

## PHARMACY AND POISONS ORDINANCE (Cap. 138)

### APPLICATION FOR A CLINICAL TRIAL/MEDICINAL TEST CERTIFICATE

<b>PART A: TRIAL INFORMATION</b>				
A1.	Title of Clinical Trial (as stated in proposed Protocol)		Protocol No.	
			Protocol Date	
A2.	Name of Applicant			
A3.	Business Address of Applicant		Tel. No.	
			Fax No.	
A4.	Name(s) of Principle Investigator(s)			
A5.	Name(s) and Address of Institution(s) Conducting the trial			
A6.	Is this a study for which a clinical trial certificate was issued previously but has expired / will soon expire?  <input type="checkbox"/> Yes, (CTC No. _____ and date of expiry _____) <input type="checkbox"/> No			
A7.	Is this study also the subject of an application for approval by the State Food and Drug Administration (SFDA)?  <input type="checkbox"/> Yes, (if available, the number of Drug Clinical Trial Approval Document(藥物臨床研究批件號) _____ and the date of approval _____)  <input type="checkbox"/> No			

<b>PART B: TRIAL DESCRIPTION</b>		
B1.	This study is	<input type="checkbox"/> single centre <input type="checkbox"/> multi-centre
B2.	No. of study sites in H.K.	Total no. of sites _____ Site name(s) _____
B3.	Study sites outside Hong Kong (if any)	No. of sites in each country (e.g. Mainland China – 2 sites, Singapore – 2 sites) _____
B4.	Type of Sponsorship	<input type="checkbox"/> Investigator initiated study <input type="checkbox"/> Pharmaceutical company initiated study Name of sponsor: _____ Address: _____
B5.	Recruitment Size	Planned number of trial subjects in H.K. _____ total planned number of trial subjects world-wide _____
B6.	Study Period	Planned start date _____ and planned end date _____
B7.	Phase of Clinical Trial to be conducted	<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 type	(e.g. NPC, DM)

<b>PART C: TRIAL DRUG(s)</b>		
C1.	Study drug(s) to be investigated	
C2.	The study involves concurrent use of	<input type="checkbox"/> placebo <input type="checkbox"/> comparator drug <input type="checkbox"/> concomitant drug <input type="checkbox"/> not applicable (non of the above)
C3.	Comparator drug(s) used (if any)	
C4.	Concomitant drug(s) used (if any)	

**PART D: DECLARATION OF THE APPLICANT**

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

- |     |   |
|-----|---|
| D1. | Agree to submit local drug related safety reports, yearly progress reports, and the final study report of the clinical trial as stated in the attached “Notice of requirement of local drug related safety reports, progress reports and final study report in clinical trial” [Appendix 1].’ |
| D2. | This study will be conducted in accordance with the Good Clinical Practice.   |
| D3. | The information given in this application is true and correct.  |

\_\_\_\_\_  
Signature

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

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

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

\* Delete as appropriate

**PART E: FOR OFFICE USE ONLY**

Date Received

Fee Paid