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.

<table>
<tr><td colspan="5">PART A: STUDY INFORMATION</td></tr>
<tr><td rowspan="2">A1.</td><td rowspan="2">Protocol title</td><td rowspan="2"></td><td>Protocol no.</td><td></td></tr>
<tr><td>Protocol date</td><td></td></tr>
<tr><td>A2.</td><td>Name of applicant</td><td colspan="3"></td></tr>
<tr><td rowspan="2">A3.</td><td rowspan="2">Business address of applicant</td><td rowspan="2"></td><td>Tel. no.</td><td></td></tr>
<tr><td>Fax no.</td><td></td></tr>
<tr><td>A4.</td><td>Name of principal investigator</td><td colspan="3"></td></tr>
<tr><td>A5.</td><td>Name and address of institution conducting the study</td><td colspan="3"></td></tr>
<tr><td>A6.</td><td colspan="4">Is this a study in which a certificate was issued previously and will soon expire?
☐ Yes (CTC no._____ and valid until_____)
☐ No</td></tr>
<tr><td>A7.</td><td colspan="4">Is this study also the subject of an application for approval by the National Medical Products Administration (NMPA)?
☐ Yes (if available, the number of Drug Clinical Trial Approval Document (臨牀試驗通知書) _____and date of approval_____)
☐ No</td></tr>
</table>

PART B: STUDY DESCRIPTION		
B1.	The study is	☐ single centre ☐ 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	☐ the sponsor is a pharmaceutical company or research organisation/institution Name of sponsor: _____ Address of sponsor: _____ ☐ the study is initiated and conducted by a sponsor-investigator Name of sponsor: _____ Address of sponsor: _____ *(Remarks: As this study is initiated and conducted by a sponsor-investigator, the sponsor should be the same person as the applicant)*
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	☐ phase I (first-in-man? ☐Yes ☐No) ☐ phase II ☐ phase III ☐ phase IV Describe if necessary:_____
B8.	The study is	☐ open label ☐ single blind ☐ double blind ☐ other (please specify)_____)
B9.	The study is	☐ non-randomized ☐ 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:	
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.
D4.	By submitting this application, consent is given to the Pharmacy & Poisons Board of Hong Kong to arrange any information provided in this application to be displayed on the website of the Board.

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

Appendix 1

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

	For all studies:	Yes	No
1.	A completed application form and this checklist.	☐	☐
2.	A cover letter listing all the submitted documents.	☐	☐
3.	A letter from the principal investigator confirming his involvement in the clinical trial or medicinal test.	☐	☐
4.	The Curriculum Vitae of the principal investigator.	☐	☐
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).	☐	☐
6.	In case of a clinical trial, the proposed patient information and patient consent form, in both English and Chinese, or in Chinese only.	☐	☐
7.	A copy of the proposed protocol for the clinical trial or medicinal test.	☐	☐
8.	Information on the drug (e.g. investigator's brochure, package insert, other information if applicable, etc.).	☐	☐
9.	A sample certificate of analysis of the drug.	☐	☐
10.	Evidence that the drug is manufactured in accordance with Good Manufacturing Practices (GMP) (e.g. copy of GMP certificate of the manufacturer).	☐	☐
11.	Application fee (HK$1,420)	☐	☐

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

12.	A copy of the previous certificate.	☐	☐
13.	Clinical trial progress report(s) (if not available, please provide justification; if the trial has not been started, please also provide justification).	☐	☐

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).	☐	☐
15.	A copy of the protocol submitted to NMPA.	☐	☐