Health Canada Santé Canada

Guidance document on the application for a certificate of a pharmaceutical product and good manufacturing practice certificate (GUI-0024)

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Canada

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1.0 Purpose

This document clarifies the requirements to be met for the issuance of a Certificate of a Pharmaceutical Product (CPP) and describes the procedure for the request of a CPP.

2.0 Background

In 1967, the Twentieth World Health Assembly requested in resolution WHA20.34 that a draft text be prepared on good manufacturing practices (GMP). The text was subsequently submitted to the Twenty-first World Health Assembly in 1968, under the title “Draft requirements for good manufacturing practice in the manufacture and quality control of drugs and pharmaceutical specialities”. In 1969, the Twenty-second World Health Assembly endorsed these requirements for “Good Practices in the Manufacture and Quality Control of Drugs” (resolution WHA22.50). These requirements have since been revised: the first revision was adopted by the World Health Assembly in 1975 (resolution WHA28.65) and the most recent revision is included in the Thirty-seventh report of the World Health Organization (WHO) Expert Committee on Specifications for Pharmaceutical Products.

These requirements also provide the basis for the WHO Certification Scheme on the Quality of the Pharmaceutical Products moving in International Commerce, recommended initially in resolution WHA22.50. The WHO Certification Scheme, an international voluntary agreement, enables countries with limited drug regulatory capacity to obtain partial assurance from exporting countries that the pharmaceutical products, which they plan to import, are safe, effective and of good quality.

All Member States of the WHO are urged to adopt and to apply these GMP standards as recommended by WHO. Canada, represented by the Regulatory Operations and Enforcement Branch Health Product Compliance Directorate (ROEB HPCD), adopted the WHO Certification Scheme on May 1, 1996. Prior to this date, Certificates of Free Sales were used to attest that the pharmaceutical products were fabricated in compliance with GMPs. These types of certificates are no longer issued. They have been replaced by Certificates of a Pharmaceutical Product (CPP) and are issued as a service to the industry when required by an importing country.

3.0 Scope

A CPP is issued for human drugs (pharmaceutical, biological and radiopharmaceutical) as well as for veterinary drugs (food producing animals and non-food producing animals). Since the *Food and Drugs Act* and *Regulations* apply also to veterinary pharmaceuticals intended for non-food producing animals, they must be fabricated according to GMP requirements and consequently, Health Canada chooses to issue CPPs for these pharmaceutical products.

Products falling under the Natural Health Products (NHP) framework are excluded from the scope of this document.

4.0 Definitions / Acronyms

Certificate of a Pharmaceutical Product (CPP): A certificate issued by the Health Product Compliance Directorate establishing the status of the pharmaceutical, biological, radiopharmaceutical or veterinary product listed and the GMP status of the fabricator of the product. This certificate is in the format recommended by the WHO.

DEL: Drug establishment licence.

Drug: Any substance or mixture of substances manufactured, sold or represented for use in:

- the diagnosis, treatment, mitigation or prevention of disease, disorder, abnormal physical state, or its symptoms, in human beings or animals;
- restoring, correcting or modifying organic functions in human beings or animals, or
- disinfection in premises in which food is manufactured, prepared or kept.

Drug Identification Number (DIN): A Drug Identification Number (DIN) is a computer-generated eight digit number assigned by Health Canada to a drug product prior to being marketed in Canada. It uniquely identifies all drug products sold in a dosage form in Canada and is located on the label of prescription and over-the-counter drug products that have been evaluated and authorized for sale in Canada. A DIN uniquely identifies the following product characteristics: manufacturer; product name; active ingredient(s); strength(s) of active ingredient(s); pharmaceutical form; route of administration.

FDA: *Food and Drugs Act*.

FDR: *Food and Drug Regulations*.

GMP: Good Manufacturing Practices.

HPCD: Health Products Compliance Directorate.

INN: International non-proprietary names.

MRA Country: A country that is a participant in a mutual recognition agreement with Canada.

NERBY: New Evidence Required By

NHP: Natural Health Product.

NOC: Notice of Compliance

NPN: Natural Product Number.

Section 37 of the FDA: Section 37 exempts certain drugs from the application of the *FDA*:

37. (1) "*This Act does not apply to any packaged food, drug, cosmetic or device, not manufactured for consumption in Canada and not sold for consumption in Canada, if the package is marked in distinct*

overprinting with the word "Export" or "Exportation" and a certificate that the package and its contents do not contravene any known requirement of the law of the country to which it is or is about to be consigned has been issued in respect of the package and its contents in prescribed form and manner."

