Syllabus BP603T. Herbal Drug Technology (Theory)

(45 hours)

Scope

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

Objectives

Upon completion of this course the student should be able to:

- 1. Understand raw material as source of herbal drugs from cultivation to herbal drug product.
- 2. Know the WHO and ICH guidelines for evaluation of herbal drugs.
- 3. Know the herbal cosmetics, natural sweeteners, nutraceuticals.
- 4. Appreciate patenting of herbal drugs, GMP.

Course Contents

Unit 1.....(11 Hours)

Herbs as raw materials: Definition of herb, herbal medicine, herbal medicinal product, herbal drug preparation Source of Herbs. Selection, identification and authentication of herbal materials Processing of herbal raw material.

Biodynamic Agriculture: Good agricultural practices in cultivation of medicinal plants including Organic farming. Pest and Pest management in medicinal plants: Biopesticides/Bioinsecticides.

Indian Systems of Medicine: Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy, Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas, Ghutika, Churna, Lehya and Bhasma.

Unit 2...... (7 Hours)

Nutraceuticals: General aspects, Market, growth, scope and types of products available in the market. Health benefits and role of Nutraceuticals in ailments like Diabetes, CVS diseases, Cancer, Irritable bowel syndrome and various Gastro intestinal diseases.

Study of following herbs as health food: Alfaalfa, Chicory, Ginger, Fenugreek, Garlic, Honey, Amla, Ginseng, Ashwagandha, Spirulina

Herbal-Drug and Herb-Food Interactions: General introduction to interaction and classification. Study of following drugs and their possible side effects and interactions: Hypercium, kava-kava, Ginkobiloba, Ginseng, Garlic, Pepper and Ephedra.

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 and perfumes.

Herbal formulations: Conventional herbal formulations like syrups, mixtures and tablets and Novel dosage forms like phytosomes.

Unit 4...... (10 Hours)

Evaluation of Drugs: WHO and 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 and Neem.

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

Unit 5...... (07 Hours)

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.

Contents

Preface	
Acknowledgement	ix
Syllabus	x
Unit 1	1
Unit 2	23
Unit 3	55
Unit 4	77
Unit 5	109
References	133