檔案編號：
Ref. No.

《中醫藥條例》
(第549 章)
Chinese Medicine Ordinance
(Chapter 549)

臨床證驗及藥物測試證明書申請書
《中醫藥條例》第129 條
Application Form for Certificate for Clinical Trial and Medicinal Test
Section 129, Chinese Medicine Ordinance

申請人名稱 ：_____ (中文)
Name of applicant：_____ (英文)

申請人辦公地址：_____ (中文)
Office address of applicant：_____ (英文)
_____

商業登記證號碼（如有） Business registration number (if any)：_____

聯絡電話 傳真號碼
Contact telephone number：_____ Fax number：_____

A 部: 試驗資料
PART A: TRIAL INFORMATION

申請進行 Apply for conducting*： ☐ 臨床試驗 Clinical Trial (請填寫 A、B、C 及D部 Please complete Part A, B, C & D) ☐ 藥物測試 Medicinal Test (請填寫 A、C 及D部 Please complete Part A, C & D)			
擬定的臨床試驗方案／藥物測試方案#標題 Title of Clinical Trial/Medicinal Test# as stated in the proposed protocol:			
方案編號 Protocol No.:		方案日期 Protocol Date:	
主要研究者的姓名 Name(s) of Principal Investigator(s) 中文 (Chinese)： 英文 (English)：			
進行試驗的機構名稱及地址 Name(s) and Address(es) of Institution(s) conducting the trial 中文 (Chinese)： 英文 (English)：			
聯絡電話 Contact Tel. No.		傳真號碼 Fax No.	

B 部: 試驗簡介

PART B: TRIAL DESCRIPTION

此試驗是 This study is *	☐ 單中心 single centre ☐ 多中心 multi-centre
列出香港的研究中心 Study sites in Hong Kong	共 _____個中心 Total no. of sites_____ 中心名稱 Site name(s)_____ 中心地址 Site Address(es)_____ _____ _____
列出香港以外的研究中心 (如有) Study sites outside Hong Kong (if any)	（每個國家/地區有多少個中心，如：美國共 2 個中心；新加坡共 2 個中心） (No. of sites in each country/region, e.g. USA–2 sites, Singapore–2 sites)
申辦者的類別 Type of Sponsor *	☐申辦者 Sponsor （如製造商／藥商 Manufacturer/Medicines traders） ☐申辦者－研究者 Sponsor-Investigator 申辦者名稱 Name of sponsor: 中文 (Chinese)：_____ 英文 (English)：_____ 地址 Address: 中文 (Chinese)：_____ _____ 英文 (English)：_____ _____
招募人數 Recruitment Size	計劃在香港招募的人數 Planned number of trial subjects in Hong Kong_____ 全球總招募人數 Total planned number of trial subjects world-wide_____
試驗期 Study Period	計劃開始日期 Planned start date _____ 計劃完結日期 Planned end date _____
臨床試驗為 Phase of Clinical Trial *	☐ 一期 Phase I （首次用於人 First-In-Man? ☐ 是 Yes ☐ 否 No） ☐ 二期 Phase II ☐ 三期 Phase III ☐ 四期 Phase IV 如有需要，請加以說明 Describe if necessary: _____
此試驗是 The study is *	☐ 開放式 open label ☐ 單盲 single blind ☐ 雙盲 double blind ☐ 非隨機 non-randomized ☐ 隨機 randomized ☐ 其他（請說明） Other (please specify) _____
研究的醫療狀況或疾病 Medical conditions or disease under investigation	（如中風，瘡瘍） (e.g. Stroke, Sore and ulcer)

此試驗亦屬已獲國家藥品監督管理局批准進行的臨床試驗？* Is this study also approved by the National Medical Products Administration (NMPA) for conducting the trial? * ☐ 是（如適用，藥物臨床試驗批件號為_____及批准日期 _____） Yes, (if available, the number of Clinical Trial Approval Document_____and the date of approval_____) ☐ 否 No

