動物用藥品製造廠資料(格式)

C.1 總則

C.1.1 簡介製造廠資料(包括廠名、廠址、資本額)。

C.1.2 主管機關核准之製造廠作業項目。

C.1.3 該廠區其他非藥品作業項目。

C.1.4 該廠區之名稱及明確地址，包括聯絡電話及傳真電話。

C.1.5 該廠區實際生產之藥品劑型(見附錄)，特殊毒性或有害物質處理方法之資料及述其製造方法(特殊設備或與其他藥品共用設備)。

C.1.6 簡述廠區(面積、位置、周邊環境及該廠區其他之生產作業活動)。

C.1.7 製造、品管、倉儲及運銷各部門之員工人數。

C.1.8 委託外部單位進行與製造及分析有關之科學性、分析或其他技術協助(若是，詳細內容請參考C.7，委託製造及分析單位)。

C.1.9 簡述該廠製造之品質管制制度。

C.2 人事

C.2.1 人事組織圖，製造及品管部門人數。

C.2.2 重要人員之資格、經歷及職責。

C.2.3 描述基礎及在職訓練，以及訓練紀錄之保存。

C.2.4 製造部門人員健康要求。

C.2.5 員工衛生規範。

C.3 廠房及設備

廠房

C.4.1 附有比例尺之平面圖及製造地點陳述。(無須提供建築或工程圖)

C.4.2 建材與塗料之特性。

C.4.3 簡述空調系統，有空氣污染之危險區應詳述(若有圖示更佳)。應說明無菌製品室之清淨度分級。

C.4.4 處理高度毒性、有害及致敏物質、無菌產品或生物製劑等特殊區域。

C.4.5　簡述水系統，包括滅菌處理。

設備

C.4.6　簡述主要之製造及品管實驗室設備。

C.4.7　設備之合格檢驗與校正及相關紀錄。

清潔

C.4.8　是否有清洗製造場所及設備之程序。

C.4 文件

C.4.1　製造藥品所需文件之製備，修訂與分發的安排。

C.4.2　在其他地方沒提到而會影響藥品品質的文件(如空氣及水之微生物控制)。

C.5 製造

C.5.1　儘可能使用流程圖來簡述製造過程，標明重要的項目(見附錄，動物用藥品類型)。

C.5.2　原料處理、包裝材料、未分裝前之成品、成品之處理，包括採樣，隔離管制，放行及儲存之安排。

C.5.3　拒用原、物料及成品之處理方法。

C.6 品質管制

C.6.1　說明品管制度及品管部門的工作內容、成品放行之過程。

C.7 委託製造及分析單位

C.7.1　說明該委託單位符合GMP規定的確認方法。

C.8 運銷申訴及產品回收

C.8.1　運銷的安排及紀錄系統。

C.8.2　申訴處理及產品回收的安排。

填寫指引：

C.1 總則

C.1.1 簡述製造廠的作業項目。

C.1.2 引述主管機關核發之相關文件，註明文件有效期間(假使當事國有給予文件效期)，任何情況及條件限制應明列清楚。

C.1.3 包括動物用藥品及非動物用藥品類之作業項目。(參考C.1.6)

C.1.4 廠名及廠址。

C.1.4.1 公司名稱(若有差異，註明商業形式)郵政地址及區域號碼(街名地址若不同時，請註明)。

C.1.4.2 聯絡人電話號碼。

C.1.4.3 聯絡人傳真號碼。

C.1.5 實際生產之藥品類別。

C.1.5.1 參考附件，列出實際生產之藥品類別，並附上清單。

C.1.5.2 註明任何毒性或有害物質，如Antibiotics，hormones，cytostatics，並註明該物質是否由特殊設備或與其他藥品共用設備所製造的。

C.1.5.3 註明該廠區是否同時製造動物用藥以外產品,如有則詳列之。

C.1.6 簡述廠區。

C.1.6.1 位置及周邊環境。

C.1.6.2 廠區面積。

C.1.6.3 全廠照片（需明確顯示工廠名稱，有鳥瞰圖）。

C.1.6.4 該廠區其他生產作業活動。

C.1.7 (註：包括非全職人員)

