

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

檔案編號：

Ref. No. :

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 No. (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 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 Principle Investigator(s)

中文 (Chinese) :

英文 (English) :

試驗機構名稱及地址 Name(s) and Address 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 *	<input type="checkbox"/> 單中心 single centre <input type="checkbox"/> 多中心 multi-centre
列出香港的研究中心 No. of study sites in H.K.	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；星加坡共 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 Sponsorship *	<input type="checkbox"/> 研究者發起的試驗 Investigator initiated study <input type="checkbox"/> 藥商發起的試驗 Traders initiated study 申辦者名稱 Name of sponsor: _____ 地址 Address: _____ _____
招募人數 Recruitment Size	計劃在香港招募的人數 Planned number of trial subjects in H.K. _____ 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 to be conducted *	<input type="checkbox"/> 一期 Phase I (首次用於人 First-In-Man? <input type="checkbox"/> 是 Yes <input type="checkbox"/> 否 No) <input type="checkbox"/> 二期 Phase II <input type="checkbox"/> 三期 Phase III 如有需要，請加以說明 Describe if necessary: _____ _____
此試驗是 The study is *	<input type="checkbox"/> 開放式 open label <input type="checkbox"/> 單盲 single blind <input type="checkbox"/> 雙盲 double blind <input type="checkbox"/> 非隨機 non-randomized <input type="checkbox"/> 隨機 randomized <input type="checkbox"/> 其他 (請說明) other (please specify) _____ _____
病名 Disease	(如中風，瘡瘍) (e.g. Stroke, Sore and ulcer)
此試驗亦屬已獲國家食品藥品監督管理局批准進行的臨床試驗？* Is this study also approved by the State Food and Drug Administration (SFDA) for conducting the trial? *	
<input type="checkbox"/> 是 (如已獲批准，藥物臨床研究批件號為 _____ 及批准日期 _____) Yes, (if available, the number of Drug Clinical Trial Approval Document _____ and the date of approval _____)	
<input type="checkbox"/> 否 No	

C 部: 試驗藥物**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)	
研究藥物的名稱 Name of study drug(s) to be investigated	
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)	
劑型形式： Dosage form	
此試驗需要與其他藥物同用* The study involves concurrent use of *	<input type="checkbox"/> 安慰劑 placebo <input type="checkbox"/> 對照藥 comparator drug <input type="checkbox"/> 合併用藥 concomitant drug <input type="checkbox"/> 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)	
預計試驗藥物所需數量 (Estimated quantity of study drug(s) required)	
試驗藥物是否已獲在香港以外的藥品監督管理部門批准註冊? * Did the study drug(s) approved by other regulatory authorities outside Hong Kong? <input type="checkbox"/> 是, 請註明 Yes, please specify : _____ <input type="checkbox"/> 否 No	
試驗藥物會否將根據《中醫藥條例》第121條申請中成藥註冊? * Will the study drug(s) apply for the registration of proprietary Chinese medicine according to Section 121 of the Chinese Medicine Ordinance? <input type="checkbox"/> 會 Yes <input type="checkbox"/> 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，本人同意根據「臨床證驗及藥物測試證明書持有人須知」(附錄1)呈報本地藥物安全事故、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》附錄三所要求的「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 submit local drug related safety reports, yearly progress reports and the final study report of the clinical trial, and to retain the documents listed in the Appendix III of “Good Clinical Practice for proprietary Chinese medicines” for inspection when necessary as stated in the “Guidance Notes for the Holders of Certificate for Clinical trial and Medicinal Test” (Appendix 1).

.....
申請人簽署 Signature of the applicant 聯絡電話 Contact telephone number

.....
申請人姓名（正楷）Name of person-in-charge (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 :