

Unit-5

Herbal Drug Technology

B.Pharma 6th Sem Notes

Unit: 5

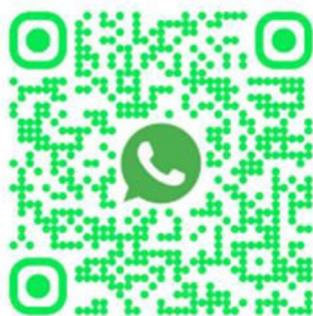
General Introduction to Herbal Industry Herbal drugs industry:

- Present scope and future prospects. A brief account of plant based industries and institutions involved in work on medicinal and aromatic plants in India.

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.

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General Introduction to Herbal Industry

The **herbal drug industry** refers to the sector involved in the **cultivation, collection, processing, manufacturing, quality control, and marketing** of herbal raw materials and herbal formulations. Herbal drugs are obtained from plant parts like leaves, roots, bark, seeds, flowers, and used for medicinal or therapeutic purposes.

In **pharmacognosy**, the herbal industry forms the backbone for sourcing raw materials used in crude drugs, phytochemicals, extracts, and herbal formulations.

Present Scope of Herbal Drug Industry

Large Market Demand

- Rising awareness about the safety and effectiveness of herbal medicines.
- Increased preference for **natural and plant-based products** over synthetic drugs.

Abundance of Medicinal Plants in India

- India has one of the richest biodiversities with nearly **7,000+ medicinal plant species**.
- Wide climatic variation supports cultivation of medicinal and aromatic plants (MAPs).

Growth of AYUSH Systems

- Ayurveda, Siddha, Unani, Yoga, Naturopathy, and Homeopathy contribute significantly.
- Government support through **Ministry of AYUSH** promotes traditional medicine.

Expansion in Herbal Formulations

Includes:

- Herbal tablets, capsules, syrups
- Churnas, Asavas, Aristas
- Herbal cosmetics
- Nutraceuticals and functional foods

Export Potential

- India exports **raw herbs, extracts, essential oils, oleoresins**, and herbal finished products.
- Countries in Europe, USA, Middle East, and Asia import Indian herbal materials.

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Increased Use in Research

- Herbal drugs are explored for anti-diabetic, anti-inflammatory, anticancer, hepatoprotective activities.
- Greater demand for standardized extracts and novel herbal delivery systems (phytosomes, nanoparticles).

Future Prospects of Herbal Industry

Standardization & Quality Assurance

- Increased use of advanced techniques like **HPTLC, HPLC, GC-MS, UV-vis spectroscopy**.
- Development of monographs and pharmacopoeial standards.

Cultivation Over Wild Collection

- Sustainable cultivation of MAPs will replace overexploitation from forests.
- Encourages farmers through buy-back policies and contract farming.

Development of Phytopharmaceuticals

- Plant-derived new drug molecules.
- Scientific validation of traditional plants.

Global Acceptance of Herbal Medicines

- WHO encourages use of herbal medicines with proper evidence.
- Indian herbal drugs expected to get wider global regulatory approval.

Growth of Herbal-based Industries

- Cosmetics
- Aromatherapy
- Nutraceuticals
- Organic farming
- Essential oil industry

Integration with Modern Healthcare

- Herbal drugs as complementary therapy.
- Increased collaborations between pharmaceutical companies and AYUSH firms.

Plant-Based Industries in India

India has a strong industrial base for medicinal and aromatic plants:

Ayurvedic & Herbal Pharmaceutical Industries

These industries prepare classical and proprietary herbal medicines.

Major Industries:

- Dabur India Ltd.
- Baidyanath Ayurved Bhawan
- Himalaya Wellness
- Patanjali Ayurved
- Zandu Pharmaceuticals
- Charak Pharma

Products:

Churna, Vati, Lehya, Asava-Arishta, syrups, extracts, capsules, ointments.

Aromatic and Essential Oil Industries

India is known for production of:

- Mint oils
- Lemongrass oil
- Eucalyptus oil
- Citronella oil
- Rose oil

Important Center:

Kannauj (U.P.) – “Perfume City of India”.

- Houses attar industries, aromatherapy oil units, and processing plants.

Herbal Cosmetic Industries

Growing demand for chemical-free cosmetics.

Examples:

- Lotus Herbals
- Biotique
- Khadi Natural
- Forest Essentials

Products: creams, lotions, face packs, shampoos, hair oils.

Nutraceutical and Health Supplement Industries

Incorporate herbs like ashwagandha, turmeric, amla, giloy, ginger.

Industries:

- Organic India
- Sri Sri Tattva
- Amway (Herbal Health Products)

Medicinal Plant Cultivation Units

States like Himachal Pradesh, Uttarakhand, Kerala, Madhya Pradesh, and Tamil Nadu have:

- Government-supported herbal gardens
- MAP cultivation clusters
- Processing units for drying, grading, extraction

Institutions Working on Medicinal & Aromatic Plants in India

1. NMPB – National Medicinal Plants Board, New Delhi

- Coordinates all medicinal plant activities.
- Supports cultivation, conservation, R&D.

2. CSIR Institutions

(a) CSIR-CIMAP, Lucknow

- Leading institute for MAP research, breeding, cultivation technologies.

(b) CSIR-NBRI, Lucknow

- Research on plant taxonomy, pharmacognosy, herbal drug development.

3. ICMR – Indian Council of Medical Research

- Conducts clinical research on herbal formulations.

4. ICAR – Indian Council of Agricultural Research

- Develops cultivation practices and high-yielding varieties of medicinal plants.

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5. Ministry of AYUSH

- Regulates ASU (Ayurveda, Siddha, Unani) drugs.
- Promotes education and research in traditional systems.

