Site Master File

The licensee shall prepare a succinct document in the form of Site Master File containing specific and factual Good Manufacturing Practices about the production and/or control of pharmaceutical manufacturing preparations carried out at the licensed premises.

It shall contain the following: -

1. General information:

(a) brief information of the firm;
(b) pharmaceutical manufacturing activities as permitted by the licensing authority;
(c) other manufacturing activities, if any, carried out on the premises;
(d) type of products licensed for manufacture with flow charts mentioning procedure and process flow;
(e) number of employees engaged in the production, quality control, storage and distribution;
(f) use of outside scientific, analytical or other technical assistance in relation to manufacture and analysis;
(g) short description of the Quality Management System of the firm; and
(h) products details registered with foreign countries.

2. Personnel:

(a) organisational chart showing the arrangement for quality assurance including production and quality control;
(b) qualification, experience and responsibilities of key personnel;
(c) outline for arrangements for basic and in-service training and how the records are maintained;
(d) health requirements for personnel engaged in production; and
(e) personnel hygiene requirements, including clothing.

3. Premises:

(a) simple plan or description of manufacturing areas drawn to scale;
(b) nature of construction and fixtures/fittings;
(c) brief description of ventilation systems. More details should be given for critical areas with potential risk of airborne contamination (schematic drawing of systems). Classification of the rooms used for the manufacture of sterile products should be mentioned;
(d) special areas for the handling of the highly toxic, hazardous and sensitizing materials;
(e) brief description of water system (schematic drawings of systems), including sanitation;
(f) description of planned preventive maintenance programs for premises and of the recording system.

4. Equipment:

(a) brief description of major equipment used in production and Quality Control Laboratories (a list of equipment required);
(b) description of planned preventive maintenance programs for equipment and of the recording system; and
(c) qualification and calibration including the recording systems and arrangements for computerized systems validation.

5. Sanitation:

(a) availability of written specifications and procedures for cleaning manufacturing areas and equipment.

6. Documentation. –

(a) arrangements for the preparation, revision and distribution of;
(b) necessary documentation for the manufacture;
(c) any other documentation related to product quality that is not mentioned elsewhere (e.g. microbiological controls about air and water).

7. Production:.

(a) brief description of production operations using, wherever possible, flow sheets and charts specifying important parameters;
(b) arrangements for the handling of starting materials, packaging materials, bulk and finished products, including sampling, quarantine, release and storage;
(c) arrangements for the handling of rejected materials and products;
(d) brief description of general policy for process validation.

8. Quality Control:

(a) description of the quality control system and of the activities of the Quality Control Department. Procedures for the release of the finished products.

9. Loan licence manufacture and licensee:

(a) description of the way in which compliance of Good Manufacturing Practices by the loan licensee shall be assessed.

10. Distribution, complaints and product recall:

(a) arrangements and recording system for distribution;
(b) arrangements for the handling of complaints and product recalls.

11. Self inspection. –

(a) short description of the self-inspection system indicating whether an outside, independent and experienced external expert was involved in evaluating the manufacturer‘s compliance with Good manufacturing Practices in all aspects of production.

12. Export of drugs. –

(a) products exported to different countries;
(b) complaints and product recall, if any