C.1.8 對於外部委託單位，請提供：

C.1.8.1 該公司之名稱及地址。

C.1.8.2 電話號碼。

C.1.8.3 傳真號碼。

C.1.8.4 簡述委託工作內容。

C.1.9

C.1.9.1 陳述該廠之品質策略。

C.1.9.2 定義品質管制部門之職責。

C.1.9.3 說明品質管制制度之要素，如：

(1) 組織架構、職責、程序、過程。

(2) 規格、檢驗方法及其他與品質有關的資料收集。

C.1.9.4 根據稽查目的，如產品之有效性及安全性，描述如何審查稽查之結果，以表示品管制度之適用性。並參考C.6.1.2。

C.1.9.5 描述成品放行供販賣之程序。

C.2 人事

C.2.1 組織結構圖（分列製造及品管部門人數）。

C.2.2 重要人員之資格、經歷及職責。

C.2.3 描述基礎及在職訓練，以及訓練紀錄之保存。
簡述訓練計畫內容包括前導與持續訓練，如下：

C.2.3.1 說明由誰及如何判定訓練需求。

C.2.3.2 詳細說明與GMP有關之訓練。

C.2.3.3 說明訓練方式如內訓、外訓、實際經驗之獲得及哪些人員被訓練。

C.2.4 製造部門人員之健康要求

C.2.4.1 誰負責檢查員工之健康。

C.2.4.2 是否有職前健康檢查。

C.2.4.3 因工作需要，員工是否定期接受檢查。

C.2.4.4 在進入危險工作區前是否有員工生病或接觸病人之呈報系統。

C.2.4.5 是否有病癒之呈報系統。

C.2.4.6 是否有對於各級清淨區之工作人員作額外之監控。

C.2.5 包括服裝之員工衛生要求

C.2.5.1 是否有適當的換洗休息區。

C.2.5.2 服裝是否適用於所從事之工作性質，請描述服裝(並提供照片)。

C.2.5.3 是否有使用保護性衣服及何時更換衣服之清潔指示。

C.3 廠房及設備

廠房

C.3.1 附有比例尺之平面圖及製造地點陳述。(無須提供建築或工程圖)

C.3.1.1 提供廠區平面圖，並標出各製造區域。標示各建築物間之距離及其用途。

C.3.1.2 提供每一製造區域之平面圖，並標示各區域之名稱及原、物料、成品與人員動線。

C.3.1.3 標示區域分級與鄰室不同區域分級之壓差。

C.3.1.4 標示各級區之清淨度及服裝規定。

C.3.1.5 提供每一作業場所照片，須含人員操作情形。

C.3.2 建材與塗料之特性

C.3.2.1 細述重要區域。

C.3.2.2 包括所有製造過程、包裝及重要儲存區域。

C.3.3 簡述空調系統，有空氣污染之危險區應詳述(若有圖示更佳)。應說明無菌製品室之清淨度分級。

註一：可能產生空氣污染之危險區應詳細描述，包括無菌製造區及粉末處理室，造粒及打錠室，對無菌製造區應提供最近環境品質確認之結果報告。

註二：為簡化敘述，應提供圖解，並應包括下列資料：

C.3.3.1 設計條件如：

- 溫度
- 濕度
- 壓差
- 簡單通路或再循環

C.3.3.2 過濾器設計及效率，並詳述空調系統之警告鈴。

C.3.3.3 應提供更換過濾器之限制。

C.3.4 處理高度毒性、有害及致敏物質、無菌產品或生物製劑之特

C.3.5 簡述水系統，包括滅菌。

註：若有系統圖更佳，並含下列資料：

C.3.5.1 此系統應回歸至該城市之供水系統。

C.3.5.2 該系統之容量(每小時最高製水量)。

C.3.5.3 容器與水管之材料。

C.3.5.4 標明系統所用濾網之規格。

C.3.5.5 製造水之規格：

(a) 化學物質

(b) 導電度

(c) 微生物

C.3.5.6 滅菌之程序。

設備

C.3.6 簡述主要之製造及品管實驗室設備

C.3.6.1 設備之設計是否易於清洗，設備之名稱，數量及產能。

C.3.6.2 一般敘述即可，如打錠機等。如果儀器設備有附加裝置應紀錄之，如附印表機之自動秤重機；附有條碼之標貼機；有批號、有效日期之印表機；附蒸氣滅菌設備之凍晶乾燥機。

C.3.6.3 品管實驗室僅需描述如：

pH meters, chromatographic equipment GLC,附電腦系統之HPLC ,particle size analyzers。

C.3.6.4 微生物實驗室僅需描述如：

Incubators(temperature ranges) facilities for LAL testing, membrane filtration sterility testing, antibiotic assay等。

