

**NIRMA UNIVERSITY**  
**Institute of Pharmacy**

**(B. Pharm)**  
**(Semester - VIII)**

L	T	P	C
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Course Code	BP806ET
Course Title	Quality Control And Standardization Of Herbals –Theory

**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

**Course Learning Outcomes (CLO):**

At the end of the course, students will be able to -

7. Understand WHO, EU and ICH guidelines for quality control of herbal drugs and comparison of pharmacopoeias
8. Describe various quality assurance parameters in herbal drug industry.
9. Illustrate the guidelines for evaluating the safety monitoring and efficacy of herbal medicines
10. Relate the applications of various chromatographic techniques and stability testing for standardization of herbal extracts/formulations.
11. Develop the understanding of regulatory requirements for herbal medicines

**Syllabus:**

**Teaching hours: 45 Hours**

**Unit I**

**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 II**

**12 hours**

**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.  
WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems

**Unit III**

**10 hours**

EU and ICH guidelines for quality control of herbal drugs.

**Unit IV** **08**  
**hours**

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. **Guidelines for Phytopharmaceutical Drugs and AYUSH**

**Unit V** **05**  
**hours**

Regulatory requirements for herbal medicines.

Role of chemical and biological markers in standardization of herbal products

Comparison of various Herbal Pharmacopoeias

**Tutorials** **Teaching hours: 15**  
**hours**

Tutorials will be based on syllabus

**Suggested Readings^: (Latest Editions)**

1. Evans, W. C. (2009). Trease and Evans' Pharmacognosy E-Book. Elsevier Health Sciences.
2. Kokate, C. K., Purohit, A. P., & Gokhale, S. B. (2007). Hand Book of Pharmacognosy.
3. Agrawal, S. S., & Paridhavi, M. (2007). *Herbal drug technology*. Hyderabad: Universities Press Private Limited.
4. European Medicines Agency. (2011). Guideline on Quality of Herbal Medicinal Products/Traditional Herbal Medicinal Products.
5. Pulok, K. M., & Mukherjee, K. (2002). Quality control of herbal drugs. *An approach to evaluation of botanicals*. New Delhi: Business Horizons-Pharmaceutical Publishers.
6. Shinde, V. M., Dhalwal, K., Potdar, M., & Mahadik, K. R. (2009). Application of quality control principles to herbal drugs. *International Journal of Phytomedicine*, 1(1). pp 4-8.
7. World Health Organization. (1998). Guidelines for the appropriate use of herbal medicines.
8. World Health Organization. (1998). Quality control methods for medicinal plant materials.
9. World Health Organization. (1981). *The International Pharmacopoeia. Vol. 2. Quality specifications* (Vol. 2, No. 3rd edition). Geneva, Switzerland.
10. Bodeker, G., & Ong, C. K. (2005). *WHO global atlas of traditional, complementary and alternative medicine* (Vol. 1). World Health Organization.
11. World Health Organization. (2009). Guidelines on Good Agricultural and Collection Practices (GACP) for medicinal plants; 2003. Available: <http://whqlibdoc.who.int/publications/2003/9241546271> (Accessed on 3 September, 2009).

L= Lecture, T= Tutorial, P= Practical, C= Credit

^ this is not an exhaustive list