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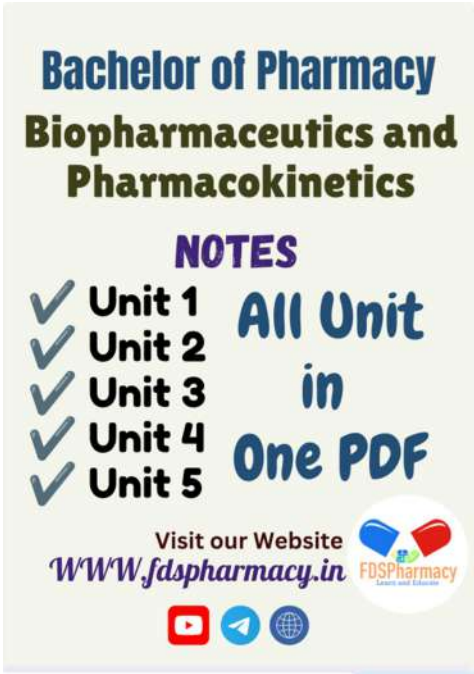
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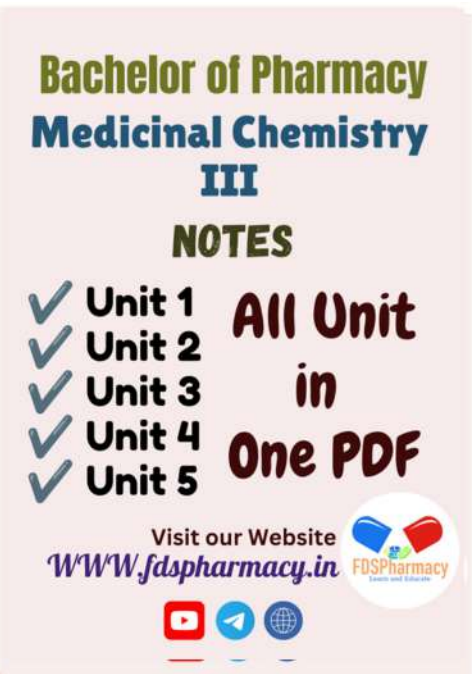
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PHARMACEUTICAL QUALITY ASSURANCE

UNIT 2

TOPIC :

- **Equipments and raw materials :** Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.

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Equipments and Raw Materials In Pharmaceutical Industry

Equipments

- Equipment in the pharmaceutical industry refers to the machines, instruments, tools, and apparatus used for manufacturing, processing, testing, packaging, storage, and quality control of pharmaceutical products.
- Proper selection, installation, operation, maintenance, and calibration of equipment are essential to ensure product quality, safety, efficiency, and compliance with Good Manufacturing Practices (GMP).

Equipment Selection

→ Selection of suitable equipment is one of the most important decisions in pharmaceutical manufacturing.

1. Quality

Equipment should meet high standards of:

- Accuracy
- Precision
- Reliability
- Durability

Importance

- Maintains product quality.
- Ensures batch-to-batch consistency.
- Reduces manufacturing errors.
- Improves productivity.

2. Suitability of Equipment

Equipment should be suitable for the intended manufacturing process.

Requirements

- Suitable for the product being manufactured.
- Compatible with batch size.
- Capable of meeting production requirements.

- Produces uniform and consistent output.

Importance

- Improves efficiency.
- Minimizes process variations.
- Reduces product defects.

3. Material of Construction

Equipment should be constructed from materials that do not affect product quality.

Requirements

- Non-toxic material.
- Corrosion-resistant material.
- Non-reactive with pharmaceutical products.
- Easy to clean and sanitize.

Common Materials

- Stainless Steel 316L
- Stainless Steel 304
- Glass
- Food-grade polymers

Importance

- Prevents contamination.
- Increases equipment life.
- Maintains product purity.

4. Design and Construction

Equipment should be properly designed for pharmaceutical use.

Features

- Smooth surfaces.
- No sharp corners.
- No dead spaces.
- Easy access for cleaning.
- Dust-free design.

Importance

- Prevents microbial growth.
- Facilitates cleaning.

