Scope: This subject gives the student the knowledge of basic understanding of the herbal drug industry, the quality of raw material, guidelines for quality of herbal drugs, herbal cosmetics, natural sweeteners, nutraceutical, etc. The subject also emphasizes Good Manufacturing Practices (GMP), patenting, and regulatory issues of herbal drugs.

Objective: Upon completion of this course the student should be able to:
1. Understand raw material as a source of herbal drugs from cultivation to herbal drug product
2. Know the WHO and ICH guidelines for the evaluation of herbal drugs.
3. Know the herbal cosmetics, natural sweeteners, nutraceuticals.
4. Appreciate patenting of herbal drugs, GMP.

Teaching and assessment scheme:

<table>
<thead>
<tr>
<th>Teaching Scheme (Hours)</th>
<th>Credits</th>
<th>Theory/ Tutorial Marks</th>
<th>Practical Marks</th>
<th>Total Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Theory</td>
<td>3</td>
<td>10</td>
<td>15</td>
<td>150</td>
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<tr>
<td>Tutorial</td>
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<tr>
<td>Practical</td>
<td>4</td>
<td>75</td>
<td>35</td>
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</tr>
</tbody>
</table>

Theory syllabus:

Unit-1 11 Hours

Unit-2 7 Hours

Unit-3 10 Hours
Herbal Cosmetics: Sources and description of raw materials of herbal origin used via, fixed oils, waxes, gums colours, perfumes, protective agents, bleaching agents, antioxidants in products such as skin care, hair care, and oral hygiene products. Herbal excipients: Herbal Excipients – Significance of substances of natural origin as excipients –colorants, sweeteners, binders, diluents, viscosity builders, disintegrants, flavors & perfumes. Herbal formulations: Conventional herbal formulations like syrups, mixtures, and tablets and Novel dosage forms like phytosomes.
**Unit-4**

**Evaluation of Drugs**: WHO & ICH guidelines for the assessment of herbal drugs. Stability testing of herbal drugs. Patenting and Regulatory requirements of natural products: Definition of the terms: Patent, IPR, Farmers right, Breeder’s right, Bioprospecting, and Biopiracy. Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma & Neem.

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

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**Unit-5**

**General Introduction to Herbal Industry**: Herbal drugs industry: Present scope and 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 equipment, standard operating procedures, health and hygiene, documentation, and records.

Tutorials will be based on the above syllabus.

Teaching hours: 15 Hours

**Practical syllabus**:  
Teaching hours: 04 Hours/week

1. To perform preliminary phytochemical screening of crude drugs.
2. Determination of the alcohol content of Asava and Arista.
3. Evaluation of excipients of natural origin.
4. Incorporation of a prepared and standardized extract in cosmetic formulations like creams, lotions, and shampoos and their evaluation.
5. Incorporation of a prepared and standardized extract in formulations like syrups, mixtures, and tablets and their evaluation as per Pharmacopoeial requirements.
6. Monograph analysis of herbal drugs from recent Pharmacopoeias.
7. Determination of Aldehyde content.
8. Determination of Phenol content.

**Recommended References (Latest edition)**:

1. Textbook of Pharmacognosy by Trease & Evans.
2. Textbook of Pharmacognosy by Tyler, Brady & Robber.
3. Pharmacognosy by Kokate, Purohit, and Gokhale.
4. Essential of Pharmacognosy by Dr. S. H. Ansari.
5. Pharmacognosy & Phytochemistry by V. D. Rangari.
6. Pharmacopoeial standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)