	Importing country:
Product name (brand name):	Product name in importing country:
DIN number (required):	Current status: Current (most recent) status date:
Dosage form:	Category: ○ Pharmaceutical ○ Biological ○ Vaccine ○ Radiopharmaceutical
Active ingredients:	**Strength/amount per unit dose:**
If necessary, attach separate sheets in the same format. Please indicate number of pages attached:	
Is this product on the market in Canada? Is this product **licensed** to be placed on the market for use in Canada? ○ Yes ○ No Is this product **currently** on the market in Canada? ○ Yes ○ No	
Is this a veterinary pharmaceutical intended for use in a non-food producing animals? ○ Yes ○ No	

Section 2.1 Batched application information

If you require identical certificates (same DIN) 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 DIN, same activities):	Brand name in importing country (if different):

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

Product name (brand name): DIN number (required):	Current status: Current (most recent) status date:

Dosage form:	Category: ○ Pharmaceutical ○ Biological ○ Vaccine ○ Radiopharmaceutical

Active ingredients:	Strength/amount per unit dose:

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

Is this product on the market in Canada?

Is this product **licensed** to be placed on the market for use in Canada? ○ Yes ○ No

Is this product **currently** on the market in Canada? ○ Yes ○ No

Is this a veterinary pharmaceutical intended for use in a non-food producing animal? ○ Yes ○ No

Section 3: Manufacturer/sponsor information

The manufacturer/sponsor is the company to whom the DIN is issued.

If the manufacturer/sponsor and address are the same as the applicant in section 1, check this box: ☐

Manufacturer/sponsor name and address

Manufacturer/sponsor name:	DEL number and building letter (if applicable):
Building name (if applicable):	

Street number/PO box:	Street name:	Suite:
City:	Province:	Postal code:	Country:

Canadian importer (if applicable)

Canadian importer name:	DEL number and building letter (if applicable):
Building name (if applicable):	

Street number/PO box:	Street name:	Suite:
City:	Province:	Postal code:	Country:

Section 4: Site(s) of production for this product

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			

Do you want the site(s) of production and type(s) of establishment to be stated in section 2.A.3.1 on the certificate?

○ Yes , all of the above ○ No, none of the above

Section 5: Applicant Attestations

Health Products Compliance Directorate
Health Canada

It is hereby certified that:

☐ 1. The above-mentioned product has been fabricated in accordance with the currently approved master production document.

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

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

☐ 4. The manufacturer as identified in section 5 will advise the Health Product Compliance Directorate (HPCD) of any quality defects or other hazards associated with the product or shipment that may be determined. The manufacturer/sponsor and/or the fabricator are also responsible for notifying the HPCD if the product is recalled.

☐ 5. 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 certificate of a pharmaceutical product (CPP) application checklist

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

Application type	Sections to be completed
☐ Electronic CPP application	☐ Electronic CPP application form (FRM-0454) ☐ Fee form for an electronic CPP and electronic GMP certificate application (FRM-0456) ☐ Letter of authorization (only if the applicant is not the DIN owner or 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-0454: Application form for an electronic certificate of a pharmaceutical product

When to use this form

Canadian applicants only may use this form when applying for an electronic certificate of a pharmaceutical product (CPP) issued under 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

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're the drug establishment licence (DEL) holder or manufacturer/sponsor, ensure that the information is the same as the information in the:
    - Drug Product Database (DPD) or
    - Drug and Health Products Inspections Database (DHPID)

    If the company name and address are different, contact the Pharmaceutical Drugs Directorate (pharma_drug_enquiries-renseignements_medicaments_pharma@hc-sc.gc.ca) about how to notify Health Canada of manufacturer/sponsor changes.

    For more information on how to notify Health Canada about DEL holder amendments, refer to Guidance on Drug Establishment Licences (GUI-0002) or contact the Drug Establishment Licensing Unit (del.questions-leppp@hc-sc.gc.ca).

- The manufacturer/sponsor is the company to whom the drug identification number (DIN) is issued (DIN owner).

1. Include the full company name, DEL number, company address, contact name, title, telephone number and email address where the completed certificate should be sent.
2. Choose the official language in which you would like us to communicate with you.