SL: Site Licence

WHO: World Health Organization

5.0 Procedure

A CPP, in the format recommended by the WHO, establishes the status of the pharmaceutical product listed on the certificate, and the GMP status of the fabricator of the pharmaceutical product, in the exporting country. The Health Product Compliance Directorate issues a CPP to one of the following applicants:

- the Drug Identification Number (DIN) owner of the pharmaceutical product; or in the case of radiopharmaceuticals the party to which an NOC has been issued
- the fabricator of the pharmaceutical product, if it is located in Canada and GMP compliant; or
- a third party that submits, along with the application, a written authorization for the issuance of the CPP from the DIN owner of the pharmaceutical product. (To be updated annually).

5.1 Requirements for issuance of a Certificate

5.1.1 When the pharmaceutical product is fabricated and packaged/labelled in Canada, a CPP is issued if all the following requirements are met:

- the fabricator and packager/labeller are GMP compliant;
- the pharmaceutical product has a valid DIN and a valid date of notification;
- or in the case of radiopharmaceuticals an NOC has been issued and the product has a valid date of notification*
- the pharmaceutical product is sold on the Canadian market;
- the applicant must be located in Canada.

* Please note: If the fabricator is other than the DIN owner, their subsidiary or legal agent, confirmation is required from the fabricator that they fabricate the product.

* Please note: the application form requests the "date of notification" and this is inserted in the field, on the certificate, identified as the date of issue. The date of notification indicates the date of issuance of the product on the market.

5.1.2 When the pharmaceutical product is fabricated in a foreign country and packaged/ labelled in Canada or fabricated in Canada and packaged/ labelled in a foreign country, a CPP is issued if all the following requirements are met:

- the packager/labeller and the fabricator are GMP compliant;
- the foreign establishment is GMP compliant and is listed on the Canadian Drug Establishment Licence (DEL);
- the pharmaceutical product has a valid DIN or an NOC and a valid date of notification;
- the pharmaceutical product is sold on the Canadian market.

5.1.3 When the pharmaceutical product is fabricated and/or packaged/labelled in Canada but **not marketed in Canada**, a CPP is issued if the following conditions are met:

- the fabricator and/or packager/labeller are/is GMP compliant;
- a DIN or an NOC has been issued, (that is the drug product has market authorization).

5.1.4 When the pharmaceutical product is **fabricated in Canada and not sold on the Canadian market, but the drug submission is under review**, a CPP is issued if the fabricator is GMP compliant and if the applicant submits information on the formulation and active ingredients of the pharmaceutical product. Furthermore, the CPP issued will carry the following statement: "The product is manufactured for export only. The Health Products and Food Branch of Health Canada is currently reviewing an application to permit the marketing of this product in Canada."

5.1.5 If the request for a Certificate is not specific for a pharmaceutical product, a GMP certificate is issued when the fabricator is GMP compliant. In this particular case, the certificate that is issued indicates the dosage forms only, instead of the product information.

5.2 Refusal of issuance of a Certificate

A CPP will not be issued:

5.2.1 If the pharmaceutical product that is fabricated and/or packaged/labelled in a building outside of Canada, is not in Compliance with GMPs (please refer to GUI-0080: "Guidance on How to demonstrate foreign building compliance with drug good manufacturing practices"*)* and is not listed on a (or the) Canadian DEL. Or;

5.2.2 If the foreign building is removed from the DEL Foreign Building Annex as a result of GMP evidence that was not submitted by the New Evidence Required by (NERBY) date or the evidence was considered unacceptable or in complete. Or;

5.2.3 If the pharmaceutical product that is fabricated and/or packaged/labelled in a building outside of Canada and is imported into Canada solely for the purpose of providing a contract packaging/labelling service or contract testing to the person that retains ownership of the pharmaceutical product. Or;

5.2.4 If the CPP lacks the appropriate required information or if the application is incomplete. Or;

5.2.5 For NHPs as of January 1, 2010, as all the DINs for NHPs should have been transferred to NPNs. International Trade Certificates from The Natural Health Products Directorate will be issued for these products. Or;

5.2.6 If the required fees are not provided. Or;

5.2.7 If Section 37 of the FDA has been invoked for the product(s) in question. Or;

5.2.8 If the country of consignment indicated in application has a Mutual Recognition Agreement with Canada.

Finally if an application is refused, refunds will **not** be provided.