C.3.7 設備之合格檢驗與校正及相關紀錄。

C.3.7.1 描述儀器設備之合格方針及紀錄保存。

C.3.7.2 描述儀器設備之校正方針及紀錄保存。

C.3.8 是否有清洗製造場所及設備之程序。

C.3.8.1 是否有清洗、清潔劑、清洗方法等之書面規格及程序。

C.3.8.2 是否定期以化學及/或微生物方法檢查該清潔方法。

C.3.8.3 供水系統、空氣處理系統及粉塵抽離系統之清潔方法為何？

C.4 文件

C.4.1 製造藥品所需文件之製備，修訂與分發的安排。

註：本節指使用於製造過程之所有文件。製造泛指於藥品於生產及品管中所有之作業。

C.4.1.1 是否有該文件系統之說明？

C.4.1.2 誰是該文件製備、修訂及分發之負責人？

C.4.1.3 主文件的存放地點為何？

C.4.1.4 是否有製備該文件的標準格式及指示？
是否有以下文件：

- 產品及製造過程之規格。
- 原料規格。
- 包裝材料規格。
- 包裝之標準(作業)程序之指示。
- 包裝之批次紀錄。
- 分析方法。
- 品質管制放行程序。

C.4.1.5 如何管制該文件？

C.4.1.6 該批次核准放行後，其文件保存多久？

C.4.2 在其他地方沒提到而會影響藥品品質的文件(如空氣及水之微生物控制)。
其他與藥品品質有關之文件是否有以下文件並使用中？

C.4.2.1 設備規格。

C.4.2.2 耗材之規格，如清潔劑。

C.4.2.3 標準作業程序。

C.4.2.4 品管程序。

C.4.2.5 訓練程序。

C.4.2.6 處理過程偏差的檔案管理。

C.4.2.7 校正及測試檔案(見C.3.9.5)。

C.4.2.8 原料及主要包裝材料，如接觸藥品之材料及印刷物，每批次的一致性。

C.5 製造

儘量減少敘述而儘可能使用圖表說明，應包含下列數點：

C.5.1 儘可能使用流程圖來簡述製造過程，標明重要的項目。以該廠房內現有的設備能勝任的製程並明確指出藥品類型(見C.1.5.1及附錄，動物用藥品類型)。

- 若只從事包裝作業，簡述即可，如貼標機、充填等，及使用之容器材料，如袋裝，temper evident glass container。
- 如為細胞毒性或放射物質應詳述該產品。
- 應可能以流程圖說明製造過程，無須描述技術細節。
- 在製造過程中如何鑑別產品及如何安排存放這些中間產物。

C.5.2 原料處理、包裝材料、未分裝前之成品、成品之處理，包括取樣、隔離管制，放行及儲存之安排。

- 供應商之批號與本廠批號之鑑別方法。
- 抽樣計畫。
- 狀況標示，如標貼表示等。
- 放行物料至製造部門及包裝部門。
- 稱重管制。
- 檢查方法。
- 如何鑑別及放行供製造使用之物料。

C.5.2.1 未分裝前之成品製造管制

- 檢查製造過程中之主要控制因素，如混合時間、過濾器完整性測驗。

- 主要控制因素的紀錄。
- 製造過程中的檢查。
- 製造過程中檢查的紀錄。
- 符合上市許可。

C.5.2.2 包裝

- 未分裝前之成品、半成品、包裝材料之放行。
- 鑑別確認及包裝線上清潔檢查。
- 包裝過程中的檢查。

C.5.2.3 成品之隔離管制及放行，應符合上市規定。

C.5.3 拒用原物料與產品之處理方法。

C.5.3.1 拒用原物料與產品是否標示清楚？是否分別存放在限制區？

C.5.3.2 說明如何處置該原物料及其廢棄物，是否有銷毀紀錄？

C.6 品質管制

C.6.1 說明品管制度及品管部門的工作內容、成品放行之過程。
品管部門之工作內容及成品放行之過程。

C.6.1.1 簡述分析檢驗、包裝、成分檢驗、生物及微生物之工作內容。

C.6.1.2 若於此部門作批次紀錄文件之審查及最終文件之放行,請詳述之(請見C.1.9.5)。

C.6.1.3 描述在其他地方沒提到有關之準備、修訂及分發的安排，特別是規格、檢驗方法及放行條件。(請見C.1.9及C.4，文件)