Section 2: Certificate information

3. 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.

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

5. **Batched certificate applications:** If submitting multiple **identical** certificates (same DIN and 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 country:	Number of certificates requested per country (same DIN and activities)	Product name (brand name) in importing country (if different)
Egypt	1	Advil Extra Strength
Mexico	2	N/A

6. 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

7. Enter the brand name or proper name (international non-proprietary name or national non-proprietary name) of the product as it appears in DPD. Enter the name of the importing country if it varies from the brand name. A single CPP application form must be completed for each product/DIN and for each importing country, unless section 2.1 is used. If you're submitting a batched application and the brand name in the importing country varies, please include this information as shown in the table above (see section 2.5).

8. Provide the DIN number, DIN status and **most current** date of notification, which is on the online DPD. In the case of a radiopharmaceutical, use the date on which the notice of compliance (NOC) or notice of compliance with conditions (NOC/c) was issued.

9. List the dosage form (for example, tablet or capsule) as it appears in the DPD. Select the correct category from the list provided and enter only 1 category per application.

10. List the active ingredient(s), strengths and amount per unit dose as they appear in the DPD.

11. Indicate if the product is licensed to be on the market in Canada and if it actually **is** on the market in Canada now. If the product is on the Canadian market, it should be flagged as "Marketed" in the DPD.

12. Confirm by checking **Yes** if the product is a veterinary pharmaceutical and is intended for use in non-food-producing animals.

Section 3: Manufacturer/sponsor information

13. If the manufacturer/sponsor is different from the applicant in Section 1, enter the manufacturer's/sponsor's full company name, DEL number (if known) and company address. In this case, authorization for issuance of the certificate is required from the manufacturer/sponsor of the pharmaceutical product. Letters of authorization from the DIN owner must include the DIN, DIN owner's information and name of the company (applicant) being authorized. Letters should be dated within the current calendar year.

14. Please ensure that the DIN owner information is identical to the information in the DPD. If the company name or address are different, please contact the Pharmaceutical Drugs Directorate

(pharma_drug_enquiries-renseignements_medicaments_pharma@hc-sc.gc.ca) for information on how to notify us of changes to DIN information.

15. You must complete the Canadian importer section if the manufacturer/sponsor of the DIN is a foreign company and any activities are performed outside of Canada. Enter the Canadian importer's full company name, DEL number (if known) and company address.

Section 4: Sites of production for this product

16. Clearly indicate the name(s) and address(es) of the sites of production of the final dosage form. If you're listing more than 1 establishment, use the extra boxes provided. The additional establishments must be linked to the DIN/product being certified. This information will allow the Health Product Compliance Directorate (HPCD) to make statements about the good manufacturing practices (GMP) compliance status of third parties at the site(s).

    - If a drug is fabricated outside of Canada, ensure the company information is identical to the information on the DEL or DHPID. In the case of a foreign building performing any activities, please include the DEL number of the DIN owner, Canadian importer or applicant on which the foreign building is listed. If the foreign building is not listed on any of the DELs, the certificate will not be issued.

17. Section 4 is required for our records. If you want the site(s) of section 4 and the associated activities to appear on the certificate, select "**Yes, all of the above"** for section 2.A.3.1. If the name and address of the site(s) of production are confidential (that is, not included on the certificate), please select "**No, none of the above"** for section 2.A.3.1. If both boxes are left blank, the name and address of the site(s) of production will be included on the certificate.

Section 5: Health Canada attestations

You must attest to all statements (except #3 if not applicable) in order for a certificate application to be accepted. The application will be rejected if not all statements are attested to.

18. #1 - Check this box to certify that the product in question has been fabricated in accordance with the currently approved master production document. Failure to certify will result in the application being rejected.

19. #2 - 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*).

20. #3 - 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*).

21. #4 - Check this box to certify that the manufacturer will advise the HPCD of any quality defects or other hazards associated with the product or shipment that arise. The manufacturer/sponsor and/or the fabricator are also responsible for notifying the HPCD if the product is recalled.

22. #5 - Check this box to certify that all the information contained in the application is accurate and complete.

23. 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 CPP application package to the CPP group to: cpp_questions@hc-sc.gc.ca.

For more information

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