

CHECKLIST

Application for Certificate for Clinical Trial and Medicinal Test

The following documents are required when applying for this certificate for the purpose of conducting a medicinal test:

	Yes	No
1. A duly completed application form and checklist	<input type="checkbox"/>	<input type="checkbox"/>
2. A letter signed by the principal investigator confirming his participation in the medicinal test concerned	<input type="checkbox"/>	<input type="checkbox"/>
3. Curriculum Vitae of the principal investigator	<input type="checkbox"/>	<input type="checkbox"/>
4. Proposed protocol for the medicinal test	<input type="checkbox"/>	<input type="checkbox"/>
5. A copy of the animal experiment licence issued under the Animals (Control of Experiments) Ordinance (Cap. 340) (if applicable)	<input type="checkbox"/>	<input type="checkbox"/>
6. Master formula of the investigational proprietary Chinese medicine (“pCm”)	<input type="checkbox"/>	<input type="checkbox"/>
7. Label of the investigational pCm and a clear photograph showing true colours of its sample	<input type="checkbox"/>	<input type="checkbox"/>

The following documents are required when applying for this certificate for the purpose of conducting a clinical trial:

1. A duly completed application form and checklist	<input type="checkbox"/>	<input type="checkbox"/>
2. Proposed protocol for the clinical trial	<input type="checkbox"/>	<input type="checkbox"/>
3. Proposed Chinese or Chinese-English bilingual version of the trial information and the informed consent form for the trial subjects	<input type="checkbox"/>	<input type="checkbox"/>
4. A letter signed by the principal investigator confirming his participation in the clinical trial concerned	<input type="checkbox"/>	<input type="checkbox"/>
5. Curriculum Vitae of the principal investigator and a copy of relevant certificate of registration	<input type="checkbox"/>	<input type="checkbox"/>
6. A letter signed by the Chinese medicine practitioner (CMP) participating in the clinical trial confirming his participation in the clinical trial concerned and a copy of his certificate of registration (not applicable if the CMP is the principal investigator)	<input type="checkbox"/>	<input type="checkbox"/>
7. Document issued by the Ethics Committee of the institution where the trial will be conducted substantiating its approval for the trial to be conducted at that institution (may be submitted within 3 months from the date of application)	<input type="checkbox"/>	<input type="checkbox"/>
8. Investigator’s brochure (including the pharmacological and toxicological information of the investigational pCm)	<input type="checkbox"/>	<input type="checkbox"/>
9. Documentation evidence showing all manufacturers involved in the manufacturing of the investigational product (which includes the investigational pCm, comparators, placebos, etc.) comply with the Hong Kong Good Manufacturing Practice Guidelines for Proprietary Chinese Medicines (hereinafter called “GMP”) or equivalent standard (not applicable to registered pharmaceutical products)	<input type="checkbox"/>	<input type="checkbox"/>
10. Master formula of the investigational product(s) (not applicable to registered pharmaceutical products. For registered pCms, the master formula may be submitted by the manufacturer or holder of certificate of registration on behalf of the applicant)*	<input type="checkbox"/>	<input type="checkbox"/>
11. Test reports on heavy metals and toxic elements, pesticide residues and microbial limit of the investigational pCm*	<input type="checkbox"/>	<input type="checkbox"/>
12. Manufacturing method of the investigational pCm*	<input type="checkbox"/>	<input type="checkbox"/>

- 13. Product specifications and its drafting note, testing methods and certificate of analysis of the investigational pCm, as well as the product specifications and certificate of analysis of the placebo(s)*
- 14. Stability test report of the investigational pCm (the test must be conducted by a GMP-compliant manufacturer or a laboratory recognized by the Chinese Medicines Board)*
- 15. Label of the investigational product(s) and a clear photograph showing true colours of its sample
- 16. Approval document(s) and information regarding the same clinical trial conducted outside Hong Kong / in other countries (if any)

If a Certificate was previously issued for the clinical trial and has expired or is about to expire, the following supplementary documents are also required

- 17. Clinical Trial Yearly Progress Report / Clinical Trial final report (please state reasons if reports are not submitted or if the trial has not commenced)

The following supplementary information is required when the clinical trial concerned has been approved by the National Medical Products Administration (“NMPA”):

- 18. The clinical trial approval document or relevant supporting document (may be submitted within 3 months from the date of application)
- 19. A copy of the trial protocol submitted to the NMPA

* If an applicant declares on the application form that findings of the clinical trial will not be used in application for pCm registration or variation of registered particulars of registered pCms (e.g. indications and target users of the pCm) and the applicant for the clinical trial is a sponsor-investigator, the Chinese Medicines Board may consider granting an exemption for the submission of these documents.