5.3 Application Process

5.3.1 The applicant must fill out one of the following as appropriate "Application Form for a Certificate of a Pharmaceutical Product", Application Form for a GMP Certificate and/ or Application Form for a Certificate, which is included in this document as Appendix 1 and Appendix 5 or is available on the Health Canada's Compliance and Enforcement website . Instructions on how to fill out these forms are included in this document as Appendix 2 and Appendix 6.

5.3.2 If the application is specific for a pharmaceutical product, one application form must be filled out per product, one application per DIN, since manufacturing arrangements and approved information for different strengths can vary. Furthermore, one application must be filled out per country of consignment.

5.3.3 The applicant must fill out the "Fee Form for a Certificate of a Pharmaceutical Product", which is included in this document as Appendix 3 or is available on the Health Canada's Compliance and Enforcement website.

5.3.4 The fee for each certificate is **$90.00** plus applicable tax in force (PST & HST is based on the current address (province) of applicant). These fees will increase by 2% on April 1st of every year.

5.3.5 For supplemental copies of the same certificate (i.e. same product and same DIN, same country), the request must be submitted at the same time as the request for the original CPP. The fee for each supplemental copy is **$90.00** plus applicable tax in force (PST & HST is based on the current address (province) of applicant).

5.3.6 One fee form copy must be submitted with each group of certificate applications.

5.3.7 A payment must accompany the application forms and the fee form. Payment may be made by:

- a cheque or money order for the total amount due, made payable to the ***Receiver General for Canada***
- company account
- Visa
- MasterCard
- Amex Card

5.3.8 Payment should be in Canadian funds. Non-payment, partial payment or payment in non-Canadian funds, may result in return of the application at the company's expense. Any overpayment will be credited against the firm's account. Any payment being charged to a company account must be

accompanied by the appropriate account number. Should an application be refused no refunds will be issued.

5.3.9 If documents relating to the product indicated on the certificate need to be stamped by Health Canada, the applicant must:

- fill out the "Request For Stamping Form", which is also included in this document as Appendix 4.
- have the form sworn before a Notary Public, and
- submit the form with two copies of the information to be stamped. One copy is stamped and returned to the applicant and the other copy is retained in Health Canada files.
- a request for stamping may not be allowed if it does not accompany a CPP request.
- in order to expedite a stamping request, the applicant should include a completed shipping form
- waybill Purolator, Fedex, Loomis, UPS, Dicom, etc.) with each request.

These documents may be stamped:

- documents pertaining to product formulation of a licensed product (example: certificate of analysis, product specifications etc)
- documents attesting to packaging and labelling of an authorized product (example: packaging and labelling specifications)
- proof of sale in Canada of an authorized product (example: sales invoice).

These types of document will not be stamped:

- any document relating to building for which a EL is not issued or a pharmaceutical product for which a DIN has not been issued.
- document attesting to a product or building receiving third party certification (example: ISO certification, advertising pre-clearance etc.)
- commercial information or any other type of document with information not on file at the Health Product Compliance Directorate.

5.3.10 The application form, the fee form, the payment and the request for stamping form, along with the documents to be stamped, must be sent to:

Drug Establishment Licensing Unit
Health Product Compliance Directorate - Regulatory Operations and Enforcement Branch Jeanne Mance Building, 13th floor
200 Eglantine Driveway
Address Locator #1913B
Ottawa, Ontario
K1A 0K9

5.3.11 In order to expedite certificate issuance, the applicant should include a completed shipping form (waybill Purolator, Fedex, Loomis, UPS, Dicom, etc.) with each request.

5.3.12 For questions related to CPPs, please contact the Health Product Compliance Directorate (same address as above):

Telephone: 613-618-4529
Facsimile: 613 957-4147
Email: hc.cpp.questions.sc@canada.ca

5.3.13 For questions related to accounts, please contact the Accounts Receivable Office:

Health Canada - Account Receivables
161 Goldenrod Driveway
Address Locator #1918B, Room 1804B
Ottawa, Ontario K1A 0K9
Telephone: 613 946-0496 or 1-800-815-0506
Facsimile: 613 957-3495

5.4 Issuance of a Certificate

5.4.1 The Health Product Compliance Directorate has a target for issuance of Certificates within 10 business days.

5.4.2 A seal is affixed on each page of the certificate. Each seal indicates in large fonts the year of issuance. Furthermore, a fluorescent watermark is incorporated as an additional security feature.

