申請編號： Application Ref. No.:

香港中醫藥管理委員會中藥組
Chinese Medicines Board of
The Chinese Medicine Council of Hong Kong

教育或科研人士或機構根據第 158(1)條之豁免申請
（有關中成藥註冊的豁免申請—供中成藥製造商使用）
Application for exemption in accordance with section 158(1) by a person or institution concerned with education or scientific research
(For application of exemption in relation to proprietary Chinese medicine registration by proprietary Chinese medicine manufacturer)

《中醫藥條例》
第 549 章
第 158(1)條

Chinese Medicine Ordinance (Cap. 549)
Section 158(1)

表格 E1D
Form E1D

教育或科研人士或機構根據第 158(1)條
（使其免受第119條的規限）之豁免申請表

Form of the application in accordance with section 158(1)
(Exemption from the application of sections 119)
by a person or institution concerned with education or scientific research

申請者請填寫甲部、乙部、丙部及丁部。Applicant please complete Part A, Part B, Part C and Part D.

甲部分 Part A	申請者資料 Particulars of applicant

中成藥製造商名稱： Name of proprietary Chinese medicine manufacturer:	(中文) (English)
通訊地址： Correspondence address:	(中文) (English)
中成藥製造商牌照編號： Licence number of the proprietary Chinese medicine manufacturer:	
授權人[註1]的姓名： Name of authorized person [Note 1]:	(中文) (English)
香港身份證號碼／護照號碼： HKID no. / Passport no.:	

職位 Position:	電郵地址 E-mail:
聯絡電話 Contact no.	傳真號碼 Fax no.

乙部分 Part B	臨床試驗申辦者及試驗機構資料 Particulars of sponsor & institution conducting the clinical trial

臨床試驗申辦者名稱： Name of the sponsor for the clinical trial:	(中文) (English)
臨床試驗申辦者地址： Address of the sponsor for the clinical trial:	(中文) (English)
負責人姓名： Name of responsible person:	(中文) (English)

職位 Position:	電郵地址 E-mail:
聯絡電話 Contact no.	傳真號碼 Fax no.

進行臨床試驗的機構名稱： Name of institution conducting the clinical trial:	(中文) (English)
進行臨床試驗的地址： Address where the clinical trial is conducted:	(中文) (English)
負責人姓名： Name of responsible person:	(中文) (English)

職位 Position:	電郵地址 E-mail:
聯絡電話 Contact no.	傳真號碼 Fax no.

丙部分 Part C	詳情 Details

欲申請豁免的範圍及理由：
Scope of exemption applied for and reason(s):

範 圍 Scope	理 由 Reason(s)
中成藥註冊 Registration of proprietary Chinese medicines ☐	
其他 Others ☐	

臨床試驗的名稱：
Title of the clinical trial:

_____

_____

臨床試驗的鑑別號（如適用）：
Identifying no. of the clinical trial (if applicable): _____

臨床試驗的內容：
Content of the clinical trial:

_____

_____

需要有關中成藥的名稱、劑型及其數量：
Name, dose form and quantity of the proprietary Chinese medicine to be acquired:

_____

_____

需要有關中成藥的原因：
The reason(s) of acquiring the concerned proprietary Chinese medicine(s):

_____

_____

參與以上項目的人士的姓名及其職位名稱：
The name and post of the person(s) involved in the above-mentioned project:

_____

_____

請詳述參與以上項目的人士所負責的工作範圍及性質：
Please give details on the duties and responsibilities of the person(s) involved in the above-mentioned project:

_____

_____

完成教育或科研項目所需的總時間：
Total time required for completion of the educational project or scientific research:

由 _____ 至 _____
From _____ to _____

(請在適當方格內加上✓號) (Please tick ✓ as appropriate)

丙部分（續） Part C (Cont'd)	詳情 Details

本人已附上以下文件作審批申請之用：

I attach the following documents for approval of the application:

(i)	填妥的申請表（表格 E1D） A duly completed application form (Form E1D)	☐
(ii)	中成藥製造商授權「授權人」處理申請的文件 Proof that the authorized person has been authorized by the manufacturer to make the application.	☐
(iii)	中成藥製造商的「授權人」的身份證明文件副本 Proof of identity of the authorized person of the manufacturer.	☐
(iv)	中成藥製造商獲委託製造臨床試驗用藥的合約副本 Copy of the contract covering the manufacture of the investigational product for the clinical trial	☐
(v)	該中成藥的完整處方及製造方法 Master formula and manufacturing method of the proprietary Chinese medicine	☐
(vi)	中成藥製造商牌照及製造商證明書（中成藥生產質量管理規範）副本 Copy of the Manufacturer Licence in proprietary Chinese medicines, and the Certificate for Manufacturer (Good Manufacturing Practice in respect of Proprietary Chinese Medicines)	☐
(vii)	科學研究（臨床試驗）計劃書 Proposed plan of the scientific research (clinical trial)	☐
(viii)	如屬為境外臨床試驗機構提供試驗用藥，須提供由當地藥物監管機構發出的證明，以確認該臨床試驗機構已獲批准使用相關中成藥在當地進行相關臨床試驗 For application related to the supply of investigation product for clinical trials conducted outside Hong Kong, documentary proof issued by regulatory authority certifying that the related clinical trial and the use of the proprietary Chinese medicine thereto have been approved.	☐

中藥組如認為有需要，可要求申請者提交任何其他文件或資料。

The Chinese Medicines Board may, if necessary, request the applicant to submit any other documents or information.

中藥組如認為有需要，可要求申請者提交任何文件或資料的正本以供核對。

The Chinese Medicines Board may, if necessary, request the applicant to submit original copy of any of the above documents or information for verification.

丁部分 Part D	聲明（人士或機構必須填寫） Declaration (To be completed by person or institution)

1. 本人謹此聲明，已閱讀並理解申請須知內的要求 [註2]，以及就本人所知及所信，此申請表的甲、乙及丙部分所提供的資料皆屬真確事實的全部。
   I hereby declare that have read through and understood the Guidelines [Note 2] and that all the foregoing information in Parts A, B and C of this application is FULL, COMPLETE and TRUE to the best of my knowledge and belief.

2. 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，核實此申請表所提供的資料。I authorize the Chinese Medicines Board of the Chinese Medicine Council of Hong Kong to verify the foregoing information in any manner as it deems fit.

3. 本人明白所提交予香港中醫藥管理委員會中藥組的個人資料及其他相關資料，將會用作執行《中醫藥條例》的條款。
   I understand that my personal data or other relevant information given to the Chinese Medicines Board of the Chinese Medicine Council of Hong Kong are for the purposes of facilitating the implementation of the relevant provisions of the Chinese Medicine Ordinance.

4. 本人明白所提交的個人資料，主要供香港中醫藥管理委員會內部使用，但亦可能因以上第 3 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；除此之外，其他個人資料祇會在本人同意、又或者在《個人資料（私隱）條例》所容許下，向其他人士披露。
   I understand that my personal data are mainly for use within the Chinese Medicine Council of Hong Kong but they may also be disclosed to other Government bureaux / departments, agencies or organizations for the purposes mentioned in paragraph 3 above. Apart from this, my personal particulars and information 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.

中成藥製造商授權人簽署：
Signature of the authorized person of the manufacturer: _____

(代表中成藥製造商簽署)
(Signing for and on behalf of the manufacturer)

中成藥製造商授權人的姓名(正楷)：
Name of authorized person of the manufacturer: _____

中成藥製造商名稱：
Name of manufacturer : _____

中成藥製造商的蓋章：
Stamp of the manufacturer: _____

日期：
Date: _____

註1：根據《香港中成藥生產質量管理規範指引》，「授權人」是中成藥製造商的關鍵人員之一，負責發放每批製成品作銷售用途。
Note 1: According《Hong Kong Good Manufacturing Practice Guidelines for Proprietary Chinese Medicines》, "Authorized person" is one of the key personnel who responsible for the release of every batch of finished products for sale.

註2：見「與教育或科研有關的人士或機構根據《中醫藥條例》第158(1)條豁免有關中成藥註冊的申請須知」（上稱申請須知）內的要求。
Note 2: Refer to the requirements of the "Guidelines on application of exemption in relation to proprietary Chinese medicine registration by a person or institution concerned with education or scientific research in accordance with section 158(1) of the Chinese Medicine Ordinance" ("the Guidelines").

一般事項：
General Remarks:

1. 請用黑色墨水筆或原子筆填寫申請表。
   Please use black inked pen or ball pen to fill in the application form.
2. 申請人須填妥申請表各有關項目（包括中英文地址），並提供正確資料。
   Applicant shall complete every relevant items of the application form (including Chinese and English addresses), and provide correct information.
3. 除註明外，請以中文正楷或英文填寫申請表格。
   Unless otherwise specified, please use Chinese or English block letters to fill in the application form.
4. 申請人如未能提供所需的所有資料，或所填寫的資料未能清楚顯示申請人符合最基本的申請規定，或申請人未能在申請之後註明的一段時間內補交所需的資料，中藥組可拒絕進一步處理或拒絕其申請。
   In the event that an applicant cannot provide all necessary information, or that the information provided does not clearly indicate the applicant has complied with all basic application requirements, or that the applicant fails to provide all necessary information within a specified period of time after application, the Chinese Medicines Board may decline to process the application further or reject the application.
5. 申請人應保留一份填妥的申請表副本，以備參考。
   Applicant should retain a photocopy of the application for reference.
6. 申請人提交申請表後，如欲更改或查詢個人資料，請與衞生署中醫藥規管辦公室聯絡（電話號碼：3904 9130）。
   If an applicant wishes to amend or inquire personal information after submission of the application form, please contact the Chinese Medicine Regulatory Office of Department of Health (telephone no. 3904 9130).
7. 如申請表空位不敷填寫，請另頁填寫，並在申請表有關部分註明。申請人須在該附頁上寫明其姓名及簽署，然後將附頁釘附在申請表內。
   If there is insufficient space in the application form, please use a separate sheet and indicate accordingly in the relevant part of the application form. The applicant shall write his / her name and sign on the sheet and attach it to the application form.