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PHARMACEUTICAL QUALITY ASSURANCE

UNIT 5

TOPIC :

- **Warehousing :** Good warehousing practice, materials management



Good Warehousing Practices (GWP)

- Good Warehousing Practices (GWP) are a set of guidelines that ensure the proper storage, handling, distribution and maintenance of pharmaceutical products to preserve their quality, safety and efficacy throughout their shelf life.
- In simple words, GWP ensures that medicines are stored and distributed under suitable conditions without deterioration.

Objectives of GWP

- To maintain product quality and stability.
- To prevent contamination, mix-ups and deterioration.
- To ensure proper storage and distribution.
- To comply with GMP and regulatory requirements.
- To facilitate product traceability and recall.
- To ensure patient safety.
- To reduce losses due to damage or expiry.

Requirements of Good Warehousing Practices

1. Storage Conditions

- Pharmaceutical products must be stored under appropriate environmental conditions.

Requirements

- Controlled temperature.
- Controlled humidity.
- Protection from direct sunlight.
- Proper ventilation.
- Clean and dry storage area.

Examples

- Room Temperature: 15–25°C
- Cold Storage: 2–8°C
- Deep Freezer: Below –20°C

2. Storage Area

The warehouse should have separate areas for:

- Raw materials
- Packaging materials

- Finished products
- Rejected materials
- Returned goods
- Expired products
- Quarantined materials

Advantages

- Prevents mix-ups.
- Improves inventory control.
- Maintains product quality.

3. Material Identification

→ All materials must be clearly labeled.

Information on Labels

- Product name
- Batch number
- Manufacturing date
- Expiry date
- Status label

Status Labels

- Approved
- Rejected
- Quarantine
- Under Test

4. Stock Rotation System

FIFO (First In First Out)

- Materials received first are issued first.
- Example: Old stock is used before new stock.

FEFO (First Expiry First Out)

- Materials expiring first are issued first.
- Example: Product expiring in June is distributed before a product expiring in December.

Importance

- Prevents expiry.
- Reduces wastage.
- Improves inventory management.

5. Pest Control

→ Warehouse should be free from insects, rodents and pests.

Methods

- Regular inspection
- Fumigation
- Pest control programs

Importance

- Prevents contamination.
- Maintains product quality.

6. Documentation and Records

→ The warehouse should maintain proper records.

Important Records

- Goods Receipt Records (GRN)
- Stock Registers
- Distribution Records
- Inventory Records
- Temperature Records
- Return Goods Records

Importance

- Traceability
- Regulatory compliance
- Easy auditing

7. Security and Safety

Requirements

- Restricted access to authorized personnel.
- Security systems and alarms.
- Fire protection systems.
- Emergency exits.
- CCTV surveillance.

Importance

- Prevents theft.
- Prevents unauthorized access.
- Ensures product safety.

8. Handling of Returned and Expired Goods

- Returned and expired products should be stored separately.

Requirements

- Clearly labeled area.
- Proper investigation of returned goods.
- Disposal according to SOPs and regulations.

Importance

- Prevents accidental distribution.
- Maintains product quality.

Importance of GWP

- Maintains drug quality and stability.
- Prevents contamination and mix-ups.
- Ensures regulatory compliance.
- Improves storage and distribution efficiency.
- Facilitates product recall.
- Enhances patient safety.

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Material Management

- Material Management is the process of planning, purchasing, receiving, storing, controlling and distributing materials required for pharmaceutical production in an efficient and economical manner.
- In simple words, material management ensures the right material is available at the right place, at the right time, in the right quantity and at minimum cost.

Objectives of Material Management

- Ensure uninterrupted production.
- Maintain adequate stock levels.
- Reduce wastage and losses.
- Improve inventory control.
- Ensure GMP compliance.
- Reduce production cost.

Steps of Material Management

1. Selection of Suppliers

Qualified suppliers are selected based on:

- Quality
- Reliability
- Cost
- Delivery performance

Importance

- Ensures quality raw materials.
- Reduces procurement problems.

2. Procurement of Materials

Purchase of:

- Raw materials
- Packaging materials
- Consumables

Requirements

- Approved vendors.
- Purchase specifications.
- Purchase orders.

3. Receipt of Materials

Materials are checked upon arrival.

Checks

- Quantity verification
- Physical condition
- Packaging integrity
- Supplier documents

Documentation

- Goods Receipt Note (GRN)
- Delivery Challan
- Invoice

4. Documentation and Entry

All received materials must be recorded.

Records Include

- Material name
- Batch number
- Quantity received
- Supplier details
- Date of receipt

5. Storage of Materials

Materials should be stored under suitable conditions.

Conditions

- Temperature control
- Humidity control
- Clean environment
- Proper labeling

6. Inventory Control

Stock levels should be monitored regularly.

Methods

- FIFO
- FEFO
- Stock verification
- Reorder level system

Benefits

- Prevents shortages.
- Prevents overstocking.

7. Issue of Materials

Materials are issued to production according to requirements.

Requirements

- Approved material only.
- Proper documentation.
- Quantity verification.

8. Prevention of Wastage

Measures include:

- Proper storage.
- Stock rotation.
- Monitoring expiry dates.
- Avoiding excess inventory.

Advantages of Material Management

- Ensures smooth production process.
- Reduces losses and wastage.
- Maintains product quality.
- Improves inventory control.
- Enhances productivity.
- Ensures GMP compliance.
- Reduces manufacturing cost.
- Improves overall operational efficiency.