C.7 委託製造及分析單位

C.7.1 說明該委託單位符合GMP規定的確認方法。
簡述雙方間的技術委託內容及確認該單位符合GMP標準的評估方法，以確保產品符合上市規定。

C.8 運銷申訴及產品回收

C.8.1　運銷的安排及紀錄系統。
說明存放及運銷方式。

C.8.1.1 是否有環境的控制？

C.8.1.2 物料儲存方法為何？

C.8.1.3 產品狀況如何判別？

C.8.1.4 保證先進先出之出貨次序，並確定批號。

C.8.2　申訴處理及產品回收的安排。
描述運銷紀錄。所保留的紀錄可追溯從工廠至客戶之批次資料，依據銷售日期、客戶明細及出貨數量。

C.8.2.1 申訴。

C.8.2.1.1 是否有書面的申訴程序。

C.8.2.1.2 是否製備書面報告？

C.8.2.1.3 由誰審閱報告？

C.8.2.1.4 該申訴報告保存時限？

C.8.2.2 產品回收。

C.8.2.2.1 是否有描述以下作業程序的書面作業程序：

1. 運銷資料的讀取。
2. 客戶通知書。
3. 回收產品的簽收、分類、檢查。
4. 申訴理由的調查及報告。
5. 報告更正作業方式。

C.8.2.2.2 由誰負責產品回收的聯絡？

C.8.2.2.3 由誰通知主管機關該申訴及回收？

附錄　動 物 用 藥 品 製 劑 劑 型

A. 動物用藥一般藥品製劑

A1散劑

A2膠囊劑

A3顆粒劑

A4錠劑

A5丸劑

A6口服液劑

A7糖漿劑

A8注射劑

A9外用散劑

A10外用液劑

A11眼用劑

A12吸入劑

A13軟膏劑

A14條帶劑

A15栓劑

A16噴霧劑

A17酊劑

A18酏劑

A19灌腸劑

B. 動物用生物藥品製劑

B1固體

B2液體

B3診斷試劑

B4診斷套組

C. 含藥物飼料添加製劑

C1散劑

C2顆粒劑

Veterinary Medicinal Products Manufacturing

Plant Master File

C.1 General Information

C.1.1 **Brief information on the firm (including name, address and capital).**

C.1.2 **Pharmaceutical manufacturing activities as licensed by the Competent Authorities.**

C.1.3 **Any other non-pharmaceutical manufacturing activities carried out on the site.**

C.1.4 **Name and exact address of the site, including telephone number, and fax.**

C.1.5 **Type of actual products manufactured on the site (see list at Appendix), and information about specifically toxic or hazardous substances handled, mentioning the way they are manufactured (in dedicated facilities or on a campaign basis).**

C.1.6 **Short description of the site (size, location and immediate environment and other manufacturing activities on the site).**

C.1.7 **Number of employees engaged in the quality assurance, production, quality control, storage and distribution.**

C.1.8 **Use of outside scientific, analytical or other technical assistance in relation to manufacture and analysis (if so, see C.7, Contract Manufacture And Analysis).**

C.1.9 **Short description of the quality management system of the firm responsible for manufacture.**

C.2 Personnel

C.2.1 **Organization chart showing the arrangements of production and quality control.**

C.2.2 **Qualifications, experience and responsibilities of key personnel.**

C.2.3 **Outline of arrangements for basic and in-service training and how records are maintained.**

C.2.4 **Health requirements for personnel engaged in production.**

C.2.5 **Personnel hygiene requirements.**

C.3 Premises And Equipment

Premises

C.3.1 Simple plan and description of manufacturing areas with indication of scale (architectural or engineering drawings are not required).

C.3.2 Nature of construction and finishes.

C.3.3 Brief description of ventilation systems. More details should be given for critical areas with potential risks of airborne contamination (schematic drawings of the systems are desirable). Classification of the rooms used for the manufacture of sterile products should be mentioned.

C.3.4 Special areas for the handling of highly toxic, hazardous and sensitizing、sterilized and biological materials.

C.3.5 Brief description of water systems including sanitation.

Equipment

C.3.6 Brief description of major production and control laboratories equipment.

C.3.7 Qualification and calibration including recording system.

Sanitation

C.3.8 Availability of written specifications and procedures for cleaning manufacturing areas and equipment.

C.4 Documentation

C.4.1 Arrangements for the preparation, revision and distribution of necessary documentation for manufacture.

