GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm

SEMESTER: II

Subject Name: Standardization and Validation of Phytomedicines
Subject Code: MPM202T

Scope: This subject deals with the quality control of herbal products which covers factors affecting the same and various physicochemical, analytical and biological methods with qualitative and quantitative approach in context to recent developments.

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

1. Describe factors affecting the quality of herbal drugs
2. Understand and discuss various physicochemical test parameters for phytomedicines.
3. Discuss and analyze various modern analytical test methods and parameters for herbal products
4. Describe biological assay based quality parameters of herbal products
5. Discuss and compare quality parameters of various regulatory bodies.

Sr No	Course Contents	Total Hrs
1	**Factors affecting quality of plant drugs:** Safe and economical methods for documentation and preservation of herbs and herbal products, detection of common adulterants, microbial contamination, toxic trace metals, pesticides and insect infestation in whole and powdered drugs, substitution and misidentification Need for standardization, issues related to herbal medicines.	10
2	**Determination of physical parameters:** Procedures, total ash, acid insoluble ash, water- soluble ash, extractive values of herbal drugs, moisture content determination and loss on drying of herbal drugs, determination of bitterness value, haemolytic activity, and foaming index, swelling index of gum and mucilage containing drugs. **Oil content:** Determination of volatile oil content herbal drugs, procedure apparatus, methods, estimation of fixed oils and lipids of herbal drugs. **Phytochemical assays:** Estimation of tannins, phenols and flavanoids, glycosides and vitamins in herbal drugs with methods and examples. **Limit tests:** Heavy metals in herbal drugs, microbial contamination of crude drugs and its detection, pesticide residues, aflatoxin. Elemental analysis	12
3	**Quantitative assays for extraction efficiency:** Active component analysis of carbohydrates, peptides & proteins, glycosides and lipids.	15

	Purity determination using UV, GC, HPLC and electrophoretic methods. Quality control of various types of official formulations including Ayurvedic preparations. HPTLC & HPLC fingerprint identification of crude drugs/raw material or congeners or their single or multi-component preparations, recognition and evaluation of fingerprints. **Markers and biomarkers:** Concept and their importance in standardization of herbal drugs, analytical method development and estimation of alkaloids, steroids, carbohydrates, polypeptides/ proteins of herbal drugs.	
4	**Potency assays** :pharmacological tests, cell line-derived assays, in-vitro biochemical tests **Stability testing of natural products:** Procedures, predictable chemical & galenical changes, technical limitations, testing methods, combination products. **Bioavailability and pharmacokinetics aspects** of herbal drugs with examples of well-known documented clinically used herbal drugs.	12
5	**Importance of monographs on standards of medicinal plants and their parts:** Comparative study of British Herbal Pharmacopoeia (BHP), Ayurvedic Pharmacopoeia of India (API), Chinese, Japanese and European Pharmacopoeias, US Formulary. WHO, EMEA and ESCOP guidelines for herbal medicinal products. Preparation of Drug Master File (DMF) for herbal medicines	10

REFERENCES:

1. Trease and Evans Pharmacognosy by William Charles Evans
2. Quality Control Methods for Medicinal Plant Materials by World Health Organization (WHO) Publication, Geneva; 1998.
3. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants, WHO Publication, Geneva; 2003.
4. National Policy on Traditional Medicine and Regulation of Herbal Medicines, A WHO Publication, Geneva; 2005.
5. Ayurvedic Pharmacopoeias of India, Latest editions
6. Quality Standards of Indian Medicinal Plants, Indian Council of Medical Research, New Delhi
7. Herbal monographs in Indian Pharamcopoeia
8. Ayurvedic Formulary of India
9. Drugs and Cosmetics Act 1940 and rules there under,
10. Quality control of herbal drugs by Pulok K Mukarjee (2002), Business Horizons Pharmaceutical Publisher, New Delhi.

11. ICH guidelines for stability testing
12. Indian Herbal Pharmacopoeia
13. Research and Review articles published in UGC –CARE approved journals regarding standardization/quality control and other aspects