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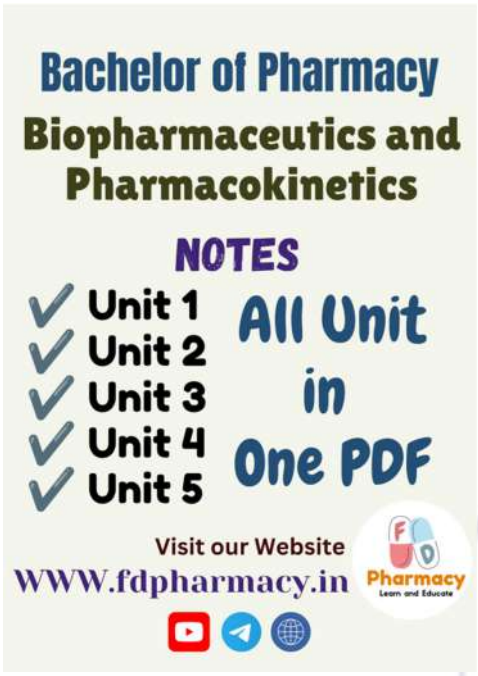
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HERBAL DRUG TECHNOLOGY

UNIT 4

TOPIC :

- **Regulatory Issues –** Regulations in India (ASU DTAB, ASU DCC), Regulation of manufacture of ASU drugs- Schedule Z of Drugs & Cosmetics Act for ASU drugs..

Regulatory Issues in ASU Drugs

ASU drugs refer to:

- Ayurvedic
- Siddha
- Unani

systems of medicine.

In India, the manufacture, sale, quality control, and regulation of ASU drugs are controlled under the:

- Drugs and Cosmetics Act, 1940
- Drugs and Cosmetics Rules, 1945

The government has established various regulatory bodies and schedules for maintaining:

- Safety
- Quality
- Efficacy
- Standardization of ASU medicines

ASU Drugs

ASU drugs are medicines used in:

- Ayurveda
- Siddha
- Unani

systems for diagnosis, treatment, prevention, and cure of diseases.

These medicines are mainly prepared from:

- Herbal sources
- Mineral sources
- Animal sources

Regulatory Bodies for ASU Drugs

1. ASU DTAB

Full Form

- Ayurveda, Siddha and Unani Drugs Technical Advisory Board

Definition

→ ASU DTAB is a technical advisory body constituted by the Government of India under the Drugs and Cosmetics Act to advise on technical matters related to ASU drugs.

Objectives

1. Advise government on ASU drug regulations
2. Ensure quality and safety of ASU medicines
3. Recommend standards for manufacturing
4. Suggest amendments in rules and schedules

Functions of ASU DTAB

1. Advises Central and State Governments
2. Recommends standards for ASU drugs
3. Examines technical issues related to quality control
4. Suggests GMP requirements
5. Helps regulate manufacture and sale of ASU drugs

Importance

- Ensures standardization
- Improves quality of herbal medicines
- Protects public health
- Promotes scientific regulation

2. ASU DCC

Full Form

- Ayurveda, Siddha and Unani Drugs Consultative Committee

Definition

ASU DCC is a consultative committee formed to ensure coordination between:

- Central Government
- State Governments

regarding administration of ASU drug regulations.

Objectives

1. Uniform implementation of ASU drug laws
2. Coordination between states
3. Discuss regulatory problems
4. Improve enforcement of rules

Functions of ASU DCC

1. Advises on administration of ASU regulations
2. Ensures uniformity in implementation
3. Discusses issues related to licensing and quality
4. Recommends measures for effective control

Importance

- Better coordination among states
- Uniform drug regulation
- Improved control over ASU drug manufacturing

Regulation of Manufacture of ASU Drugs

The manufacture of ASU drugs is regulated under:

- Drugs and Cosmetics Act, 1940
- Drugs and Cosmetics Rules, 1945

Manufacturers must follow:

- Licensing requirements
- GMP guidelines
- Quality standards

Licensing Requirements

Manufacturing License

A manufacturer must obtain a license from the State Licensing Authority before manufacturing ASU drugs.

Conditions for License

1. Adequate manufacturing area
2. Proper equipment
3. Qualified technical staff
4. Proper storage facilities
5. Quality control system

Good Manufacturing Practices (GMP)

Manufacturers must follow GMP to ensure:

- Safety
- Purity
- Quality
- Consistency

GMP Requirements for ASU Drugs

1. Premises

- Clean environment
- Proper ventilation
- Adequate lighting

2. Equipment

- Properly maintained
- Clean and calibrated

3. Raw Materials

- Proper identification
- Free from contamination

4. Quality Control

- Testing of raw materials
- In-process testing
- Finished product testing

5. Documentation

- Batch records
- Manufacturing records
- Distribution records

Schedule Z of Drugs and Cosmetics Act for ASU Drugs

Schedule Z deals with requirements and guidelines related to clinical evaluation and evidence of efficacy for ASU drugs.

It helps ensure:

- Safety
- Efficacy
- Scientific validation of traditional medicines.

Objectives of Schedule Z

1. Scientific evaluation of ASU drugs
2. Ensure therapeutic efficacy
3. Maintain product safety
4. Improve credibility of traditional medicines
5. Promote evidence-based herbal medicine

Main Provisions of Schedule Z

1. Evidence of Effectiveness

Manufacturers should provide:

- Clinical evidence
- Traditional evidence
- Scientific data for claimed therapeutic uses.

2. Safety Documentation

Information related to:

- Toxicity
- Side effects
- Contraindications

must be maintained.

3. Clinical Evaluation

Clinical studies may be required for:

- New ASU formulations
- Proprietary medicines

4. Labeling Requirements

Labels should contain:

- Ingredients
- Dose
- Indications
- Warnings

- Expiry date

5. Quality Standards

Products must comply with:

- Pharmacopoeial standards
- Purity requirements
- Microbial limits

Categories of ASU Drugs

1. Classical ASU Medicines

Prepared according to:

- Ayurvedic texts
- Siddha texts
- Unani texts

No major modification allowed.

2. Patent or Proprietary Medicines

Formulations containing:

- Traditional ingredients
- New combinations

These require additional evidence of safety and efficacy.

Quality Control of ASU Drugs

Important Parameters

Parameter	Purpose
Identity testing	Correct plant identification
Purity testing	Absence of contaminants
Microbial testing	Safety
Heavy metal testing	Toxicity prevention
Stability testing	Shelf-life determination

Labeling Requirements for ASU Drugs

Labels should mention:

1. Name of drug
2. Ingredients
3. Manufacturer details
4. Batch number
5. Manufacturing date
6. Expiry date
7. Dose
8. Storage conditions

Challenges in Regulation of ASU Drugs

1. Lack of standardization
2. Adulteration of raw materials
3. Variation in herbal ingredients
4. Inadequate scientific evidence
5. Poor quality control in small industries

Advantages of ASU Drug Regulations

1. Better quality assurance
2. Safer herbal medicines
3. Scientific validation
4. Increased public confidence
5. International market acceptance

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