5.4.3 A CPP or GMP Certificate is valid for a maximum period of 1 year from the date of the issuance of the Certificate. In reference to section 5.1.2, when the pharmaceutical product is fabricated in a **foreign country** and packaged/ labelled in **Canada** or fabricated in **Canada** and packaged/ labelled in a **foreign country** - one requirement is that the packager/labeller and the fabricator are GMP compliant.

5.4.4 **If a certificate is not issued because one of the above mentioned requirements is not met, the Health Product Compliance Directorate will inform the applicant and the fees will not be refunded. The applicant must reapply for the Certificate. Please note that if a certificate is issued and it contains an error for which the Health Product Compliance Directorate is responsible, the Health Product Compliance Directorate will issue a new certificate, upon request, free of charge.** The replacement certificate will be issued with the original date of issue unless otherwise requested.

6.0 Effective date

This document will become effective April 1, 2019.

7.0 Reference documents

1. *Guidance on How to demonstrate foreign building compliance with drug good manufacturing practices (GUI-0080)*
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents/guidance-evidence-demonstrate-drug-compliance-foreign-sites-0080.html

2. *Guidance Document on the Commercial Importation and Exportation of Drugs in Dosage Forms under*

the Food and Drugs Act and its Regulations (POL-0060)

https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/importation-exportation/policy-health-products-under-food-drugs-act-regulations-0060.html

3. *Certification scheme on the quality of pharmaceutical products moving in international commerce*
http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/en/

4. *Guidelines on the implementation of the WHO certification scheme on the quality of pharmaceutical products moving in international commerce*
http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/guidelines/en/

Appendix 1
Application Form
Certificate of a Pharmaceutical Product

This is a request for a Certificate of a Pharmaceutical Product (CPP) in the format recommended by the World Health Organization (WHO). (**one form must be completed for each product and country**)

i) Country of consignment:

ii) Brand name:

iii) Proper name:

Potency:

iv) Dosage Form:

v) DIN:

☐ This is a veterinary pharmaceutical intended for use in a non-food producing animal[1]

Date of notification:

☐ I certify that this product is currently on the Canadian market

☐ This product is not on the Canadian market for the following reason(s):

vi) ☐ I certify that the above mentioned product has been fabricated in accordance with the currently approved master production document.

vii) Manufacturer's/sponsor's name:
Canadian address:

viii) Site(s) (name and address) of the production of this product:

ix) ☐ I certify that the above mentioned product is fabricated in compliance with the Canadian Good Manufacturing Practice (GMP) provisions.
Date of most recent inspection:

[1] Please note: CPP's issued for veterinary pharmaceuticals intended for use in non-food producing animals will carry the following statement: "The WHO does not recommend issuance of Certificate of Pharmaceutical Products for veterinary pharmaceuticals intended for non-food producing animals because the WHO has not issued a manufacturing standard for these drugs. However, this certificate has been issued because the Health Product Compliance Directorate's compliance and enforcement program and the *Food and Drug Regulations* apply to both human and veterinary pharmaceuticals."

x) ☐ If the above-mentioned product is fabricated at a foreign site; I certify that I have evidence it complies with Canadian Good Manufacturing Practices (GMP) provisions and the foreign site appears on my Drug Establishment Licence (DEL).

DEL #:
Expiration date on DEL:
Date of most recent inspection:

xi) ☐ I certify that the manufacturer as identified in (vii), will advise the Health Product Compliance Directorate (HPCD) of any quality defects or other hazard associated with the product or shipment that may be determined.

xii) ☐ The certificate must be returned by prepaid courier.

☐ The certificate may be returned by regular mail.

xiii) ☐ English certificate

☐ French certificate

Name_____Telephone (_____)

Title_____Facsimile (_____)

Company: _____

I certify that all above information is accurate and complete.

Signature_____Date _____

Appendix 2
Instructions on How to fill out an Application for the Request of a Certificate of a Pharmaceutical Product.

