

**DEPARTMENT OF HEALTH
PHARMACEUTICAL SERVICE
PHARMACEUTICALS REGISTRATION
SECTION**

**Certificate for Clinical Trial/Medicinal Test
Notes for the Guidance of Applicants**

1. Under Regulation 36B of the Pharmacy and Poisons Regulations, a Certificate for Clinical Trial/Medicinal Test is required for the purpose of conducting a clinical trial on human beings or a medicinal test on animals.

How to apply

2. Applications for a Certificate for Clinical Trial/Medicinal Test should be made, by hand or by post, to the following address:

Pharmaceuticals Registration Section
Department of Health
3/F Public Health Laboratory Centre,
382 Nam Cheong Street,
Shek Kip Mei, Kowloon
Hong Kong

(Enquiries : 2319 8458)

The application should contain:

- (a) a completed application form and a completed CT checklist;
- (b) the prescribed application fee (currently \$1,420);
- (c) a copy of the proposed protocol for the clinical trial or medicinal test;
- (d) information on the new drug (e.g. its pharmaceutical data, pharmacological action, toxicology, studies on human if any, package insert, etc.);
- (e) copies of pre-clinical studies (if not submitted, please provide justification);
- (f) a sample of the product or substance;
- (g) a letter from the principal investigator confirming his involvement in the clinical trial or medicinal test;
- (h) the Curriculum Vitae of the principal investigator;
- (i) in the 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);

- (j) in the case of a clinical trial, the proposed patient information and patient consent form, in both English and Chinese, or in Chinese only;
- (k) evidence that the trial medication is manufactured in accordance with Good Manufacturing Practices (GMP) (e.g. copy of GMP Certificate of the manufacturer);
- (l) a sample certificate of analysis of the drug;

For studies for which a clinical trial certificate was issued previously but has expired/will soon expire, the following additional documents:

- (m) a copy of the previous clinical trial certificate;
- (n) clinical trial progress report(s) (if not available, please provide justification. If the trial has not been started, please provide justification also).

For studies which are also the subject of an application for approval by the State Food and Drug Administration (SFDA), the following additional documents:

- (o) drug clinical trial approval document (藥物臨床研究批件) issued by SFDA (this may be submitted when available at a later date);
- (p) a copy of the protocol submitted to SFDA.

3. When the Certificate for Clinical Trial/Medicinal Test is ready for collection, the applicant will be informed thereof and asked to pay the certificate fee (currently \$1,420) and to collect the certificate at the same time.

4. Payment of the certificate fee and collection of the certificate should be in person at the Pharmaceuticals Registration Section, Department of Health at the above address and at the following hours:

Monday to Friday
9:00 am – 1:00 pm
2:00 pm – 5:30 pm
(up to 5:45 pm on Monday)

If payment is made by cheque, the cheque should be made payable to “The Government of the Hong Kong Special Administrative Region” and crossed.

Pharmaceuticals Registration Section
Department of Health

Sep 2007