

Checklist (1)

1. This checklist is applicable to Group I registration only.
2. The applicant is required to submit this checklist with the relevant documents listed below.
3. Please tick (x) in the appropriate box to indicate the documents submitted.

- ³ Completed 「Application Form for Registration of Proprietary Chinese Medicines」
- ³ Personal information of the person-in-charge of the company
- ³ Documentary proofs of manufacture or sales history of the product
- ³ Copy of manufacturing authorization issued by the country of origin (if applicable)
- ³ Copy of free sale documentation issued by the country of origin (if applicable)
- ³ Product sample and prototype sales pack
- ³ Label which has complied to the legal requirements
- ³ Package insert which has complied to the legal requirements
- ³ Master formula (names and quantities of all active ingredients and excipients)
- ³ Heavy metals and toxic element test report
- ³ Pesticide residues test report
- ³ Microbial limit test report
- ³ Acute toxicity test report
- ³ Long-term toxicity test report (only applicable to the health product in the non well-established category)
- ³ Local toxicity test report (only applicable to a pCm to be administered on the skin or mucus membranes)
- ³ Summary report on all product safety documents
- ³ Interpretation and principle of formulating a prescription (submission of this document can be exempted for single Chinese medicine granules)
- ³ Reference materials on product efficacy
- ³ Summary report on all product efficacy documents
- ³ Manufacturing method
- ³ Physiochemical properties of crude drugs
- ³ Product specification, method and certificate of analysis 【For pCm that is manufactured, or sold on/before 19 December 2003, the applicant can submit the standard, test method and result on assay of the product upon the application for renewal of such registration.】
- ³ *General stability test report / accelerated stability test report / real-time stability test report (general stability test report or accelerated stability test report is not required, if the applicant submits the real-time stability test report) 【For pCm that is manufactured, or sold on/before 19 December 2003, the applicant can submit the test report upon the application for renewal of such registration.】
「*delete as appropriate」