- Reduces contamination risks.

5. Ease of Cleaning and Operation

Requirements

- Easy dismantling and assembly.
- Easy cleaning and sanitization.
- User-friendly controls.
- Simple operating procedures.

Benefits

- Saves time.
- Reduces cleaning costs.
- Improves operational efficiency.

6. GMP and Safety Requirements

➢ Equipment should comply with GMP guidelines.

Requirements

- Safe operation.
- Proper guarding of moving parts.
- Emergency stop systems.
- Validation capability.

Importance

- Ensures operator safety.
- Meets regulatory requirements.
- Prevents accidents.

7. Capacity

Capacity should be selected according to present and future production requirements.

Considerations

- Production scale.
- Batch size.
- Expansion plans.
- Market demand.

Importance

- Avoids underutilization.
- Supports future growth.

- Improves cost effectiveness.

Purchase Specifications of Equipment

→ Purchase specifications are written requirements describing the equipment before procurement.

1. Technical Specifications

Must include:

- Equipment name
- Model number
- Capacity
- Performance characteristics
- Operating parameters

Importance

- Helps select appropriate equipment.
- Avoids purchasing errors.

2. Material Quality Requirements

Must Specify

- Material of construction.
- Surface finish.
- Pharmaceutical-grade standards.

Importance

- Ensures product safety.
- Facilitates cleaning.

3. Utility Requirements

Include

- Electrical requirements.
- Water requirements.
- Compressed air requirements.
- Steam requirements.
- Space requirements.

Importance

- Ensures proper installation.
- Prevents operational problems.

4. Supplier Documentation

Supplier should provide:

- Operating manuals.
- Maintenance manuals.
- Validation documents.
- Calibration certificates.
- Test reports.

Importance

- Facilitates qualification and validation.
- Supports regulatory compliance.

5. Warranty and After-Sales Service

Considerations

- Warranty period.
- Availability of spare parts.
- Technical support.
- Maintenance services.

Importance

- Reduces downtime.
- Ensures long-term operation.

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Maintenance of Equipments

- Maintenance is the process of keeping equipment in proper working condition to ensure efficiency, safety, and reliability.

1. Routine Maintenance

Routine maintenance is performed regularly.

Activities

- Cleaning.
- Lubrication.
- Visual inspection.
- Tightening loose parts.

Benefits

- Prevents wear and tear.
- Improves performance.

2. Preventive Maintenance

Preventive maintenance is carried out at predetermined intervals.

Activities

- Replacement of worn parts.
- Inspection of critical components.
- System checks.

Advantages

- Prevents unexpected breakdowns.
- Increases equipment lifespan.

3. Calibration

Calibration is the comparison of an instrument's measurements with a recognized standard to ensure accuracy.

Importance

- Ensures accurate readings.
- Maintains product quality.
- Meets GMP requirements.

Examples

- Weighing balances.
- Thermometers.
- Pressure gauges.

4. Breakdown Maintenance

Performed when equipment fails unexpectedly.

Activities

- Fault identification.
- Repair or replacement.
- Functional testing.

Requirements

- Use approved spare parts.
- Maintain repair records.

5. Records and Documentation

Maintenance records should include:

- Equipment identification.
- Maintenance date.
- Work performed.
- Spare parts used.
- Technician details.
- Calibration records.

Importance

- Supports audits.
- Demonstrates GMP compliance.
- Facilitates troubleshooting.

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Raw Materials

→ Raw materials are the substances used in the manufacture of pharmaceutical products.
→ The quality of raw materials directly affects the safety, efficacy, and quality of finished pharmaceutical products.
→ Raw materials should be procured only from approved suppliers and comply with recognized pharmacopoeial standards.

Types of Raw Materials

1. Active Pharmaceutical Ingredients (APIs)

➢ APIs are substances responsible for the therapeutic effect of a medicine.

Examples

- Paracetamol, Amoxicillin, Metformin

2. Excipients

➢ Inactive ingredients used to assist formulation and drug delivery.

Examples

- Lactose
- Starch
- Microcrystalline cellulose

Functions

- Improve stability.
- Improve appearance.
- Aid manufacturing.