The following information and declarative statements must be provided by the applicant when requesting a CPP. Clarification regarding the sections of the Application Form is provided below:

i) *Country of consignment:*
The importing country (example: Nigeria, Thailand)

ii) B*rand name:*
The trade name appearing on the product label. If the product is marketed under a different name in the importing country and it is requested to be on the CPP, it must clearly be indicated on the application.

iii) *Proper name and potency declaration:*
International non-proprietary names (INN) or national non-proprietary names should be used.

iv) *Dosage form:*
Describe the dosage form in detail (example: film coated tablet, pressurized aerosol spray).

v) *DIN:*
Provide the number and the date of notification. Indicate if the product is currently marketed in Canada and if not, provide a statement as to the reason. The date of notification is the date the product was issued onto the market.

Check the box if the product is a veterinary pharmaceutical intended for use in non-food producing animals.

vi) Check this box to certify that the product in question has been fabricated in accordance with the currently approved master production document. Failure to so certify may result in rejection of the application.

vii) *Manufacturer's/sponsor's name and Canadian address:*
The address of the DIN owner or the legal agent in Canada.

viii) *Site(s) (name and address) of production of this product:*
It must be completely clear as to the site(s)/buildings of fabricating and packaging. This information allows the Health Product Compliance Directorate to make statements about the GMP compliance status of third parties. The names and addresses of third parties will be included on the certificate unless you request that this information remain confidential. A CPP for a drug fabricated outside of Canada will refer to the most recent evaluation of the foreign site(s). If the applicant is a person other

than the legal agent (DIN owner) authorization for issuance of the certificate is required from the DIN owner of the pharmaceutical product.

If the fabricator is other than the DIN owner, their subsidiary or legal agent. Confirmation is required from the fabricator that they fabricate the product.

ix) Check this box to certify that the product in question is fabricated in compliance with Canadian GMP provisions (Division 2, part C, *Food and Drug Regulations*). The date of the last inspection must be indicated.

x) If the product is fabricated in a foreign site, check this box to certify that you have evidence the product in question is fabricated in compliance with Canadian GMP provisions (Division 2, Part C, *Food and Drug Regulations*). The expiration date assigned to the foreign site must correspond with what appears on your current DEL. Please ensure your DEL lists all foreign fabricators. The date of the last inspection must also be indicated.

xi) Check this box to certify that the fabricator will advise the Health Product Compliance Directorate of any quality defects or other hazard associated with the product or shipment that may be determined. The DIN owner and/or the fabricator are also responsible for notifying the Health Product Compliance Directorate if the product is recalled.

xii) Check the appropriate box to indicate how the certificate should be shipped. If the certificate is to be returned by courier, please provide the name of your courier and your account number on the Certificate of a Pharmaceutical Product Fee Form.

xiii) Indicate which Official Language the certificate will be issued in: English or French.

The name, signature, phone number, etc. of the applicant must also be provide.

Signing the application certifies that all information contained is accurate and complete.

Appendix 3
Fee Form
Certificate of a Pharmaceutical Product

To: Drug Establishment Licensing Unit
Health Products Compliance Directorate
Jeanne Mance Building, 13th floor
200 Eglantive Driveway
Address Locator # 1913B
Ottawa, Ontario
K1A 0K9

Re: Application for a Certificate of a Pharmaceutical Product

Please find enclosed, applications for_____# certificates.

Fee calculation: number of certificates_____x **$90.00 + HST**=$

*** The applicants from Quebec, Ontario, New Brunswick, Newfoundland and Labrador, and Nova Scotia must calculate and add the applicable taxes in force (PST & HST).**

Payments

□ Prepayment
□ Cheque (A cheque or money order in the amount of $_____made payable to the *Receiver General for Canada*, is enclosed with this application).
□ Credit Card Visa □ MasterCard □ AMEX □

Card #_____+ (for MasterCard 4 digit #_____above cardholder's name)

Valid Date:_____Expiry Date:_____Amount: $

Name and Telephone number of contact person: _____

Return of issued certificates by collect courier is hereby authorized:

Name of Courier: **Account Number:**
Signature of applicant:
Name (printed): **Title:**
Company name:
Address:
Phone number: **Facsimile:**
Email:
Date:

Note: if courier services are used for payments, please call first 1-800-815-0506

Appendix 4
Request for Stamping Form

*(Submit this form with **two copies** of any material that is to be stamped. One copy of the material will be stamped and returned to you with your Certificates. The other copy will be retained in Health Canada files.)*

The undersigned Company requests that Health Canada stamp and return one copy of the enclosed information for attachment to a Certificate of Pharmaceutical Product.

