

中醫藥條例
Chinese Medicine Ordinance
 (香港法例第 549 章)
 (Cap. 549)

製造商證明書（中成藥生產質量管理規範）申請表
Application Form for Certificate for Manufacturer
(Good manufacturing practice in respect of proprietary Chinese medicines)

本公司 _____ 地址為 _____
 We, _____, at _____
 (公司名稱 Name of Company)

 (公司地址 Address of Company)

已領有中成藥製造商牌照。

have been granted a manufacturer licence in proprietary Chinese medicines.

(牌照編號 Licence number : _____)

現根據《中醫藥條例》第 133 條的規定，申請製造商證明書，以證明製造商在製造中成藥方面並在品質控制方面依循優良的規範。

We wish to apply for the certificate for manufacturer in accordance with Section 133 of the Chinese Medicine Ordinance, certifying that the manufacturer follows the requirements of good practices in manufacture and quality control of proprietary Chinese medicines.

甲部 Part A 營業資料 Business Information

營業處所公司名稱 Company name of business premises

中文 (Chinese) :

英文 (English) :

營業處所地址 Address of business premises

中文 (Chinese) :

英文 (English) :

商業登記號碼 Business Registration No. :

營業電話號碼 Business Tel. No. :

電子郵件地址(如適用) E-mail Address (if any) :

營業傳真號碼 Business Fax No. :

貯存倉地址及商業登記號碼（如與上述地址不同）：

Address of Warehouse and Business Registration No. (if different from above):

乙部 Part B 製造商證明書的領取安排 Arrangement for collection of Certificate for Manufacturer

如製造商證明書申請獲得批准，本公司選擇：

If application for certificate for manufacturer is approved, we choose to:

- 以郵遞方式領取製造商證明書* collect the certificate for manufacturer by post*
- 親身領取製造商證明書 collect the certificate for manufacturer in person

請在適當的方格內加上“√”號 Please tick “√” in the appropriate box.

*如因郵遞錯誤，申請人未能領取製造商證明書，中藥組將不會為有關申請人補發製造商證明書。申請人可向中藥組申請製造商證明書的核證副本。If the applicant does not receive the certificate for manufacturer due to postal error, the applicant will not be re-issued another certificate for manufacturer from the Chinese Medicines Board. The applicant can apply to the Chinese Medicines Board for a certified true copy of the certificate for manufacturer.

丙部 Part C 聲明 Declaration

- 本人謹此聲明，就本人所知及所信，此申請表 1E 所提供的資料及核對表 2E 所要求遞交的資料皆屬真確事實的全部。
I hereby declare that all the foregoing information in Application Form 1E and information as required in documentation checklist 2E is FULL, COMPLETE and TRUE to the best of my knowledge and belief.
- 本人授權香港中醫藥管理委員會中藥組按其認為合適的方式，核實此申請所提供的資料。
I authorize the Chinese Medicines Board of the Chinese Medicine Council to verify the foregoing information in any manner as it deems fit.
- 本人明白根據《中醫藥條例》第 153(3)條的規定，任何人在向中藥組提出申請或在給予任何資料時，在要項上作出他知道是虛假或他不相信是真實的陳述或申述，即屬犯罪，最高可處第 6 級罰款及監禁 2 年。
I understand that according to Section 153(3) of the Chinese Medicine Ordinance, any person who, in making an application to the Chinese Medicines Board or in giving any information, makes a statement or representations which he knows to be false or does not believe to be true in a material particular, commits an offence and shall be liable to maximum penalty of a fine at level 6 and to imprisonment for 2 years.
- 本人明白所提交的資料如有任何更改，須盡快以書面通知衛生署中醫藥規管辦公室。
I understand that if there is any amendment to the submitted information, I shall send it in writing to the Chinese Medicine Regulatory Office of the Department of Health as soon as possible.
- 本人明白所提交的個人資料，將會用作執行《中醫藥條例》的條款。
I understand that the personal data provided by me are for the purposes of facilitating the execution of the provisions of the Chinese Medicine Ordinance.
- 本人明白所提交的個人資料，主要由香港中醫藥管理委員會內部使用，但亦可能因以上第 5 段所列目的，向其他政府部門、中介機構或行政管理機構披露；除此以外，這些資料只會在本人的同意，又或是《個人資料（私隱）條例》所容許下，才會向其他人士透露。
I understand that the personal data provided by me are mainly for use within the Chinese Medicine Council but they may also be disclosed to other Government bureaux/departments, agencies or authorities for the purposes mentioned in paragraph (5), if required. Apart from this, the information provided herein will only be disclosed to parties where I have given consent to such disclosure or where such disclosure is allowed under the Personal Data (Privacy) Ordinance.
- 本人明白根據《個人資料（私隱）條例》第 18 條及 22 條以及其附表 1 第 6 原則所述，本人有權查閱及修正個人資料，但查閱資料時，可能要繳交費用。
I understand that I have the right of access and correction with respect to personal data as provided for in Section 18 and 22 and Principle 6 of schedule 1 of the Personal Data (Privacy) Ordinance. A fee may be imposed for complying with a data access request.

.....
公司負責人簽署 Signature of person in charge of the business

.....
姓名（正楷）Name (Block Letter)

.....
公司蓋章 Company Chop

.....
職位 Position Held

.....
日期 Date

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收到申請表日期 Date of receipt of application form :