UNIT-5

Herbal Drugs Industry

Herbal extracts have been used since ancient times in traditional medicine. ASU system of medicine is 5000 years old which recommends a combination of lifestyle management and treatment with specific herbs and minerals to cure various diseases.

Nature has presented a massive wealth of medicinal plants in India and thus it is often referred to as the medicinal garden of the world.

Present scope

Worldwide, there is a growing demand for Ayurveda and other traditional forms of medicine.

India has world's oldest and largest tradition of medicine systems.

→ The popularity of natural products is increasing day-by-day due to the facts that they are comparatively safe, less toxic, less side effects, easily available and affordable prices as compared to synthetic drugs.

→ The herbal drug industry is a very fast growing sector in the international market. In India, various systems of medicine like Ayurveda, Siddha, Unani, Homeopathy, Yoga and Naturopathy are being utilised for the healthcare of people.

→ About 80% of people in developing countries are estimated to rely for their primary healthcare on traditional medicines.

→ About 500 medicinally useful plants are mentioned in ancient literature and around 800 plants have been used in indigenous medicine system.

→ Plants are important sources of medicines and around 25% of pharmaceutical prescriptions in the United states have at least one ingredient that has been derived from plants.

→ Total global herbal market size is $87 billion in 2020. And in this, India's contribution is only one billion dollars. Hence, there is a vast scope for Indian manufacturers to enter herbal pharmaceutical field.

Future Prospects

1) Increasing Consumer Demand

- According to report by Grand View Research, the global herbal medicine market size market size was valued at USD 86.74 billion in 2020 and is expected to grow at a CAGR of 5.88% from 2021 to 2028.

2) Scientific Research and Innovation

- Advancements in scientific research are validating the efficacy of herbal medicines. For instance, a study published in the Journal of Ethnopharmacology demonstrated the anti-inflammatory properties of curcumin, a compound found in turmeric.
- Research institutions, such as National Institute of Health (NIH), are investing in studies to explore the therapeutic potential of herbal compounds, driving innovation in the field.

3) Regulatory Evolution

- Regulatory agencies worldwide are increasingly recognising the importance of regulating herbal drugs. The WHO has published guidelines for the assessment of herbal medicines to ensure their safety, efficacy and quality.
- European Medicines Agency (EMA) has established a regulatory framework for herbal medicinal products, including requirements for registration and quality control.

4) Sustainability and Ethical Sourcing

- With growing environmental awareness, there is a concerted effort to promote sustainable and ethical sourcing practices within the herbal drugs industry.
- Organisations such as the Fairwild Foundation are working to ensure fair trade practices and biodiversity conservation in the wild harvesting of medicinal plants.

Plant-Based Industries and Intitutions

Government of India has expressed support and encouragement for the Traditional Indian Medicine.

→ A separate department for Indian Systems of Medicine known as AYUSH (Ayurveda, Yoga, Unani, Siddha and Homeopathy was established in march 1995 to promote indigenous system.

→ Priorities include education, standardisation of drugs, enhancement of availability of raw materials, research and development, information, communication and larger involvement in the national system for delivering health care.

List of few herbal industries in India

1) Ansar Drug Laboratories (Surat)
2) Acis Laboratories (Kanpur)
3) Allen Laboratories Pvt. Ltd (Kolkata)
4) Basic Ayurveda (Ghaziabad)
5) Dabur India Ltd (Ghaziabad)
6) Herbal (APS) Pvt. Ltd (Patna)
7) Herbo-Med Pvt. Ltd (Kolkata)
8) The Himalaya Drug Company (Mumbai)
9) Shilpachem (Indore)
10) Hamdard Laboratories (Delhi)
11) Shri Baidyanath Ayurved Bhavan (Patna)
12) Charak Pharmaceuticals (Mumbai)
13) Cipla Research Centre and Factory (Bengaluru)
14) Government Quinine Factory (Mungpoo)
15) Vicco Laboratories (Nagpur)
16) Nagarjuna Herbal Concentrates (Kerala)
17) Shree Dhootapapeshwar Ltd (Mumbai)
18) Sandu Pharmaceutical Ltd (Goa)
19) Patanjali Ayurved (Haridwar)
20) Shri Shri Ayurved (Bengaluru)
21) Biocon India Pvt. Ltd (Bengaluru)
22) Emami Group (Guwahati)
23) Ayur Herbals (Delhi)
24) Zandu Pharmaceuticals (Kolkata)

