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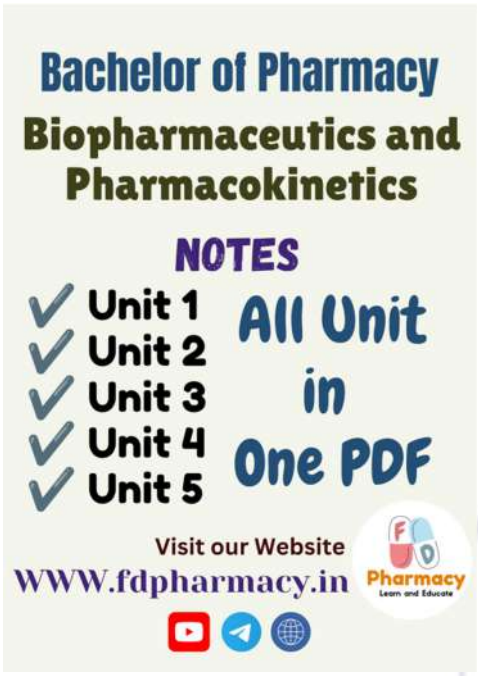
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HERBAL DRUG TECHNOLOGY

UNIT 5

TOPIC :

- **Schedule T– Good Manufacturing Practice of Indian systems of medicine**

  Components of GMP (Schedule– T) and its objectives

  Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.

Schedule T – Good Manufacturing Practice (GMP) Of Indian Systems Of Medicine

Schedule T is a part of the Drugs and Cosmetics Act and Rules of India that provides Good Manufacturing Practices (GMP) requirements for Ayurvedic, Siddha, and Unani (ASU) medicines.

It was introduced to ensure that herbal and traditional medicines are manufactured under hygienic and controlled conditions to maintain:

- Quality
- Safety
- Purity
- Efficacy of products.

Schedule T mainly applies to manufacturers of Indian systems of medicine.

Definition of GMP

→ Good Manufacturing Practice (GMP) refers to the practices and guidelines followed during manufacturing, processing, packaging, storage, and distribution of medicines to ensure consistent product quality and safety.

Objectives of Schedule T (GMP)

1. To ensure quality and purity of ASU medicines
2. To prevent contamination and adulteration
3. To maintain consistency in manufacturing
4. To ensure proper hygiene and sanitation
5. To maintain proper documentation and records
6. To provide safe and effective herbal medicines
7. To standardize manufacturing procedures

Components Of GMP (Schedule T)

The major components of Schedule T include:

1. Location and surroundings
2. Building and premises
3. Working space
4. Storage area
5. Machinery and equipment
6. Standard operating procedures (SOPs)
7. Health and hygiene
8. Documentation and records
9. Quality control
10. Waste disposal

1. Location And Surroundings

Requirements

- Factory should be located in a clean and hygienic area.
- Surroundings should be free from pollution, dust, smoke, and foul odour.
- Proper drainage and waste disposal systems should be available.

Importance

- Prevents contamination of raw materials and finished products.
- Maintains hygienic manufacturing conditions.

2. Building And Premises

Requirements

a) Construction

- Building should be strong and properly maintained.
- Walls and floors should be smooth and easy to clean.

b) Ventilation

- Adequate ventilation should be provided.

c) Lighting

- Proper lighting facilities should be available.

d) Water Supply

- Safe and potable water supply should be available.

e) Drainage

- Proper drainage system should be maintained.

Importance

- Prevents contamination
- Maintains cleanliness and safety

3. Working Space

Requirements

- Adequate working space should be provided for all operations.
- Different operations should be carried out in separate areas to avoid cross-contamination.
- Proper movement of workers and materials should be ensured.

Areas Required

1. Raw material area
2. Manufacturing area
3. Packaging area
4. Quality control area
5. Finished goods area

Importance

- Ensures smooth workflow
- Reduces chances of contamination and errors

4. Storage Area

Requirements

Separate storage facilities should be available for:

1. Raw materials
2. Packaging materials
3. Finished products
4. Rejected materials

Storage Conditions

- Cool and dry conditions
- Protection from moisture, insects, rodents, and sunlight
- Proper labeling and identification

Importance

- Prevents deterioration of medicines
- Maintains product stability and quality

5. Machinery and Equipment

Requirements

- Equipment should be suitable for manufacturing operations.
- Machinery should be properly cleaned and maintained.
- Equipment should not react with medicines.
- Calibration and validation should be performed regularly.

Common Equipments Used

1. Pulverizers
2. Mixers
3. Granulators
4. Tablet machines
5. Dryers
6. Filling machines

Importance

- Ensures uniform product quality
- Prevents contamination and manufacturing defects

6. Standard Operating Procedures (SOPs)

→ SOPs are written instructions describing procedures to be followed during manufacturing and quality control operations.

Purpose of SOPs

1. Maintain consistency in operations
2. Reduce errors
3. Ensure proper documentation
4. Improve quality assurance

SOPs Should Include

1. Raw material handling
2. Manufacturing process
3. Cleaning procedures
4. Equipment operation
5. Packaging and labeling
6. Storage procedures

Importance

- Ensures uniform manufacturing process
- Improves product quality and safety

7. Health and Hygiene

Requirements

a) Personnel Hygiene

- Workers should wear clean uniforms.
- Hands should be washed before work.
- Use of gloves, masks, and caps is recommended.

b) Medical Examination

- Workers should undergo regular health check-ups.
- Sick persons should not work in manufacturing areas.

c) Cleanliness

- Manufacturing areas should be cleaned regularly.

Importance

- Prevents microbial contamination
- Ensures safe manufacturing conditions

8. Documentation and Records

→ Documentation includes written records related to manufacturing, testing, storage, and distribution of medicines.

TYPES OF RECORDS

a) Batch Manufacturing Records

- Contain details of each production batch.

b) Raw Material Records

- Details of purchase and testing of raw materials.

c) Equipment Cleaning Records

- Records of equipment cleaning and maintenance.

d) Distribution Records

- Details of product distribution and sale.

e) Quality Control Records

- Records of testing and analysis.

Importance of Documentation

1. Ensures traceability
2. Helps in quality assurance
3. Facilitates regulatory inspection
4. Reduces manufacturing errors

9. Quality Control

Requirements

- Raw materials should be tested before use.
- Finished products should be tested for quality and purity.
- Quality control laboratory should be available.

Tests Performed

1. Identity tests
2. Purity tests
3. Microbial testing
4. Physicochemical testing

Importance

- Ensures safety and efficacy of products
- Maintains batch consistency

10. Waste Disposal

Requirements

- Waste materials should be disposed properly.
- Waste disposal should not contaminate environment.

Importance

- Maintains cleanliness
- Prevents environmental pollution

Advantages of Schedule T (GMP)

1. Ensures quality herbal medicines
2. Prevents contamination and adulteration
3. Improves consumer confidence
4. Supports export of herbal products
5. Promotes standardization of ASU medicines

Limitations

1. High implementation cost
2. Need for trained personnel

Role of Schedule T in Herbal Industry

- Improves manufacturing standards
- Ensures quality assurance
- Supports international acceptance of herbal medicines
- Promotes safe and effective traditional medicine