

**Documentation Requirements on
Application for Certificate for Manufacturer
(Good Manufacturing Practice in respect of Proprietary Chinese Medicines)
(Guidelines for the Trade)**

Under section 133 of the Chinese Medicine Ordinance, the holder of a manufacturer licence in proprietary Chinese medicines (“pCms”) may apply to the Chinese Medicines Board (“CMB”) under the Chinese Medicine Council of Hong Kong for a Certificate for Manufacturer (“pCm GMP Certificate”) to certify that he or she follows the requirements of good practices in manufacture and quality control of pCms.

2. Applicants are required to submit the following information when applying for a pCm GMP Certificate:

- i. The duly completed Application Form for Certificate for Manufacturer (Good manufacturing practice in respect of proprietary Chinese medicines) (Form 1E); and
- ii. Documentation Checklist - Application for Certificate for Manufacturer (Good manufacturing practice in respect of proprietary Chinese medicines) (Checklist 2E) and all the documents or information listed therein.

3. To help manufacturers of pCms better understand the requirements on documents for implementation of GMP as listed in Checklist 2E and potential applicants for a pCm GMP Certificate prepare application documents systematically, the CMB has formulated this set of Guidelines for the Trade.

4. General requirements on the application documents^[Note] are specified in **Appendix 1** to this set of Guidelines. Potential applicants for a pCm GMP Certificate may refer to the requirements when preparing and submitting their application documents.

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Note: Where necessary, the CMB may request the applicant to submit other information and documents.

If there is any inconsistency or ambiguity between the English version and the Chinese version of this document, the Chinese version shall prevail.

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1. Basic information of manufacturer

1.1 Manufacturer licence and contact information

- Copies of valid Business Registration Certificate and Manufacturer Licence in proprietary Chinese medicines (“pCms”);
- Company name and address of the manufacturer specified in the licence;
- Address of the manufacturing premises and warehouse (if different from the company address specified in the licence); and
- Contact information of the manufacturer, including 24-hour telephone number of the contact person in the case of product defects or recalls.

1.2 Brief description of quality management system of manufacturer

1.2.1 Quality management system of manufacturer

- Brief description of the quality management system implemented and the reference standards adopted by the manufacturer (*for various aspects of the quality management system, please refer to section 1.2 “Quality Assurance” of the “Hong Kong Good Manufacturing Practice Guidelines for Proprietary Chinese Medicines”*); and
- Responsibilities of departments related to the quality management system, relationships between those departments as well as responsibilities of senior management, authorized person and heads of quality assurance department, quality control department and manufacturing department.

1.2.2 Release procedures of finished products

- General description of the procedures for certifying the products for release, including the roles of the authorized person in quarantine and release of finished products and assessment of compliance with the requirements of the Chinese Medicine Ordinance/marketing authorization.

1.2.3 Management of suppliers

- Brief description of the qualification system of the manufacturers/suppliers of starting materials and suppliers of other critical materials.

1.3 Organization chart and number of personnel

- Organization chart showing the posts/titles responsible for quality assurance, manufacture and quality control, including the senior management, authorized person and department heads; and
- Respective numbers of personnel involved in quality assurance, manufacture, quality control as well as storage and distribution of materials and products, and total number of personnel.

1.4 Medicine manufacturing business engaged

- Brief description of the manufacturing, import, export, distribution and other activities of different dosage forms/products as authorized by the Chinese Medicines Board and relevant drug regulatory authorities (including foreign authorities); and
- List of dosage forms and type of products being manufactured or to be manufactured, including the product name, “Certificate of registration of pCm” (HKC) number, packing specification and active ingredients of the products, with products containing Schedule 1 Chinese herbal medicines or materials known to be highly toxic or sensitizing, if any, clearly indicated.

1.5 Non-pCm manufacturing business engaged on the manufacturing premises (if applicable)

- Description of non-pCm (including medicine and non-medicine) manufacturing business, if any, engaged on the manufacturing premises and whether the facilities and equipment are for shared-use.

1.6 Major changes since last GMP inspection conducted by the Chinese Medicine GMP Team of the Department of Health (if applicable)

- Brief description of changes related to key personnel, equipment, facilities as well as dosage forms and type of products being manufactured since last GMP inspection.

2. Personnel information

- Qualifications (evidence of academic qualifications and/or documentary proofs of relevant working experience, years of relevant working experience) of key personnel (*for qualification requirements, please refer to “Hong Kong Good Manufacturing Practice Guidelines for Proprietary Chinese Medicines” Qualification and Experience Requirements for Key Personnel (Guidelines for the Trade)*);
- Brief description of the responsibilities of key personnel (*reference to paragraph 1.2.1 can be made*);
- Brief description of training program for personnel; and
- Brief description of personal hygiene measures (including the frequency of health examinations and items to be examined, requirements of working clothing, etc.).