3. Solvents and Reagents

➢ Used during manufacturing and purification processes.

Examples

- Ethanol, Methanol, Acetone

4. Packaging Materials

➢ Materials used to protect pharmaceutical products.

Examples

- Bottles, Blister packs
- Cartons

- Labels

Purchase Specifications of Raw Materials

Purchase specifications describe the quality requirements for raw materials before procurement.

1. Name of Raw Material

- Official name should be clearly mentioned.
- Avoids confusion and mix-ups.

2. Grade and Quality

Examples

- Pharmaceutical grade
- Analytical grade
- Laboratory grade

Importance

- Ensures suitability for intended use.

3. Pharmacopoeial Standards

Materials should comply with standards such as:

- IP (Indian Pharmacopoeia)
- BP (British Pharmacopoeia)
- USP (United States Pharmacopeia)

Importance

- Ensures quality and purity.

4. Description of Material

Should specify:

- Color
- Odor
- Appearance
- Physical form

Example

White crystalline powder with characteristic odor.

5. Identification Tests

➢ Tests used to confirm identity of raw material.

Importance

- Prevents use of wrong materials.
- Ensures authenticity.

6. Microbial Limits

➢ Required for contamination-prone materials.

Includes

- Total bacterial count.
- Total fungal count.
- Absence of specified pathogens.

7. Packaging Requirements

Should specify:

- Container type.
- Pack size.
- Protection from light, moisture, and air.

8. Storage Conditions

Should define:

- Temperature.
- Humidity.
- Light protection.

Example

Store below 25°C in a dry place.

9. Labeling Requirements

Label should include:

- Material name.
- Batch number.
- Manufacturing date.
- Expiry date.
- Supplier name.

10. Approved Supplier Details

Materials should be purchased only from approved and qualified suppliers.

Importance

- Ensures consistency.

- Reduces quality risks.

Steps of Purchasing Raw Materials

Purchase Requisition
↓
Selection of Vendors
↓
Inviting Quotations
↓
Placing Purchase Order
↓
Receiving Materials
↓
Sampling and Testing
↓
Invoice Verification
↓
Recording in Purchase Records
↓
Release of Payment

Purchase Records

The following information should be recorded:

- Date of receipt.
- Name of material.
- Batch number.
- Purchase order number.
- Supplier name.
- Quantity received.
- Manufacturer name.
- Invoice details.
- Manufacturing date.
- Expiry date.

Maintenance Of Raw Materials

Location of Stores

Requirements

- Near manufacturing area.
- Easy accessibility.
- Proper material flow.
- Secure storage facilities.

Storage Area Requirements

Features

- Adequate storage space.
- Clean and dry conditions.
- Good ventilation.
- Controlled temperature and humidity.
- Pest control measures.

Inventory Systems

FIFO

- First In First Out
- Materials received first are used first.

FEFO

- First Expiry First Out
- Materials with earlier expiry dates are used first.

Storage Facilities

Storage facilities should include:

Receiving Area

- For incoming materials.

Sampling Area

- For quality control sampling.

Quarantine Area

- For materials awaiting approval.

Approved Material Area

- For released materials.

Rejected Material Area

- For rejected materials.

Hazardous Material Area

- For dangerous chemicals and solvents.

Storage Conditions

Room Temperature Storage

- Generally 20–25°C.

Refrigerated Storage

- 2–8°C.

Light-Sensitive Materials

- Stored in amber-colored containers.

Moisture-Sensitive Materials

- Stored in airtight containers.

Labeling of Raw Materials

Every container should be properly labeled with:

- Material name.
- Material code.
- Batch number.
- Quantity.
- Manufacturer name.
- Date of receipt.
- Expiry date.
- Storage conditions.
- Material status.

Material Status Labels

- Quarantine
- Approved
- Rejected
- Under Test

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Importance of Proper Equipment and Raw Material Management

- Ensures product quality.
- Prevents contamination.
- Improves manufacturing efficiency.
- Maintains GMP compliance.
- Reduces operational risks.
- Ensures patient safety.
- Facilitates regulatory approval.

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