C.4.2 Any other documentation related to product quality which is not mentioned elsewhere (e.g. microbiological controls on air and water).

C.5 Production

C.5.1 Brief description of production operations using, wherever possible, flow sheets and charts specifying important parameters (see at Appendix the list of products manufactured).

C.5.2 Arrangements for the handling of starting materials. packaging materials, bulk and finished products, including sampling, quarantine, release and storage.

C.5.3 Arrangements for the handling of rejected materials and products.

C.6 Quality Control

C.6.1 Description of the quality control system and of the activities of the quality control department procedures for the release of finished products.

C.7 Contract Manufacture And Analysis

C.7.1 Description of the way in which the GMP compliance of the contract acceptor is assessed.

C.8 Distribution, Complaints And Product Recall

C.8.1 Arrangements and recording system for distribution.

C.8.2 Arrangements for the handling of complaints and product recalls.

GUIDANCE

C.1 General Information

C.1.1 Outline the firm's activities.

C.1.2 Quote the relevant document as issued by the Competent Authority. State period of validity of license document (if the validity of the document is given in the country concerned). Any conditions and/or restriction should be stated.

C.1.3 This covers both pharmaceutical and non-pharmaceutical activities. (see C.1.6)

C.1.4 Name and address of site

C.1.4.1 Name of company (and trading style if different). Postal address including code (street address if different).

C.1.4.2 Telephone no. of contact person.

C.1.4.3 Fax no. of contact person.

C.1.5 Type of Actual Products Manufactured.

C.1.5.1 Quote the type of actual products as described at Appendix.

C.1.5.2 Note any toxic or hazardous substances handled e.g. antibiotics, hormones, cytostatics. Note whether the products are manufactured in a dedicated facility or on a campaign basis.

C.1.5.3 Mention if any product other than the veterinary products in the same site, please describe.

C.1.6 A Short description of the site.

C.1.6.1 The location and immediate environment.

C.1.6.2 The size of the site.

C.1.6.3 The pictures of the whole facility (the pictures should show the facility name and bird’s-eye view)

C.1.6.4 Other manufacturing activities on the site.

C.1.7 (Note: Include employees working only part-time on fulltime equivalent basis.)

C.1.8 For each outside contractor give:

C.1.8.1 Name and address of the company.

C.1.8.2 Telephone no.

C.1.8.3 Fax no.

C.1.8.4 Brief outline of the activity.

C.1.9

C.1.9.1 State the firm's Quality Policy.

C.1.9.2 Define the responsibility of the Quality Assurance function.

C.1.9.3 Describe the elements of the QA system

(1) Organizational structure, responsibilities, procedures, processes.

(2) Specification, checking procedure and other quality related capital collection

C.1.9.4 Describe how the results are reviewed to demonstrate the adequacy of the quality system in relation to the objective i.e. quality efficacy and safety of the product. See C.6.1.2

C.1.9.5 Describe the release for sale procedure for finished products.

C.2 Personnel

C.2.1 Organization chart

C.2.2 Qualifications, experience and responsibilities of key personnel.

C.2.3 Outline of arrangements for basic and in-service training and how records are maintained

Give brief details of the training programmed and include induction and continuous training, as follows:

C.2.3.1 Describe how training needs are identified and by whom.

C.2.3.2 Give details of training relative to GMP requirements.

C.2.3.3 State the form of training e.g. in-house, external, and how practical experience is gained and which staff are involved.

C.2.4 Health Requirements for Personnel Engaged in Production

C.2.4.1 Who is responsible for checking health of employees?

C.2.4.2 Is there a pre-employment medical examination?

C.2.4.3 Are employees routinely checked from time to time depending on nature of their work?

C.2.4.4 Is there a system for reporting sickness or contact with sick people before working in a critical area?

C.2.4.5 Is there a system of reporting back after illness?

C.2.4.6 Are those who work in clean areas subject to additional monitoring?

C.2.5 Personnel hygiene requirements

C.2.5.1 Are there suitable washing, changing and rest areas?

C.2.5.2 Is the clothing suitable for the activity undertaken? Briefly describe the clothing.

C.2.5.3 Are there clear instructions on how protective clothing should be used and when it should be changed?

C.3 Premises And Equipment

C.3.1 Premises

C.3.1.1 Provide a site plan and indicate all production areas. Indicate the distance between buildings and the use of each building.

C.3.1.2 Provide a floor plan of each production area. Indicate the name of each area, and show the flow diagram for the movement of raw materials, final products, and personnel.

C.3.1.3 Indicate area classification and the pressure differential between adjacent rooms located in different areas.

C.3.1.4 Indicate the cleanliness and clothing procedure for each area.

C.3.1.5 Provide pictures for each operation area, working personnel should be showed.

C.3.2 Nature of construction and finishes.

C.3.2.1 To reduce narrative for a large complex plant, the details should be limited to critical areas.

C.3.2.2 These areas must include all processing and packaging and critical storage areas.

C.3.3 Brief Description of Ventilation Systems etc.

Note 1: More details should be given for critical areas with potential risks of airborne contamination. This will include sterile product areas as well as areas for processing powders, granulation and tablet. For sterile product areas a summary of the results of the most recent qualification/requalification should be given.

Note 2: To reduce the narrative, schematic drawings should be used. The following data should be given:

C.3.3.1 Design criteria

- Temperature
- Humidity
- Pressure differentials and air change rate
- Simple pass or recirculation (%)

C.3.3.2 Filter design and efficiency. Details of any alarms on the ventilation system should be given.

C.3.3.3 The limits for changing the filters should be given.

C.3.4 Special areas for the handling of highly toxic hazardous and sensitizing materials

C.3.5 Brief description of water systems, including sanitation.

Note:Schematic drawings of the systems are preferred. The following information must appear:

C.3.5.1 The schematic must go back to the city supply system.

C.3.5.2 The capacity of the system (maximum quantity produced per hour).

C.3.5.3 Construction materials of the vessels and pipe work.

C.3.5.4 Specification of any filters in the system must be given.

C.3.5.5 The specification of the water produced

a) chemical

b) conductivity

c) microbiological

C.3.5.6 The procedure and frequency for sanitation.

C.3.6 Equipment

Brief Description of major production and control laboratory equipment

C.3.6.1 Is the equipment designed with ease of cleaning in mind? Name of equipment、amount.

C.3.6.2 Only a general description is required e.g. a rotary tablet press etc. If the equipment has additional devices, these should be recorded e.g. automatic weighing machines with printer; a labeller incorporating a bar code reader for the label; a lot number and expiry date over printer; a freeze drier equipped with a steam sterilization facility.

C.3.6.3 In the quality control laboratory only general descriptions such as pH meters, chromatographic equipment GLC (gas liquid chromatography), HPLC (high performance liquid chromatography) with computer systems, particle size analyzers.
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C.3.6.4 In microbiology use general descriptions such as incubators (temperature ranges) facilities for LAL (limulus amebocyte lysate) testing, membrane filtration sterility testing, antibiotic assay, etc.

C.3.7 Qualification and calibration

C.3.7.1 Describe equipment qualification policy and records kept.

C.3.7.2 Describe equipment calibration policy and records kept.

C.3.8 Sanitation

Cleaning procedures for manufacturing areas and equipment

C.3.8.1 Are there written specifications and procedures for cleaning, cleaning agents and their concentration for the method of cleaning?

C.3.8.2 Are cleaning methods monitored routinely by chemical and/or microbiological methods?

C.3.8.3 What are the cleaning methods for the water supply system, air handling system and dust extraction system?

C.4 Documentation

Note: This section refers to all documentation used in manufacture. Manufacture involves all activities relating to the production and control of pharmaceutical products.

C.4.1.1 Is there a description of the documentation system?

C.4.1.2 Who is responsible for the preparation revision and distribution of documents?

C.4.1.3 Where are the master documents stored?

C.4.1.4 Is there a standard format and instruction of how documents are to be prepared?

Are there documents for:

- Product/process specifications
- Raw material specifications
- Packaging component specifications
- Standard process instructions including packaging
- Batch records including packaging
- Analytical methods
- QA release procedures.

C.4.1.5 How is the documentation controlled?

C.4.1.6 For how long are documents kept after release of the batch?

C.4.2 Other documentation related to product quality are the following documents available and in use?

C.4.2.1 Equipment specifications.

C.4.2.2 Specifications for disposables i.e. cleaning materials.

C.4.2.3 Standard operating procedures.

C.4.2.4 Quality Control Procedures.

C.4.2.5 Training procedures.

C.4.2.6 Documentation control of process deviations.

C.4.2.7 Calibration and test documents (see C.3.9.5)

C.4.2.8 Reconciliation of batches of raw materials, major packing components i.e. product contact and printed materials.