C 部: 試驗用藥

PART C: STUDY DRUG(s)

中成藥製造商的名稱及地址 Name and address of manufacturer of study drug(s)	中文 (Chinese)：_____ _____ _____ 英文 (English)：_____ _____ _____
試驗用藥的名稱 Name of study drug(s) to be investigated	中文 (Chinese)：_____ 英文 (English)：_____
中成藥註冊編號／過渡性註冊編號（如有）The registration number/transitional registration number of the proprietary Chinese medicine (if applicable) ：_____	
「確認中成藥註冊（非過渡性）申請通知書」上的申請編號（如有）Application serial number of the "Notice of confirmation of (non-transitional) registration application of pCm"（if applicable) ：_____	
所有有效成分的名稱(中文及拉丁文)及份量 Names (Chinese and Latin) and quantities of all active ingredients	
輔料的名稱及份量 (如有) Names and quantities of excipient(s) (if any)	
劑型 Dosage form	
此試驗需要與其他藥物同用* The study involves concurrent use of *	☐ 安慰劑 placebo ☐ 對照藥 comparator drug ☐ 合併用藥 concomitant drug ☐ 不適用（以上皆不是） not applicable (none of the above)
安慰劑 (如有，請說明所有成分名稱及份量) Placebo used (if any, please specify the names and quantities of all ingredients)	
對照藥（如有，請說明所有成分名稱及份量） Comparator drug(s) used (if any, please specify the names and quantities of all ingredients)	

合併用藥（如有，請說明所有成分名稱及份量） Concomitant drug(s) used (if any, please specify the names and quantities of all ingredients)	
預計試驗用藥所需數量 Estimated quantity of study drug(s) required	

試驗用藥是否已獲在香港以外的藥品監督管理部門批准註冊? *
Has the study drug(s) been approved by other regulatory authorities outside Hong Kong?

☐ 是，請註明 Yes, please specify：_____
☐ 否 No

試驗結果會否將用作支持試驗用藥根據《中醫藥條例》第121 條申請中成藥註冊（包括新的註冊或增加適應症等）? *

Will the study results be used for supporting application for registration of proprietary Chinese medicine for the study drug(s) according to Section 121 of the Chinese Medicine Ordinance (including new registration or addition of indications etc.)?

☐ 會 Yes ☐ 不會 No

D 部： 申請人聲明

PART D: DECLARATION OF THE APPLICANT

1. 本人明白根據《中醫藥條例》第153 條第3款的規定，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。本人現聲明盡本人所知及所信，申請書所提供的資料均屬真確事實的全部。

   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. I hereby declare that all the foregoing information in this application form is full, complete and true to the best of my knowledge and belief.

2. 如屬臨床試驗：本人承諾臨床試驗的進行將會符合《中成藥藥品臨床試驗質量管理規範》。

   For clinical trial：I promise the clinical trial will be conducted in accordance with the “Good Clinical Practice for proprietary Chinese medicines”.

3. 如屬臨床試驗：若申請獲得批准，本人同意遵守「臨床證驗及藥物測試證明書持有人須知」的規定並根據規定使用「疑似不良反應報告表格」呈報本地藥物安全事故、呈交「臨床試驗年度進度報告」及「臨床試驗最後報告」，及保存《中成藥藥品臨床試驗質量管理規範》附錄二所要求的臨床試驗保存文件，以供在有需要時查核。

   For clinical trial: If the application is approved, I agree to abide by the requirements as stated in the “Guidance Notes for Holders of the Certificate for Clinical Trial and Medicinal Test” and submit, in accordance with the requirements, local drug-related safety reports using “Suspect Adverse Reaction Report”, to submit “Clinical Trial Yearly Progress Report” and “Clinical Trial Final Report”; and to retain the documents listed in the Appendix II of “Good Clinical Practice for proprietary Chinese medicines” for inspection when necessary.