List of Herbal Research Institutes / centres in India

1) CCRAS (Central Council for Research in Ayurved and Siddha) (New Delhi).
2) RRL (Regional Research Laboratory) (Jammu-Tavi)
3) National Botanical Research Institute (Lucknow)
4) Gujarat Ayurveda University (Jamnagar)
5) National Institute of Ayurveda (Jaipur)
6) Arya Vaidya Shala (Kottakal)
7) Interdisciplinary school of Health Sciences (Pune)
8) BHU (Varanasi)
9) Indian Council for Medical Research (ICMR) - New Delhi
10) National Medicinal Plants Board (New Delhi)
11) Indian Drugs Manufacturers (Mumbai)
12) Central Council for Research in Unani Medicine (Delhi)
13) National Institute of Science Communication (Delhi)
14) ACARTS (Mumbai)
15) Bhavan's SPARC (Mumbai)
16) Zandu Foundation (Mumbai)
17) Pharmexcil (Hyderabad)
18) Central Drug Research Institute (Lucknow)
19) Botanical Survey of India (Kolkata)

Schedule T - GMP of Indian Medicine Systems

Schedule T describes the Good Manufacturing Practices for Ayurvedic, Siddha and Unani Medicines.

Objectives of GMP - shedule T

1) To describe the manufacturing processes as per the standards.
2) To ensure that the manufactures use authentic raw materials of prescribed quality and free from contamination.
3) Adequate quality control measures are adopted during processing of drugs.
4) To ensure that the manufactured drug is of prescribed quality before being released for sale.
5) To maintain documentation of the procedure as a manual for reference and inspection.

Components of GMP - shedule T

The manufacturing plant should have sufficient space for different purposes, like manufacturing process areas, quality control section, finished goods store, offic for receiving and storing raw materials and an offic for rejected goods/drugs store.

(A) Infrastructural Requirements

1) The premises should be located and surrounded where there is no open sewage or no excessive soot, smoke and dust.
2) Building should be compatible with manufacturing operations.
3) There should be proper drainage system.
4) There should be proper water supply within the premises because large amount of water is required for washing the premises and containers used in the manufacturing processes.
5) Waste should be disposed off after proper treatment as described in the guidelines issued by the Pollution Control Board,
6) The containers used in the manufacturing processes should be washed, cleaned and dried properly.

(B) Working Space

1) The manufacturing area should be spacious enough to provide adequate space for manufacturing and quality control processes
2) Adequate measures should be taken to prevent cross-contamination of one drug by another drug being manufactured, stored or handled in the same premises.

(C) Storage Area

The storage area should be spacious enough for proper storing of raw materials, finished products and packing materials (bottles, jars, capsules, etc.)

(D) Machinery and Equipment

1) Machinery and equipment should be according to the size of operation and nature of manufactured product.

2) Adequate space should be available between two machines or rows of machines for easy and proper movement of workers and orderliness in operations.

(E) Standard Operating Procedures (SOPs)

Proper SOPs should be established for cleaning, maintenance and performance of every machine as per the given standards.

(F) Health and Hygiene

1) All the employees in the factory should be healthy and free from any infectious diseases.
2) Clothing and other apparels of workers should be clean.

(G) Medical services

1) Annual medical check-up of all the workers.
2) At the time of recruitment, a medical examination of the workers should be performed.
3) All the records regarding the health and check-ups of each worker should be maintained.

(H) Documentation and Records

1) Records should be maintained for the raw materials used, quantity obtained from the store, tests conducted during manufacturing.
2) It is important to maintain a record of date, manpower, machine, and equipment used.
3) All the manufacturing records should be signed by the production and quality control personnel.
4) Records should be maintained for sale and distribution of each batch of ASU drugs.
5) A complain register should be maintained for keeping records of the received market complaints related to the products sold in the market.

(I) Quality Control

1) Facilities for quality control should be provided by each licensee either in his own premise or in a government testing laboratory.
2) The quality control tests should be performed as per the standards of Ayurveda, Siddha and Unani (ASU) Pharmacopoeia.