6. SMPB – State Medicinal Plants Boards

- Present in every state for regional cultivation and conservation activities.

7. FRLHT – Foundation for Revitalisation of Local Health Traditions, Bengaluru

- Works on traditional knowledge and medicinal plant conservation.

8. CCRAS, CCRUM, CCRS, CCRH (AYUSH Research Councils)

- Conduct research on Ayurveda, Unani, Siddha, Homeopathy.

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Schedule T – Good Manufacturing Practices (GMP) for Indian Systems of Medicine (ISM)

(Ayurveda, Siddha, Unani)

Introduction

Schedule T of the **Drugs and Cosmetics Act, 1940** lays down **Good Manufacturing Practices (GMP)** for Ayurvedic, Siddha and Unani (ASU) medicines.

It ensures:

- Quality herbal drug production
- Safety, efficacy, and purity
- Standardization and uniformity of formulations

GMP helps manufacturers follow scientific procedures during production, processing, packaging, and storage of herbal medicines.

Objectives of GMP (Schedule T)

1. **To ensure consistent quality** of ASU drugs at every stage of production.
2. **To prevent contamination and cross-contamination** of herbal materials.
3. **To maintain proper hygiene** and safe working environment.
4. **To ensure that raw materials, intermediate products and finished products** are handled correctly.
5. **To maintain accurate documentation** for traceability.
6. **To ensure safety of workers** during manufacturing.
7. **To use appropriate equipment and adequate space** for proper processing.

Components of GMP (as per Schedule T)

GMP under Schedule T includes the following main components:

1. **Infrastructural Requirements**
2. **Working Space**
3. **Storage Area**
4. **Machinery and Equipment**
5. **Standard Operating Procedures (SOPs)**
6. **Health and Hygiene**
7. **Documentation and Records**



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Infrastructural Requirements

A manufacturing unit must have:

- Proper **building** with durable construction.
- Smooth walls, washable surfaces, good ventilation.
- Adequate **lighting**, drainage and waste disposal system.
- Separate sections for:
 - Raw material storage
 - Production area
 - Quality control
 - Packaging
 - Finished goods storage
 - Microbial testing (if required)
- Pest-free environment.

The layout must support **unidirectional flow** of materials to avoid contamination.

Working Space

The working space must be:

- Sufficient to allow smooth workflow.
- Free from dust, smoke, and moisture.
- Separate areas for different operations such as:
 - Crushing, grinding
 - Drying
 - Mixing
 - Extraction
 - Tableting and packaging
- Space for workers to move freely without mixing of materials.

Cross-contamination must be avoided by providing **partitions** or separate rooms.

Storage Area

Schedule T requires **three types of storage areas**:

a) Raw Material Storage

- Separate for **crude drugs, minerals, poisonous plants, volatile oils**.
- Proper ventilation.
- Shelves raised above floor.
- Suitable temperature and humidity.

b) In-Process Material Storage

- Clean, labelled containers.



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- Stored separately to prevent mix-ups.

c) Finished Product Storage

- Dust-free, moisture-free area.
- Products arranged batch-wise.
- Quarantine area for rejected goods.

Storage must follow **FIFO (First In First Out)** or **FEFO (First Expiry First Out)** system.

Machinery and Equipment

Machinery used must be:

- Suitable for the type of ASU formulation.
- Easy to clean and maintain.
- Non-reactive to plant materials (stainless steel preferred).
- Calibrated regularly.

Common equipment:

- Pulverizers, grinders
- Mixers, churna machines
- Extractors, distillation units
- Capsule filling machine
- Tablet compression machine
- Sieves, dryers
- Ointment mixers
- Liquid filling machines

Each machine must have:

- A unique identification number
- Logbook
- Maintenance record

Standard Operating Procedures (SOPs)

SOPs are written instructions for performing routine tasks. They ensure consistency, quality and safety.

Schedule T requires SOPs for:

a) Cleaning and sanitation



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- Cleaning frequency, type of disinfectants used.

b) Equipment operation and maintenance

c) Raw material handling

- Identification, drying, powdering, sieving.

d) Manufacturing process

- Step-by-step procedure for churna, arista, asava, gheeta, bhasma etc.

e) Packaging and labelling

f) Waste disposal

All SOPs must be:

- Controlled documents
- Updated regularly
- Signed by authorized personnel

Health and Hygiene of Workers

Schedule T stresses on the health of workers because contamination can occur due to human contact.

Workers must:

- Wear aprons, hand gloves, masks, caps and shoes.
- Undergo medical check-ups periodically.
- Maintain personal cleanliness (trimmed nails, no jewellery).
- Not handle materials if suffering from infectious diseases.

Hand-washing facilities and toilets must be provided outside the production area.

Documentation and Records

Documentation ensures **traceability** and **accountability**.

Schedule T requires:

a) Raw Material Records

- Source, batch number, date of receipt, quality testing report.



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b) Batch Manufacturing Records (BMR)

- Quantity of raw materials
- Step-by-step manufacturing details
- Yield and wastage
- Name of responsible personnel

c) Quality Control Records

- Testing of raw materials, in-process materials, finished goods.

d) SOP Records

e) Logbooks

- For each machine/equipment.

f) Distribution Records

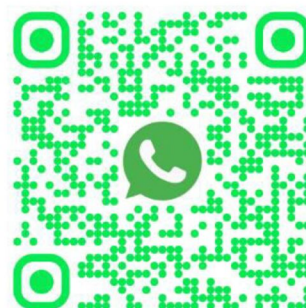
- Batch number, customer details, expiry date.

g) Complaint and Recall Records

- For unsafe or poor-quality batches.

Proper documentation ensures compliance with regulatory authorities.

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