

## B. PHARMACY

### Syllabus ♦ Semester-8

**Elective subject-4** name with code: **13PH0806 Quality Control and Standardization of Herbals**

#### Course Objective

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

#### Course Outcomes

Upon completion of the course, the student shall be able to

1. Know WHO guidelines for quality control of herbal drugs.
2. Know Quality assurance in the 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 and assessment scheme

Teaching Scheme (Hours)			Credits	Theory/ Tutorial Marks			Practical Marks		Total Marks
Theory	Tutorial	Practical		CSE	IA (I)	ESE (E)	TW	Viva (V)	
3	1	0	4	10	15	75	0	0	100

#### Theory syllabus

**Teaching hours: 45 Hours**

##### Unit-1

**10 Hours**

**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.

##### Unit-2

**10 Hours**

**Quality assurance in the herbal drug industry:** 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.

##### Unit-3

**10 Hours**

**EU and ICH guidelines:** for quality control of herbal drugs. Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines

##### Unit-4

**8 Hours**

**Stability testing of herbal medicines.** Application of various chromatographic techniques in the standardization of herbal products. Preparation of documents for new drug application and export registration. GMP requirements and Drugs & Cosmetics Act provisions.

##### Unit-5

**7 Hours**

**Regulatory requirements for herbal medicines:** WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems Comparison of various Herbal Pharmacopoeias. Role of chemical and biological markers in standardization of herbal products.

**Tutorials will be based on the above syllabus.**

**Teaching hours: 15 Hours**

#### Recommended references (Latest edition)

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Rangari, V.D., Textbook of Pharmacognosy and Phytochemistry Vol. I, Carrier Pub., 2006.
4. Agrawal, 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 Pharmacopoeia, Vol. 2: Quality Specifications, 3rd ed. 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.