3. Premises and facilities information

3.1 Brief description of premises

- Brief description of the manufacturing premises including the type, location and surrounding environment of the buildings; gross area of the site; size of areas for manufacture (areas of different cleanliness grades), storage and quality control; and list of buildings on the site;
- Brief floor plans of premises (areas for pre-treatment of herbal medicines, extraction and concentration of processed herbal medicines, manufacture, storage and quality control, and location of utilities) with indication of scale;
- Layout plans and workflow charts of the manufacturing areas showing the cleanliness grade of each room, pressure differential between the rooms and adjoining areas, and manufacturing procedures (e.g. preparation, filling, storage, packing, etc.) carried out in the rooms;
- Flow charts showing the flow of personnel and materials in the manufacturing areas;
- Layout plans of warehouse and storage areas, with areas designated for the storage and processing of materials known to be highly toxic and sensitizing, if any, clearly indicated;

- Brief description of special storage conditions not indicated in the layout plans above; and
- Layout plans of quality control laboratories, including microbiological laboratory (if any).

3.2 Brief description of facilities

- 3.2.1 Brief description of the heating, ventilation and air conditioning (HVAC) system
- Operating principles, design standards and operating conditions of the HVAC system, such as air supply, temperature, humidity, pressure differential, air change rate, air recirculation rate (%), etc.;
 - Routine monitoring and maintenance of the HVAC system; and
 - Drawings of the HVAC system (air supply, return and exhaust drawings).
- 3.2.2 Brief description of the water system
- Quality references of water produced by the water system;
 - Operating principles, design standards and operating conditions of the water system, such as production capacity, materials for construction of storage vessels and pipes, etc.;
 - Routine monitoring and maintenance of the water system; and
 - Drawings of the water system (including distribution of water points).
- 3.2.3 Brief description of other relevant utilities, such as steam, compressed air, nitrogen, etc.
- Relevant quality references (if applicable);
 - Operating principles, design standards and operating conditions of the relevant utilities;
 - Routine monitoring and maintenance of the relevant utilities; and
 - Drawings of the relevant utilities (if applicable).

4. Equipment information

- List of major manufacturing equipment and quality control equipment (serial number, name, manufacturer, specification/model, capacity/precision, location, date and frequency of qualification, date and frequency of calibration of equipment, if applicable).
- Cleaning and sanitation
 - Brief description of the cleaning and sanitation methods (e.g. manual cleaning, automatic clean-in-place (CIP) system, etc.) of the product contact surfaces of equipment and their cleaning validation.
- GMP-related computerized systems (if applicable)
 - Brief description of the design, utilization and validation of the GMP-related critical computerized systems.

5. Brief description of documentation system

- Description of documentation system (e.g. electronic and paper documents);
- Brief description of the drafting, revision, approval, release, control and filing system of documents; and
- List of standard operating procedures (SOPs).

6. Manufacturing management information

6.1 Type of products

- Type of products manufactured (*reference to paragraph 1.4 can be made*), including:
 - list of dosage forms of pCms and non-pCms (if any) being manufactured or to be manufactured on the premises;
 - list of dosage forms of investigational medicinal products manufactured on the premises for clinical trials (if applicable).
- Processing procedures of materials known to be highly toxic or sensitizing (e.g. Schedule 1 Chinese herbal medicines); and
- Simple flow chart of the manufacturing processes of each type (dosage form) of pCm products with indication of major in-process control points and items.

6.2 Process validation

- Brief description of the policies on and practice of process validation; and
- Brief description of the policies on reprocessing and recovery of products.

6.3 Management and storage of materials

- Simple flow chart describing the arrangements for handling starting materials, packing materials, bulk products and finished products (including the arrangements for receipt, sampling, quarantine, release and storage); and
- Simple flow chart describing the arrangements for handling rejected materials and products (including the arrangements for rejection, storage and disposal).

7. Quality control information

- Description of the quality control activities carried out on the premises, including the conduct of physical, chemical, microbiological and biological tests, the practice of validation, etc.; and
- Responsibilities of quality control department (*reference to paragraph 1.2.1 can be made*).

8. Complaint handling and product recall information

- Brief description of measures for handling complaints about product quality; and
- Brief description of product recall system.

9. Self-inspection program

- Brief description of the self-inspection system with a focus on the selection criteria for areas to be covered during planned self-inspections as well as the practical arrangements and follow-up actions of self-inspections.

10. Contract manufacture and test information

- Brief description of the qualification system of contractors of contract manufacturing and contract testing (if any); and
- List of contract manufacturers and laboratories, including the address, contact information, activities being undertaken, etc., if contract manufacturing and contract testing are involved.