|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Site Master File  Document No.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Version No. | Prepared by | Date of prepared | Approved by | Date of approval | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |
| Table of Contents 1 General information on the manufacturer  1.1 Contact information on the manufacturer  1.2 Authorized pharmaceutical manufacturing activities of the site including those from foreign regulatory authorities  1.3 Any other manufacturing activities carried out on the site  2 Quality management system of the manufacturer  2.1 The quality management system of the manufacturer  2.2 Release procedure of finished products  2.3 Management of suppliers and contractors  2.4 Quality risk management (QRM)  2.5 Product Quality Reviews  3 Personnel  3.1 Organization chart of the site  3.2 Number of employees in the manufacturing site  4 Premises and Equipment  4.1 Premises  4.2 Equipment  5 Documentation  5.1 Description of documentation system  6 Production  6.1 Type of products  6.2 Process validation  6.3 Material management and warehousing  7 Quality Control  7.1 Quality control activities carried out on the site  8 Distribution, complaints, product defects and recalls  8.1 Distribution(to the part under the responsibility of the manufacturer)  8.2 Complaints, product defects and recalls  9 Internal audit 1 General information on the manufacturer 1.1 Contact information on the manufacturer  1.1.1 Name and official address of the manufacturer  Name:  Address:  1.1.2 Name and street address of the manufacturing site  Name:  Address:  1.1.3 Contact information of the manufacturer including 24 hrs. telephone number of the contact personnel in the case of product defects or recalls;  Name and title of the contact personnel:  Tel: 　　　　　　　　　 Fax:  E-mail:  Telephone number for contact of business hours:  1.1.4 Identification number of the site as e.g. GPS details, D-U-N-S (Data Universal Numbering System) Number (a unique identification number provided by Dun & Bradstreet) of the site, or any other geographic location system.  D-U-N-S number:  GPS information: |
| 1.2 Authorized pharmaceutical manufacturing activities of the site including those from foreign regulatory authorities  1.2.1 Information about drug manufacturing license  1.2.2 Brief description of manufacture, import, export, distribution and other activities as authorized by or registered to the relevant Competent Authorities including foreign authorities.   1. Domestic: 2. Country A: 3. Country B:   1.2.3 Type of products currently manufactured on- site  1.2.4 List of GMP Inspections of the site within the last 5 years     |  |  |  |  |  | | --- | --- | --- | --- | --- | | Name /country of the Competent Authority | Dates | Product(s) covered | Results | Type of inspection on-site/desk-top | |  |  |  |  |  | |  |  |  |  |  |   1.2.5 GMP certificate |
| 1.3 Any other manufacturing activities carried out on the site |
| 2 Quality management system of the manufacturer 2.1 The quality management system of the manufacturer  2.1.1 Brief description of the quality management system run by the company and reference to the standards used  2.1.2 Responsibilities related to maintaining of quality system including senior management  2.1.3 Information of activities for which the site is accredited and certified |
| 2.2 Release procedure of finished products  2.2.1 Detailed description of qualification requirements (education and work experience) of the Authorized Person(s) responsible for batch certification and releasing procedures  2.2.2 General description of batch certification and releasing procedure |
| 2.3 Management of suppliers and contractors  2.3.1 A brief summary of the establishment/knowledge of supply chain and the external audit program    2.3.2 Brief description of the qualification system of contractors manufacturers of API and other critical materials suppliers    2.3.3 Measures taken to ensure that products manufactured are compliant with TSE (Transmissible animal spongiform encephalopathy) guidelines  2.3.4 Measures adopted where counterfeit/falsified products, bulk products (i.e. unpacked tablets), active pharmaceutical ingredients or excipients are suspected or identifies  2.3.5 Use of outside scientific, analytical or other technical assistance in relation to manufacture and analysis  2.3.6 List of contract manufacturers and laboratories including the addresses and contact information and flow charts of supply chains for outsourced manufacturing and Quality Control activities |
| 2.4 Quality risk management (QRM)  2.4.1 Brief description of QRM methodologies used by the manufacturer    2.4.2 Scope and focus of QRM |
| 2.5 Product Quality Reviews |
| 3 Personnel 3.1 Organization chart of the site    3.2 Number of employees in the manufacturing site |
| 4 Premises and Equipment 4.1 Premises  [1] Short description of plant  Site area:  Manufacturing facility:  Warehouse:    Laboratories:    4.1.1 Brief description of heating, ventilation and air conditioning (HVAC) systems  4.1.1.1 Cleanliness of the rooms within the facilities  4.1.1.2 Temperature/humidity control  Manufacturing area  Storage area  4.1.1.3 Pressure differential control  4.1.1.4 Number of air change rate, air recycling  4.1.2 Brief description of water systems    4.1.3 Other utilities |
| 4.2 Equipment  4.2.1 Listing of major production and control laboratory equipment  4.2.2 Cleaning and sanitation  4.2.3 GMP critical computerized systems |
| 5 Documentation 5.1 Description of documentation system |
| 6 Production 6.1 Type of products  6.1.1 Type of products manufactured at this manufacturing site  6.1.2 Types of investigational medicinal products (IMPs) being manufactured at this site  6.1.3 Toxic or hazardous substances handled (e.g. with high pharmacological activity and/or with sensitizing properties)  6.1.4 Products manufactured in a dedicated facility/equipment or in a shared facility/equipment  6.1.5 Process Analytical Technology(PAT) applications |
| 6.2 Process validation  6.2.1 Brief description of general policy for process validation  6.2.2 Policy for reprocessing or reworking |
| 6.3 Material management and warehousing  6.3.1 Arrangements for the handling of starting materials, packaging materials, bulk and finished products including sampling, quarantine, release and storage  6.3.2 Handling of rejected materials and products |
| 7 Quality control 7.1 Quality control activities carried out on the site |
| 8. Distribution, complaints, product defects and recalls 8.1 Distribution(to the part under the responsibility of the manufacturer)  8.1.1. Types (wholesale license holders, manufacturing license holders, etc.) and locations of the companies to which the products are shipped from the site  8.1.2 Description of the system used to verify that each customer/recipient is legally entitled to receive medicinal products from the manufacturer  8.1.3 Brief description of the system to ensure appropriate environmental conditions during transit, e.g. temperature monitoring/control  8.1.4 Arrangements for product distribution and methods by which product traceability is maintained  8.1.5 Measures taken to prevent manufacturers/products to fall in the illegal supply chain |
| 8.2 Complaints, product defects and recalls  Complains  Recall |
| 9. Internal audit |