

INSPECTION REPORT (MODEL)

The following recommendations are made regarding aspects to be covered in the inspection report during full routine inspection:

Manufacturer details – General Information

Summary of activities performed at the site

For example, manufacture of active pharmaceutical ingredient(s) (APIs), manufacture of finished pharmaceutical products (FPPs), intermediates or bulk packaging, laboratory testing, batch release, distribution and importer activities

Inspection Details:

Date of Inspection:

Names & designation of inspectors:

Type of inspection: For example, initial, routine, follow-up, special

INTRODUCTION BRIEF SUMMARY OF THE MANUFACTURING ACTIVITIES

- Description of main activities (including, e.g. FPP(s) or API(s) manufactured; use of outside scientific, analytical or other technical assistance in manufacture and quality control.
- Brief description of the quality management system of the firm responsible for manufacture. Reference can be made to a site master file.

History

- **Previous inspection date & Summary of past inspections.**

- **Remarks on Observations on CAPA from previous inspection**
- **Major change since previous inspection and planned future changes**
- **GMP-related recalls from the market of any product in the past two years**

BRIEF REPORT OF INSPECTION ACTIVITIES UNDERTAKEN:

Scope and limitations:

For example, blocks inspected, areas of interest, focus of inspection Out-of-scope: areas, activities or product lines not inspected

Restrictions: constraints noted in inspecting specific areas

Areas inspected For example, dosage form(s) included in the inspection

Key persons met Names and job titles

BRIEF SUMMARY OF THE FINDINGS AND RECOMMENDATIONS (WHERE APPLICABLE) REGARDING THE FOLLOWING QUALITY SYSTEMS:

- 1. Pharmaceutical Quality System,**
- 2. Production System,**
- 3. Facilities and Equipment System,**
- 4. Laboratory Control System,**
- 5. Materials System,**
- 6. Packaging and Labelling System.**

The observations made during the inspection that are considered to be non-compliant with GMP should be listed. Where positive observations are included in the report, a clear distinction should be made between positive and noncompliant.

1. Pharmaceutical Quality System

Describe the pharmaceutical quality system (PQS) in place and how well the elements are institutionalized and implemented, including the product quality review (PQR)

2. Good Manufacturing Practices for Pharmaceutical Products

Briefly describe how the elements of GMP are implemented

3. Sanitation and hygiene

Describe procedures and records relating to sanitation and hygiene for personnel, premises, equipment, production materials, cleaning materials and others that could become a source of contamination

4. Qualification and validation

Describe policies, procedures, records and any other evidence for qualification and validation and how the validation status is monitored and maintained

5. Complaints

Describe procedures, responsibilities and records for handling complaints, including extension of investigation to other batches, possibility of counterfeits, trending and consideration for recall and notification of competent authorities

6. Product recalls

Describe the existence of a recall procedure and evidence of its effectiveness; provisions for notification of customers and competent authorities and segregation of recalled products

7. Contract production, analysis and other activities

Describe how contractors are evaluated, how compliance with marketing authorization is ensured, existence of comprehensive contracts and clarity of responsibilities and limit

8. Self-inspection, quality audits and suppliers' audits and approval

a) Self-inspection:

describe the procedures and items for self-inspection and quality audits; constitution of self-inspection team(s); frequency of self-inspection; existence of selfinspection schedules and report; system for monitoring follow-up actions.

b) Suppliers' audits and approval:

describe procedures for evaluation and approval of suppliers including applications of risk management principles, especially determining the need and frequency for on-site audits.

9. Personnel

Describe availability of adequate numbers of sufficiently qualified and experienced personnel, clarity of their responsibilities, limits and reporting hierarchy. Qualifications, experience and responsibilities of key personnel (head of production, head(s) of the quality unit(s), authorized person) and procedures for delegation of their responsibilities

10. Training

Describe comprehensiveness of procedures and records for induction, specialized and continuing training and evaluation of its effectiveness; coverage of GMP and concepts of quality assurance during training; training of visitors and evaluation consultants and contract staff

11. Personal hygiene

Describe system in place for initial and regular health examination of staff appropriate to their responsibilities. Measures and facilities to impart, maintain and monitor knowledge of a high level of personal hygiene. Measures to ensure personnel do not become a source of contamination to the product, including hand-washing and gowning. Appropriate restriction of smoking, eating, drinking, chewing and related materials from production, laboratory and storage areas

12. Premises

Description of the appropriateness of the location, design, construction and maintenance of premises to minimize errors, avoid cross-contamination, permit effective cleaning and maintenance; measures for dust control; specific measures for ancillary areas, storage areas, weighing areas, production areas and quality control areas; measures for appropriate segregation and restricted access; provisions for appropriate lighting, effective ventilation and air-control to prevent contamination and cross-contamination, as well as control of temperature and, where necessary, humidity

13. Equipment

Describe the adequacy of the numbers, type, location, design and construction, and maintenance of equipment to minimize errors, avoid cross-contamination, permit effective cleaning and maintenance; use, cleaning and maintenance procedures, records and logs; calibration of balances and other measuring instruments; status labeling

14. Materials

Describe measures in place to select, store, approve and use materials (including water) of appropriate quality and how these measures cover starting materials, packaging materials, intermediate and bulk products, finished products, reagents, culture media and reference standards. Describe also the measures for the handling and control of rejected, recovered, reprocessed and reworked materials; recalled products; returned goods; and waste material

15. Documentation

Describe the comprehensiveness and adequacy of the documentation system in place (labels; specifications and testing procedures, starting, packaging materials, intermediate, bulk products and finished products; master formulas; packaging instructions; batch processing and packaging records; standard operating procedures (SOPs) and records) and how principles of good documentation and data management (attributable, legible, contemporaneous, original, accurate (ALCOA)) are institutionalized, implemented and maintained

16. Good Practices in Production

Describe procedures, facilities and controls in place for production (processing and packaging); prevention of risk of mix-up, cross-contamination and bacterial contamination during production

17. Good Practices in Quality Control

Describe the extent of the organizational and functional independence of the quality control function and the adequacy of its resourcing. Describe the procedures, facilities, organization and documentation in place which ensure that the necessary and relevant tests are actually carried out and that materials are not released for use, nor products released for sale or supply, until their quality has been judged to be compliant with the requirements. Describe the procedures for the control of starting materials and intermediate, bulk and finished products; test requirements; procedures and responsibilities for batch record review; procedures, records and facilities for initial and ongoing stability studies; policy, procedures, facilities and records for retention samples.

Samples taken (if applicable)

Assessment of the site master file (if applicable)

Annexes attached (if any)

List of deficiencies:

Deficiencies should be listed with reference to the relevant section(s) of Schedule M / any other provisions of Drugs and Cosmetics Act & Rules made there under.

Conclusion: Final statement of GMP compliance

References: List of rules/guidelines referenced in the inspection (Schedule M, Schedule L-1, Rule 96, Rule 97 of Drugs & Cosmetics Rules etc.)

Signatures of the Inspecting Officers:

Date: