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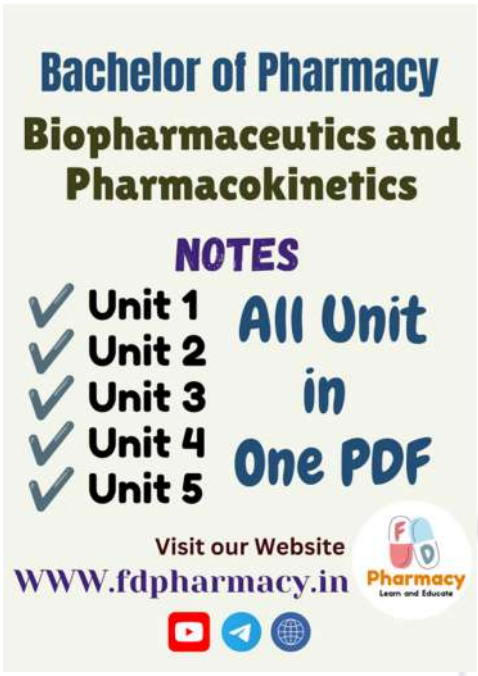
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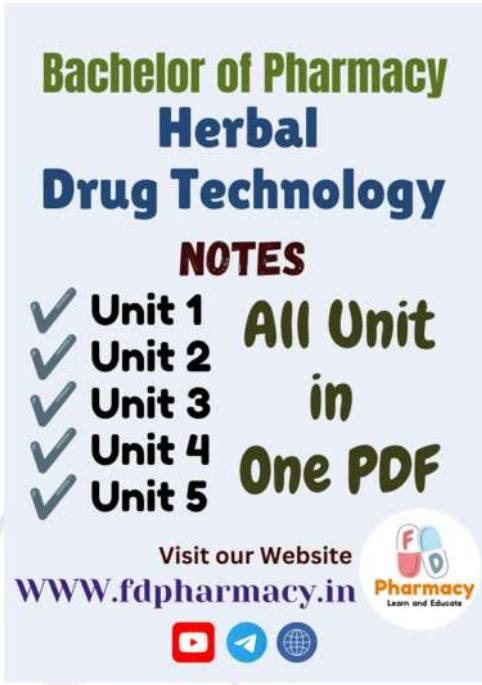
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PHARMACEUTICAL QUALITY ASSURANCE

UNIT 4

TOPIC :

- **Document maintenance in pharmaceutical industry :** Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records.

Documents, Quality Audit, Quality Review & Distribution Records

Documents

→ Documents are written and approved records that provide evidence of activities performed during pharmaceutical manufacturing, quality control, packaging, storage and distribution.
→ They ensure traceability, consistency, accountability and compliance with Good Manufacturing Practices (GMP).

Objectives of Documentation

- To maintain product quality and safety.
- To provide evidence of compliance with GMP and regulatory requirements.
- To ensure traceability of all manufacturing activities.
- To prevent errors, mix-ups and deviations.
- To facilitate investigations, audits and inspections.
- To maintain accountability of personnel.

Types of Pharmaceutical Documents

1. Master Formula Record (MFR)
2. Batch Manufacturing Record (BMR)
3. Standard Operating Procedure (SOP)
4. Batch Packaging Record (BPR)
5. Validation Protocols
6. Specifications
7. Log Books
8. Distribution Records

Master Formula Record (MFR)

→ Master Formula Record (MFR) is an authorized and approved document containing complete instructions for manufacturing a specific pharmaceutical product.

→ It serves as the master reference document for preparation of Batch Manufacturing Records.

Purpose of MFR

- Ensures uniformity in manufacturing.
- Maintains consistent product quality.
- Reduces manufacturing errors.
- Provides standard operating instructions.
- Ensures GMP compliance.

Contents of MFR

1. Product Information

- Product name
- Generic name
- Brand name
- Dosage form
- Strength
- Batch size
- Pack size
- Shelf life
- Storage conditions
- Product description

2. Document Identification

- MFR number
- Revision number
- Effective date
- Approval details
- Superseded document number

3. Flow Chart

Shows complete manufacturing process flow from raw material receipt to finished product storage.

4. Equipment Details

- Equipment name
- Equipment identification number
- Equipment capacity

5. Manufacturing Formula

- List of APIs
- List of excipients
- Quantity required

6. Manufacturing Process

- Dispensing
- Mixing
- Granulation
- Drying
- Compression/Filling
- Coating
- Packaging

7. Special Instructions

- Safety precautions
- Environmental requirements
- Material handling instructions

8. Calculations

- API calculations
- Potency adjustment
- Yield calculations

9. Packaging Instructions

- Packaging materials
- Label details
- Packaging procedure

10. Yield Details

- Theoretical yield
- Expected yield
- Acceptable yield limits

Preparation of MFR

- Prepared by R&D/Formulation Department.
- Reviewed by Production Department.
- Approved by Quality Assurance (QA).

Batch Manufacturing Record (BMR)

→ Batch Manufacturing Record (BMR) is a document that records all manufacturing activities performed during production of a specific batch.
→ It provides complete batch history and traceability.

Purpose of BMR

- Provides batch traceability.
- Serves as legal evidence.
- Supports investigations.
- Ensures GMP compliance.
- Records actual manufacturing operations.

Contents of BMR

Product Information

- Product name
- Dosage form
- Strength
- Batch number
- Batch size

Raw Material Details

- Material name
- Material code
- Quantity issued
- Quantity used

Manufacturing Instructions

- Processing steps
- Equipment used
- Processing conditions

In-Process Controls

- Weight variation
- Hardness
- Dissolution
- pH
- Moisture content

Yield Details

- Theoretical yield
- Actual yield
- Percentage yield

Equipment Details

- Equipment name
- Equipment number
- Cleaning status

Signatures

- Operator
- Supervisor
- Production Head
- QA Approval

Importance of BMR

- Maintains manufacturing history.
- Helps in batch investigations.
- Ensures accountability.
- Facilitates audits and inspections.

Standard Operating Procedure (SOP)

→ Standard Operating Procedure (SOP) is a written and approved document containing step-by-step instructions for performing a specific task in a consistent and controlled manner.

Objectives of SOP

- Ensures uniformity in operations.
- Reduces errors.
- Maintains quality standards.
- Provides employee guidance.
- Ensures GMP compliance.

Types of SOPs

1. Operational SOP

- Equipment operation and production procedures.

2. Cleaning SOP

- Cleaning of equipment and premises.

3. Quality Control SOP

- Sampling and testing procedures.

4. Maintenance SOP

- Equipment maintenance procedures.

5. Safety SOP

- Emergency handling and safety procedures.

Contents of SOP

Title Page

- SOP title
- SOP number
- Revision number
- Effective date

Purpose

- Explains why SOP is prepared.

Scope

- Defines area of application.

Responsibilities

- Operator
- Supervisor
- QA personnel

Materials and Equipment

- Lists required materials and instruments.

Procedure

- Detailed step-by-step instructions.

Safety Precautions

- PPE requirements
- Hazard warnings
- Emergency measures

Documentation

- Required records and log books.

Deviations and CAPA

- Actions to be taken in case of deviations.

Approval Section

- Prepared by
- Reviewed by
- Approved by

Characteristics of Good SOP

- Clear and simple language.
- Easy to understand.
- Logical sequence.
- Approved by QA.
- Periodically reviewed and updated.

Quality Audit

→ Quality Audit is a systematic, independent and documented examination of activities, records and processes to verify compliance with GMP, SOPs and regulatory requirements.

Objectives of Quality Audit

- Ensure GMP compliance.
- Verify SOP implementation.
- Detect deviations and non-compliance.
- Improve quality systems.
- Maintain product quality and safety.

Types of Quality Audit

1. Internal Audit

- Conducted by the company itself for self-assessment.

2. External Audit

- Conducted by customers, suppliers or third-party organizations.

3. Regulatory Audit

- Conducted by regulatory authorities such as:
  - CDSCO
  - FDA

Scope of Quality Audit

- Production department
- Quality control laboratory
- Quality assurance system
- Documentation
- Equipment maintenance
- Personnel training
- Warehousing and distribution

Steps in Quality Audit

1. Planning

- Preparation of audit schedule and checklist.

2. Execution

- Inspection of facilities, records and processes.

3. Observation

- Identification of deficiencies and deviations.

4. Reporting

- Preparation of audit report.

5. CAPA

- Implementation of Corrective and Preventive Actions.

Advantages of Quality Audit

- Improves quality systems.
- Reduces defects.
- Enhances compliance.
- Improves efficiency.
- Supports continuous improvement.

Quality Review

→ Quality Review is a periodic evaluation of products, processes and records to ensure consistent quality and compliance with GMP requirements.

Objectives of Quality Review

- Ensure consistent product quality.
- Review manufacturing performance.
- Identify trends and deviations.
- Improve process performance.
- Maintain GMP compliance.

Elements of Quality Review

- Review of BMR/BPR
- Review of deviations
- Review of CAPA
- Review of complaints
- Review of recalls
- Review of stability data
- Review of QC results
- Review of process yields

Importance of Quality Review

- Continuous quality improvement.
- Detection of recurring problems.
- Assurance of product safety.
- Support during regulatory inspections.

Quality Documentation

→ Quality Documentation includes all written documents and records that demonstrate compliance with GMP and approved procedures.

Objectives

- Ensure GMP compliance.
- Maintain consistency.
- Provide evidence of activities.
- Ensure traceability.
- Support audits and inspections.

Types of Quality Documentation

1. Documents

Documents provide instructions for performing activities.

Examples:

- SOP
- MFR
- Specifications
- Validation Protocols

2. Reports

Reports provide evidence of completed activities.

Examples:

- BMR
- Validation Reports
- Audit Reports
- Investigation Reports
- Test Reports

Importance

- Regulatory compliance.
- Product traceability.
- Investigation support.
- Audit readiness.
- Quality assurance.

Distribution Records

→ Distribution Records are documents that contain complete information regarding movement and distribution of pharmaceutical products from manufacturer to wholesalers, distributors and pharmacies.

Department Responsible

➢ Warehousing and Distribution Department.

Contents of Distribution Records

- Product name
- Dosage form
- Strength
- Batch/Lot number
- Quantity distributed
- Distribution date
- Name and address of consignee
- Transport details
- Storage conditions

Importance of Distribution Records

- Tracks product movement.
- Facilitates product recall.
- Maintains accountability.
- Ensures regulatory compliance.
- Provides complete distribution history.

Advantages

- Quick recall management.
- Better inventory control.
- Improved traceability.
- Regulatory inspection suppo