4. 本人明白根據《中醫藥條例》第129 條的規定，「臨床證驗及藥物測試證明書」在中藥組認為適合的期間內以及在適合的條件的規限下有效。本人明白在未能遵守任何所施加的條件規限的情況下將導致該證明書失效。

   I understand that according to Section 129 of the Chinese Medicine Ordinance, the certificate for clinical trial and medicinal test shall be valid for such period and subject to such conditions as the Chinese Medicines Board thinks fit. I understand that failure to abide by any of the conditions as imposed shall lead to revocation of the certificate.

……..	……
申請人簽署 Signature of applicant	聯絡電話 Contact telephone number
……..	……
申請人姓名（正楷）Name of applicant (block letters)	公司蓋章(如有) Company chop (if any)
……..	……
職位 Position	日期 Date

* 請在適當的□空格內加上✓號 Please tick ✓ in the appropriate box.
# 請將不適用者刪去。 Please delete as appropriate.

【註: 以上資料乃申請人提供作申請中成藥臨床證驗及藥物測試證明書參考之用，其真確性尚有待証實。
Note: The information is provided by the applicant for reference purposes in connection with an application for certificate for clinical trial and the medicine test. The authenticity of these information is subject to verification.】

如申請書空位不敷填寫，請另頁填寫，並在申請書有關部份註明。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書內。
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.

此欄供有關部門填寫 **For Office Use Only**
日期 Date：…… 繳交申請費 Paid application fee：……

個人資料 Personal Data:

(一) 收集個人資料的目的 The purpose of collecting personal data

1 申請人向中藥組所提供的個人資料，將會用作執行《中醫藥條例》的條款。The personal data provided by applicants to the Chinese Medicines Board are used for the purpose of implementing the provisions of the Chinese Medicine Ordinance ("CMO").

2 個人資料的提供是出於自願性質，如果申請人不提供充份資料，中藥組可能無法處理其提出的「臨床證驗及藥物測試證明書」申請。The provision of personal data is on a voluntary basis. However, if an applicant fails to provide sufficient personal data, the Chinese Medicines Board may be unable to process the application for certificate for clinical trial and medicinal test.

(二) 個人資料的轉介 Transfer of personal data

3 中藥組所獲取的個人資料，主要是由衞生署及香港中醫藥管理委員會內部使用，但亦可能為了執行《中醫藥條例》內各條款向其他政府部門、中介機構及行政管理機構披露。The personal data provided by applicants are mainly for use within the Department of Health and the Chinese Medicine Council of Hong Kong. However, for the purpose of implementing the provisions of the CMO, such data may also be disclosed to other Government bureaux / departments, agencies or authorities.

4 除此以外，這些資料只會在申請人或其代表（例如：代表律師）同意下，又或是《個人資料(私隱)條例》所容許下，才會向其他人士透露。Apart from these, such personal data will only be disclosed where the applicants, their representatives (e.g. attorney) have given consent to such disclosure or where such disclosure is allowed under the Personal Data (Privacy) Ordinance.

(三) 查閱及修正個人資料 Access to and correction of personal data

5 根據《個人資料(私隱)條例》第 18 條及第 22 條以及其附表 1 第 6 原則所述，申請人有權查閱及修正個人資料，但查閱資料時，可能須繳交費用。Applicants have the right of access and correction with respect to personal data as provided for under sections 18 & 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.

6 申請人的個人資料或其他申報資料如有任何更改，須盡快以書面或傳真方式通知衞生署中醫藥規管辦公室。Should there be any amendment to the personal data or other information submitted, the applicant should notify the Chinese Medicine Regulatory Office of the Department of Health in writing, by post or by fax, as soon as possible.

地址 Address：九龍觀塘巧明街 100 號 LANDMARK EAST 友邦九龍大樓 16 樓
16/F, AIA Kowloon Tower, Landmark East, 100 How Ming Street, Kwun Tong, Kowloon
傳真號碼 Fax Number：2319 2664