Product name:

Summary of attached information and material:

We certify that the attached information and material are accurate and up-to-date and that copies of this information and material are on file with Health Canada.

Name of Company

Name of Company Representative Title of Company Representative

Signature of Company Representative Date

This Document must be Sworn before a Notary Public.

Name

_____ (Seal)

Signature

_____

Date

This form is subject to the Health Product Compliance Directorate revision.

Appendix 5
Application Form GMP Certificate

(One form must be completed for each country)

i) Country of Consignment: _____

ii) Dosage Forms: _____

iii) □ I certify that the above mentioned dosage form has been fabricated in accordance with the currently approved master production document.

iv) Applicant for Certificate (name and Address):

v) Site (s) (name and address) of the production of this product:

□ I certify that I have authorization from the above fabricator to apply for a Certificate listing them as a site of production.

vi) □ I certify that the above mentioned product is fabricated in compliance with the Canadian Good Manufacturing Practices (GMP) provisions:

Date of most recent inspection:

vii) □ If the above-mentioned product is fabricated at a foreign site; I certify that I have evidence it complies with Canadian Good Manufacturing Practices (GMP) provisions and the foreign site appears on my Drug Establishment Licence (DEL).

DEL #:
Expiration date on DEL:
Date of most recent inspection:

viii) □ I certify that the applicant as identified in (iv), will advise the Health Product Compliance Directorate (of any quality defects or other hazard associated with the dosage form or shipment that may be determined.

ix) □ The certificate must be returned by prepaid courier.

□ The certificate may be returned by regular mail.

x) □ English Certificate

□ French certificate

Name_____ Telephone _____

Title_____ Facsimile _____

Company_____

I certify that all above information is accurate and complete.

Signature_____ Date_____

Appendix 6
GMP Certificate Application Form Instructions

The following information and declarative statements must be provided by the applicant when requesting a GMP Certificate. Clarification regarding the sections of the Application Form is provided below:

i) *Country of consignment:*
The importing country (example: Nigeria, Thailand)

ii) *Dosage forms:*
Describe the dosage form in detail (example: film coated tablet, pressurized aerosol spray).

iii) Check this box to certify that the dosage form in question has been fabricated in accordance with the currently approved master production document. Failure to so certify may result in rejection of the application.

iv) The name and address of the company requesting the GMP Certificate.

v) *Site(s) (name and address) of production of this product:*
It must be completely clear as to the site(s)/buildings of fabricating and/or packaging. This information allows the Health Product Compliance Directorate to make statements about the GMP compliance status of third parties. The names and addresses of third parties will be included on the certificate unless you request that this information remain confidential. A GMP Certificate for a drug fabricated outside of Canada will refer to the most recent evaluation of the foreign site(s). If the applicant is a person other than the DIN owner, authorization for issuance of the certificate is required from the fabricator of the dosage form.

vi) Check this box to certify that the product in question is fabricated in compliance with Canadian GMP provisions (Division 2, part C, *Food and Drug Regulations*). The date of the last inspection must be indicated.

vii) If the product is fabricated in a foreign site, check this box to certify that you have evidence the product in question is fabricated in compliance with Canadian GMP provisions (Division 2, Part C, *Food and Drug Regulations*). The expiration date assigned to the foreign site must correspond with what appears on your current DEL. Please ensure your DEL lists all foreign fabricators. The date of the last inspection must also be indicated.

viii) Check this box to certify that the fabricator will advise the Health Product Compliance Directorate of any quality defects or other hazard associated with the product or shipment that may be determined. The DIN owner and/or the fabricator are also responsible for notifying the Health Product Compliance Directorate if the product is recalled.

ix) Check the appropriate box to indicate how the certificate should be shipped. If the certificate is to be returned by courier, please provide the name of your courier and your account number on the Certificate of a Pharmaceutical Product Fee Form.

x) Indicate which Official Language the certificate will be issued in: English or French.
The name, signature, phone number, etc. of the applicant must also be provide.
Signing the application certifies that all information contained is accurate and complete.