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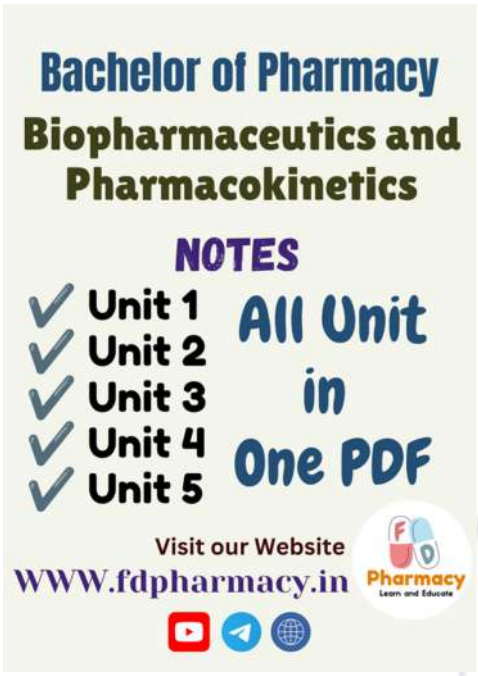
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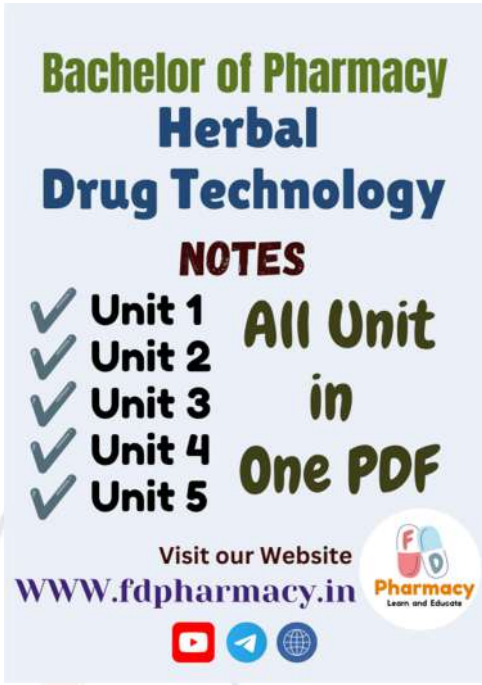
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PHARMACEUTICAL QUALITY ASSURANCE

UNIT 2

TOPIC :

Premises : Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination.

Premises

→ Premises refer to the building and surrounding areas where pharmaceutical activities such as manufacturing, testing, packaging, storage, and distribution of medicines are carried out.

→ Proper design, construction, maintenance, and sanitation of premises are essential to ensure product quality, safety, hygiene, and compliance with Good Manufacturing Practices (GMP).

Design, Construction and Plant Layout

→ The pharmaceutical plant should be designed and constructed to facilitate efficient operations and prevent contamination.

Requirements of Pharmaceutical Premises

1. Location

- The factory should be located away from open drains, sewage systems, smoke, dust, and industrial pollution.
- The location should be free from biological and environmental contamination.
- The surroundings should be clean and well maintained.

2. Building Design

- The premises should allow smooth manufacturing operations.
- The building should comply with the provisions of the Factories Act, 1948.
- Manufacturing, packaging, testing, and storage areas should be suitably designed according to their functions.
- The design should ensure logical flow of personnel and materials.

3. Space Requirements

- Adequate space should be provided for:
  - Equipment installation
  - Material movement
  - Personnel movement
  - Cleaning and maintenance activities
- Proper spacing prevents mix-ups and cross-contamination.

4. Construction Features

- Floors should be smooth, crack-free, non-porous, and washable.
- Walls should be smooth and easy to clean.
- Ceilings should minimize dust accumulation.
- Doors and windows should prevent entry of insects and rodents.

5. Environmental Control

- HVAC systems should be installed where environmental control is required.
- Proper temperature and humidity control should be maintained.

6. Drainage System

- Efficient drainage should be provided.
- Water stagnation must be avoided.
- Backflow and pest entry should be prevented.

Principal Areas of Pharmaceutical Premises

1. Ancillary Areas

➢ Ancillary areas are support areas provided for employees.

Examples

- Changing rooms
- Wash rooms
- Toilets
- Rest rooms

Requirements

- Should be separated from production areas.
- Must be clean and hygienic.
- Adequate facilities should be available for workers.

2. Warehousing Areas

➢ Warehousing areas are used for storage of materials and products.

Materials Stored

- Raw materials
- Packaging materials
- Intermediate products
- Finished products
- Rejected materials

Requirements

- Separate storage for different materials.
- Controlled temperature and humidity.
- Proper labeling and identification.
- Protection from contamination and damage.

3. Production Areas

➢ Production areas are the places where manufacturing operations are performed.

Requirements

- Adequate working space.
- Proper ventilation.
- Controlled environmental conditions.
- Logical movement of personnel and materials.
- Prevention of contamination and mix-ups.

Objectives

- Safe manufacturing.
- Efficient workflow.
- Compliance with GMP requirements.

4. Quality Control Areas

→ Quality Control (QC) areas are used for testing and analysis.

Functions

- Testing raw materials.
- Testing packaging materials.
- In-process quality checks.
- Finished product testing.

Requirements

- Separate from production areas.
- Proper laboratory facilities.
- Suitable instruments and equipment.
- Controlled environmental conditions.

