

香港中醫藥管理委員會

Chinese Medicine Council of Hong Kong

申請製造商證明書(中成藥生產質量管理規範)文件核對表

Documentation Checklist**Application for Certificate for Manufacturer****(Good manufacturing practice in respect of proprietary Chinese medicines)**

請將此文件核對表連同下列文件，與製造商證明書（中成藥生產質量管理規範）申請表（表格 1E）一併親身提交或郵寄衛生署中醫藥規管辦公室。假如你對下述第 1 至 12 項，任何一項的答案是「否」，請附上書面解釋。

Please submit in person or by post this documentation checklist together with the following documents and the **Application Form for Certificate for Manufacturer (Good manufacturing practice in respect of proprietary Chinese medicines) (Form 1E)** to the Chinese Medicine Regulatory Office of the Department of Health. If your answer to any one of the following items 1 to 12 is “No”, please attach an explanation in writing.

你是否已經提交 Have you submitted:	是 Yes	否 No
1. 一份填妥的製造商證明書(中成藥生產質量管理規範)申請表 (表格 1E) A duly completed “Application Form for Certificate for Manufacturer (Good manufacturing practice in respect of proprietary Chinese medicines)” (Form 1E)	<input type="checkbox"/>	<input type="checkbox"/>
2. 商業登記證副本 Copy of Business Registration Certificate	<input type="checkbox"/>	<input type="checkbox"/>
3. 中成藥製造商牌照副本 Copy of Manufacturer Licence in proprietary Chinese medicines	<input type="checkbox"/>	<input type="checkbox"/>
4. 製造商的基本資料 Basic information of manufacturer		
a. 製造商的品質管理系統簡述 Brief description of quality management system of manufacturer	<input type="checkbox"/>	<input type="checkbox"/>
b. 公司組織架構圖 (包括各部門的職責及相互關係、部門主管) Organization chart (including responsibilities of departments, relationships between departments, department heads)	<input type="checkbox"/>	<input type="checkbox"/>
c. 所製造或擬製造的產品劑型和品種表 Table of dosage forms and type of products being manufactured or to be manufactured	<input type="checkbox"/>	<input type="checkbox"/>
d. 所經營的製造業務 (包括藥品和非藥品製造業務) Manufacturing business carried out (including medicine and non-medicine manufacturing business)	<input type="checkbox"/>	<input type="checkbox"/>
e. 從事製造、品質控制、物料和產品的貯存和分銷的員工數目 Number of personnel involved in manufacture, quality control, and storage and distribution of materials and products	<input type="checkbox"/>	<input type="checkbox"/>

5. 人員資料 Personnel information

- a. 關鍵人員的資歷 (學歷證明及/或有關工作經驗證明) 及其職責
Qualifications (evidence of academic qualifications and/or documentary proofs of relevant working experience) and responsibilities of key personnel
- b. 人員訓練計劃
Training program for personnel
- c. 個人衛生措施 (健康檢查、工作服裝的要求等)
Personal hygiene measures (health examinations, requirements of working clothing, etc.)

6. 廠房和設施資料 Premises and facilities information

- a. 廠房簡述 (地點、平面簡圖、總面積)
Brief description of premises (location, brief floor plan, total area)
- b. 設施簡述
Brief description of facilities

7. 設備資料 Equipment information

- a. 主要製造設備和品質控制設備的清單
List of major manufacturing equipment and quality control equipment

8. 文件系統簡述
Brief description of documentation system

9. 製造管理資料 Manufacturing management information

- a. 製造流程簡圖，並註明主要製造過程控制點
Simple flow chart of manufacturing processes with indication of major in-process control points
- b. 物料和產品處理流程簡圖 (接收、拒收、發放、貯存和棄置的安排)
Simple flow chart of materials and products handling (arrangements for receipt, rejection, release, storage and disposal)

10. 品質控制資料 Quality control information

- a. 品質控制系統簡述
Brief description of quality control system
- b. 品質控制部門的職責
Responsibilities of quality control department

11. 處理投訴和產品回收資料 Complaint handling and product recall information

- a. 處理有關產品品質的投訴的措施
Measures for handling complaints about product quality
- b. 產品回收系統簡述
Brief description of product recall system

	是 Yes	否 No
12. 自檢計劃 Self-inspection program	<input type="checkbox"/>	<input type="checkbox"/>
13. 合約製造和合約檢驗資料 Contract manufacture and test information		
a. 委託其他製造商進行合約製造的資料 (如有) Information on contract manufacturing given out to other manufacturers (if any)	<input type="checkbox"/>	<input type="checkbox"/>
b. 委託其他檢驗機構進行合約檢驗的資料 (如有) Information on contract test given out to test organizations (if any)	<input type="checkbox"/>	<input type="checkbox"/>
c. 接受委託進行合約製造的資料 (如有) Information on contract manufacture accepted (if any)	<input type="checkbox"/>	<input type="checkbox"/>
14. 其他資料 (如有): Other information (if any): _____ _____ _____	<input type="checkbox"/>	<input type="checkbox"/>

註： 如有需要，中藥組可要求申請人提交其他證明文件及上述文件的正本，以供核對。

Note: Where necessary, the Chinese Medicines Board may require the applicant to submit other documentary proofs and the originals of the said documents for verification.