

**PHARMACY AND POISONS ORDINANCE (CHAPTER 138)**

**APPLICATION FOR CERTIFICATE FOR CLINICAL TRIAL/MEDICINAL TEST**

*(This form is used for application for a clinical trial submitted under the Standard Scheme  
or application for a medicinal test)*

Please tick one of the following:

- This is an application for a clinical trial submitted under the Standard Scheme.  
 This is an application for a medicinal test.

<b>PART A: STUDY INFORMATION</b>				
A1.	Protocol title		Protocol no.	
			Protocol date	
A2.	Name of applicant			
A3.	Business address of applicant		Tel. no.	
			Fax no.	
A4.	Name of principal investigator			
A5.	Name and address of institution conducting the study			
A6.	Is this a study in which a certificate was issued previously and will soon expire? <input type="checkbox"/> Yes (CTC no. _____ and valid until _____) <input type="checkbox"/> No			
A7.	Is this study also the subject of an application for approval by the National Medical Products Administration (NMPA)? <input type="checkbox"/> Yes (if available, the number of Drug Clinical Trial Approval Document (臨牀試驗通知書) _____ and date of approval _____) <input type="checkbox"/> No			

<b>PART B: STUDY DESCRIPTION</b>		
B1.	The study is	<input type="checkbox"/> single centre <input type="checkbox"/> multi-centre
B2.	No. of study centres in Hong Kong	Total no. of centres _____ Centre name(s) _____
B3.	Study centres outside Hong Kong (if any)	No. of centres in each country (e.g. Mainland China – 2 centres, Singapore – 2 centres) _____
B4.	Sponsor of the study	<input type="checkbox"/> the sponsor is a pharmaceutical company or research organisation/institution Name of sponsor: _____ Address of sponsor: _____  <input type="checkbox"/> the study is initiated and conducted by a sponsor-investigator Name of sponsor: _____ Address of sponsor: _____ <i>(Remarks: As this study is initiated and conducted by a sponsor-investigator, the sponsor should be the same person as the applicant)</i>
B5.	Recruitment size	Planned no. of subjects in Hong Kong _____ Total planned no. of subjects world-wide _____
B6.	Study period	Planned start date _____ and planned end date _____
B7.	The study is	<input type="checkbox"/> phase I                      (first-in-man? <input type="checkbox"/> Yes <input type="checkbox"/> No) <input type="checkbox"/> phase II <input type="checkbox"/> phase III <input type="checkbox"/> phase IV Describe if necessary: _____
B8.	The study is	<input type="checkbox"/> open label <input type="checkbox"/> single blind <input type="checkbox"/> double blind <input type="checkbox"/> other (please specify) _____)
B9.	The study is	<input type="checkbox"/> non-randomized <input type="checkbox"/> randomized
B10.	Therapeutic area	(e.g. Oncology, Endocrinology)
B11.	Disease/Disease type	(e.g. Nasopharyngeal cancer, Diabetes mellitus)

**PART C: STUDY DRUG**

C1. Study drug to be investigated

Name of drug

Strength

Manufacturer

C2.

The study involves concurrent use of

 placebo concomitant drug comparator drug none of the above

C3. Comparator drug/ placebo used (if any)

Name of drug

Strength

Manufacturer

C4. Concomitant drug used (if any)

Name of drug

Strength

Manufacturer

Examples for strength:

- Solution for injection e.g. 5mg/5ml (total amount in total volume)
- Powder for reconstitution e.g. 5mg/vial (total amount in a vial)
- Oral dosage form e.g. 100mg/tab

**PART D: DECLARATION OF THE APPLICANT**

I/We\* hereby declare that, if the application is approved and the study proceeds:

D1.	Agree to submit local drug related safety reports, yearly progress reports and final study report of the study as stated in “Notice of requirement on reporting of local drug related safety report, progress report and final study report in clinical trial”.
D2.	This study will be conducted in accordance with the principles established in Good Clinical Practice.
D3.	The information given in this application is true and correct.

\* Delete as appropriate

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Company stamp (if the applicant is a company)

\_\_\_\_\_  
Signatory’s name in block letters

\_\_\_\_\_  
Date (DD/MM/YY)

**PART E: FOR OFFICE USE ONLY**

Date Received

Fee Paid

## Checklist for Clinical Trial Application Submitted under the Standard Scheme / for Medicinal Test Application

<u>For all studies:</u>		Yes	No
1.	A completed application form and this checklist.	<input type="checkbox"/>	<input type="checkbox"/>
2.	A cover letter listing all the submitted documents.	<input type="checkbox"/>	<input type="checkbox"/>
3.	A letter from the principal investigator confirming his involvement in the clinical trial or medicinal test.	<input type="checkbox"/>	<input type="checkbox"/>
4.	The Curriculum Vitae of the principal investigator.	<input type="checkbox"/>	<input type="checkbox"/>
5.	In case of a clinical trial, documentary evidence that the clinical trial has been approved by the Ethics Committee of the institution in which it is to be conducted (this may be submitted when available at a later date).	<input type="checkbox"/>	<input type="checkbox"/>
6.	In case of a clinical trial, the proposed patient information and patient consent form, in both English and Chinese, or in Chinese only.	<input type="checkbox"/>	<input type="checkbox"/>
7.	A copy of the proposed protocol for the clinical trial or medicinal test.	<input type="checkbox"/>	<input type="checkbox"/>
8.	Information on the drug (e.g. investigator's brochure, package insert, other information if applicable, etc.).	<input type="checkbox"/>	<input type="checkbox"/>
9.	A sample certificate of analysis of the drug.	<input type="checkbox"/>	<input type="checkbox"/>
10.	Evidence that the drug is manufactured in accordance with Good Manufacturing Practices (GMP) (e.g. copy of GMP certificate of the manufacturer).	<input type="checkbox"/>	<input type="checkbox"/>
11.	Application fee (HK\$1,420)	<input type="checkbox"/>	<input type="checkbox"/>

### For studies in which a certificate was issued previously and will expire, the following additional documents:

12.	A copy of the previous certificate.	<input type="checkbox"/>	<input type="checkbox"/>
13.	Clinical trial progress report(s) (if not available, please provide justification; if the trial has not been started, please also provide justification).	<input type="checkbox"/>	<input type="checkbox"/>

### For studies which are also the subject of an application for approval by the National Medical Products Administration (NMPA), the following additional documents:

14.	Drug clinical trial approval document (臨牀試驗通知書) issued by NMPA (this may be submitted when available at a later date).	<input type="checkbox"/>	<input type="checkbox"/>
15.	A copy of the protocol submitted to NMPA.	<input type="checkbox"/>	<input type="checkbox"/>