Maintenance Of Premises

→ Maintenance refers to activities performed to keep pharmaceutical premises in good operating condition.

Areas Requiring Maintenance

- Roofs
- Floors
- Walls
- Pipelines
- Doors
- Windows
- Electrical systems
- HVAC systems

Common Problems

- Roof leakage
- Broken tiles
- Cracked walls
- Faulty plumbing
- Damaged doors and windows
- Electrical faults

Importance of Maintenance

- Prevents contamination.
- Prevents pest infestation.
- Ensures smooth operations.
- Improves safety.
- Maintains GMP compliance.

Sanitation

→ Sanitation refers to maintaining cleanliness and hygiene of premises, equipment, and working areas to prevent contamination of pharmaceutical products.

Objectives

- Maintain cleanliness.
- Prevent microbial growth.
- Prevent product contamination.
- Ensure product quality and safety.

Sanitation Practices

Cleaning

- Regular cleaning of floors, walls, ceilings, and equipment.
- Removal of dust and dirt.

Disinfection

- Use of approved disinfectants.
- Disinfection according to SOPs.

Pest Control

- Elimination of rodents.
- Control of insects and birds.
- Regular pest monitoring.

Importance of Sanitation

- Reduces contamination risks.
- Maintains product quality.
- Improves employee safety.
- Ensures GMP compliance.

Environmental Control

→ Environmental control is the maintenance of appropriate environmental conditions such as temperature, humidity, air quality, and pressure within pharmaceutical premises.

Components of Environmental Control

Temperature Control

- Maintains drug stability.
- Prevents degradation of products.

Humidity Control

- Prevents moisture absorption.
- Reduces microbial growth.

Air Quality Control

- Removes dust particles.
- Controls airborne microorganisms.

Pressure Control

- Maintains pressure differentials.
- Prevents contamination transfer.

HVAC System

HVAC stands for:
H – Heating
V – Ventilation
A – Air Conditioning
C – Control

Functions of HVAC

- Temperature regulation.
- Humidity control.
- Air filtration.
- Ventilation.
- Pressure control.

Importance

- Maintains GMP standards.
- Protects product quality.
- Ensures employee comfort and safety.

Utilities

- Utilities are support services required for efficient operation of pharmaceutical facilities.

Major Utilities

1. Water Supply

Water is used for:

- Manufacturing, Cleaning, Sterilization, Laboratory activities

Types of Water

- Potable Water
- Purified Water
- Water for Injection (WFI)

2. Electrical Supply

- Provides power to equipment.
- Supports lighting systems.
- Operates HVAC systems.

Requirements

- Continuous supply.
- Emergency backup systems.

3. HVAC System

- Controls environmental conditions.
- Maintains air quality.

4. Steam Supply

Used for:

- Sterilization
- Heating
- Cleaning operations

5. Compressed Air

Used in:

- Pneumatic equipment, Production machinery, Packaging operations.

6. Drainage System

- Removes wastewater.
- Prevents water accumulation.
- Prevents contamination.

Maintenance of Sterile Areas

→ Sterile areas are specialized pharmaceutical areas where sterile products are manufactured under highly controlled conditions.

Requirements

Structural Design

- Smooth walls and ceilings.
- Non-porous surfaces.
- Easy-to-clean construction.

Environmental Control

- Controlled temperature and humidity.
- Positive air pressure.
- HEPA-filtered air supply.

Cleaning and Disinfection

- Regular cleaning schedules.
- Validated cleaning procedures.
- Approved disinfectants.

Environmental Monitoring

Regular monitoring of:

- Air quality
- Temperature
- Humidity
- Pressure differentials
- Microbial count

HEPA Filter Maintenance

- Regular testing.
- Periodic replacement.
- Performance verification.

Importance

- Prevents microbial contamination.
- Ensures sterility assurance.
- Maintains GMP compliance.
- Protects patient safety.

Control of Contamination

→ Contamination control involves preventing the entry, generation, and spread of microorganisms, dust, chemicals, and foreign particles in pharmaceutical premises.

Sources of Contamination

Physical Contamination

- Dust
- Glass particles
- Metal fragments

Chemical Contamination

- Cleaning agents
- Solvents
- Cross-contamination from products

Microbial Contamination

- Bacteria
- Fungi
- Viruses

Methods of Contamination Control

1. Area and Facility Control

Measures

- HEPA filtration systems.
- Positive air pressure.
- Smooth and crack-free surfaces.
- Controlled entry systems.
- Segregated manufacturing areas.

2. Personnel Control

Personnel are one of the major sources of contamination.

Requirements

- Maintain personal hygiene.
- Wear protective garments.
- Follow gowning procedures.
- Disinfect gloves regularly.
- Report illness immediately.

Prohibited Activities

- Smoking
- Eating
- Drinking
- Wearing jewelry
- Using cosmetics
- Unnecessary talking

3. Cleaning and Disinfection

Principles

- Cleaning must precede disinfection.
- SOPs should be strictly followed.
- Approved disinfectants should be used.
- Correct concentration must be maintained.
- Cleaning effectiveness should be verified.

Importance of Premises in Pharmaceutical Industry

- Ensures production of quality medicines.
- Prevents contamination and mix-ups.
- Facilitates GMP compliance.
- Improves operational efficiency.
- Protects product safety and efficacy.
- Ensures regulatory compliance.