

Subject Code: BP806ET	Subject Title: QUALITY CONTROL AND STANDARDIZATION OF HERBALS - THEORY
Pre-requisite Subject	- NONE -

Scope: In this subject the student learns about the various methods and guidelines for evaluation and standardization of herbs and herbal drugs. The subject also provides an opportunity for the student to learn cGMP, GAP and GLP in traditional system of medicines.

Objectives: Upon completion of the subject student shall be able to;

1. know WHO guidelines for quality control of herbal drugs
2. know Quality assurance in herbal drug industry
3. know the regulatory approval process and their registration in Indian and international markets
4. appreciate EU and ICH guidelines for quality control of herbal drugs

Teaching Scheme (Hours per week)				Evaluation Scheme (Marks)		
Lecture	Tutorial	Practical	Credit	Theory(T)		Total Marks
				University Assessment	Continuous Assessment	
3	1	NA	4	75	25	100

Sr. No.	Subject Contents	Total Hours (45 hours)	Weight (%)
	Topic		
1	UNIT-I Basic tests for drugs – Pharmaceutical substances, Medicinal plants materials and dosage forms WHO guidelines for quality control of herbal drugs Evaluation of commercial crude drugs intended for use	10	22
2	UNIT-II Quality assurance in herbal drug industry of cGMP, GAP, GMP and GLP in traditional system of medicine. WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines WHO Guidelines on GACP for Medicinal Plants	10	22
3	UNIT-III EU and ICH guidelines for quality control of herbal drugs Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines	10	22
4	UNIT-IV Stability testing of herbal medicines. Application of various chromatographic techniques in standardization of herbal products. Preparation of documents for new drug application and export registration GMP requirements and Drugs & Cosmetics Act provisions	08	18
5	UNIT-V Regulatory requirements for herbal medicines WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems	07	16

	Comparison of various Herbal Pharmacopoeias Role of chemical and biological markers in standardization of herbal products		
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Recommended Books (Latest Editions)

1. Pharmacognosy by Trease and Evans.
2. Pharmacognosy by Kokate, Purohit and Gokhale.
3. Rangari, V.D., Text book of Pharmacognosy and Phytochemistry Vol. I, Carrier Pub., 2006.
4. Aggrawal, S.S., Herbal Drug Technology. Universities Press, 2002.
5. EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products.
6. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.
7. Shinde M.V., Dhalwal K., Potdar K., Mahadik K. Application of quality control principles to herbal drugs. International Journal of Phytomedicine 1(2009); p. 4-8.
8. WHO. Quality Control Methods for Medicinal Plant Materials, World Health Organization, Geneva, 1998. WHO. Guidelines for the Appropriate Use of Herbal Medicines. WHO Regional Publications, Western Pacific Series No 3, WHO Regional office for the Western Pacific, Manila, 1998.
9. WHO. The International Pharmacopeia, Vol. 2: Quality Specifications, 3rd edⁿ. World Health Organization, Geneva, 1981.
10. WHO. Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999.
11. WHO. WHO Global Atlas of Traditional, Complementary and Alternative Medicine. 2 vol. set. Vol. 1 contains text and Vol. 2, maps. World Health Organization, Geneva, 2005.
12. WHO. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.