C.5 Production

This narrative should be kept to a minimum and generalized schematic layouts used where possible. The following points should be addressed:

C.5.1 Describe the operations capable of being carried out at the site with the existing facilities and specify the types of pharmaceutical products. (See C.1.5.1 and the Appendix for types of products manufactured).

- When packaging only is undertaken, give a brief description only, e.g. labeling, filling etc, and the nature of containers used e.g. sachets, tamper evident glass containers.
- If cytotoxic or radio active substances are handled give details of the products.
- Describe the production operations using flow charts if possible. Technical details are not required.
- Describe how products are identified during production and how in-process storage is organized.

C.5.2 Arrangements for handling Starting Materials, Packing Materials, Bulk and Finished Products including Sampling Quarantine Release and Storage

- Identification of suppliers lot number with the company's lot number.
- Sampling plans.
- Status labeling e.g. by using labels or by computer.
- Issue of materials to manufacture and package.
- The control of weighing.
- Checking methods.
- How are materials being used for manufacture identified and released?

C.5.2.1 Control of Bulk Manufacture

- Checks on key parameters during manufacture e.g. blend times, filter integrity tests.

- Records of key parameters.
- In-process checks.
- Records of in-process checks.
- Compliance with the Marketing Authorization.

C.5.2.2 Packing

- Release of bulk, semi-finished products, packing materials.
- Confirmation of identity and line clearance checks.
- In-process checks.

C.5.2.3 Quarantine and release of finished products; compliance with the Marketing Authorization.

C.5.3 Arrangements for Handling Reject Materials and Products

C.5.3.1 Are reject materials and products clearly labeled? Are they stored separately in restricted areas?

C.5.3.2 Describe arrangements for sentencing the materials and their disposal. Is destruction recorded?

C.6 Quality Control

C.6.1 Activities of the quality control department

C.6.1.1 Briefly describe the activities of analytical testing, packaging, component testing, biological and microbiological testing.

C.6.1.2 If the review of batch documentation and release of final documentation takes place in this department, give details. (See also para 1.9.5)

C.6.1.3 Outline the involvement in the arrangements for the preparation, revision and distribution of documents in particular those for specification test methods and release criteria if not mentioned elsewhere. (See also para 1.9 and Chapter 4, Documentation)

C.7 Contract manufacture and analysis

C.7.1 Describe briefly the details of the technical contract between the contract giver and acceptor and the way in which the GMP compliance is assessed to ensure product compliance with the Marketing Authorization.

C.8 Distribution

C.8.1 A Description of storage and distribution practices

C.8.1.1 Is it environmentally controlled?

C.8.1.2 How are the materials stored?

C.8.1.3 How is the status of products controlled?

C.8.1.4 Does the despatch order ensure first in/first out and identify the lot number?

C.8.2 Records of Distribution

Do the retained records permit full batch traceability from the factory to the customer, in terms of the date of sale, customer details and quantity dispatched?

C.8.2.1 Complaints

C.8.2.1.1 Is there a written complaints procedure?

C.8.2.1.2 Are written reports prepared?

C.8.2.1.3 Who reviews these reports?

C.8.2.1.4 For how long are complaints records kept?

C.8.2.2 Product Recalls

C.8.2.2.1 Is there a written procedure which describes the sequence of actions to be followed including:

1. Retrieval of distribution data.
2. Notification of customers.
3. Receipt/segregation/inspection of returned product.
4. Investigation/reporting of cause.
5. Reporting corrective action.

C.8.2.2.2 Who is responsible for coordinating product recalls?

C.8.2.2.3 Who notifies the Competent Authority of complaints and recalls.

APPENDIX

TYPE OF PRODUCTS MANUFACTURED

(referred to in paragraph C.1.5)

A. General product

- A1 Powder
- A2 Capsule
- A3 Granule
- A4 Tablet
- A5 Pill
- A6 Oral Solution
- A7 Syrup
- A8 Injection
- A9 Powder for external use
- A10 Solution for external use
- A11 Eye use
- A12 Inhalant
- A13 Ointment
- A14 Collar
- A15 Suppository
- A16 Aerosol spray
- A17 Tincture
- A18 Spirit
- A19 Enema

B. Biological product

- B1 Solid
- B2 Solution
- B3 Diagnostic reagent
- B4 Diagnostic kit

C. Feed additive

- C1 Powder
- C2 Granule