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|---|---|
| **INSTITUTE** | **FACULTY OF PHARMACY** |
| **PROGRAM** | **BACHELOR OF PHARMACY** |
| **SEMESTER** | **8** |
| **COURSE TITLE** | **QUALITY CONTROL AND STANDARDIZATION OF HERBALS** |
| **COURSE CODE** | **13PH0806** |
| **COURSE CREDITS** | **4** |

**Objective:**

1 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:** After completion of this course, student will 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.

5 Appreciate EU and ICH guidelines for quality control of herbal drugs.

6 Know the regulatory approval process and their registration in Indian and international markets.

**Pre-requisite of course:**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.

**Teaching and Examination Scheme**

| Theory Hours | Tutorial Hours | Practical Hours | ESE | IA | CSE | Viva | Term Work |
|---|---|---|---|---|---|---|---|
| 3 | 1 | 0 | 75 | 15 | 10 | 0 | 0 |

| Contents : Unit | Topics | Contact Hours |
|---|---|---|
| 1 | **Basic tests for drugs**<br>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 |

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**Digitally signed by (Name of Dean/ Principal)**

| Contents : Unit | Topics | Contact Hours |
|---|---|---|
| 2 | **Quality assurance in the herbal drug industry**<br>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. | 10 |
| 3 | **EU and ICH guidelines**<br>EU and ICH guidelines: for quality control of herbal drugs. Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines | 10 |
| 4 | **Stability testing of herbal medicines.**<br>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. | 8 |
| 5 | **Regulatory requirements for herbal medicines**<br>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. | 7 |
| **Total Hours** | | **45** |

**Suggested List of Experiments:**

| Contents : Unit | Topics | Contact Hours |
|---|---|---|
| 1 | **Tutorials**<br>Tutorial 1, Tutorial 2, Tutorial 3, Tutorial 4, Tutorial 5, Tutorial 6, Tutorial 7, Tutorial 8, Tutorial 9, Tutorial 10, Tutorial 11, Tutorial 12, Tutorial 13, Tutorial 14, Tutorial 15 | 15 |
| **Total Hours** | | **15** |

**Textbook :**

1 Pharmacognosy, by , Trease and Evans, 2009

**References:**


1 Pharmacognosy by Kokate, Purohit and Gokhale

2 Rangari, V.D., Textbook of Pharmacognosy and Phytochemistry Vol. I, Carrier Pub., 2006.

3 Agrawal, S.S., Herbal Drug Technology. Universities Press, 2002.

4 EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products,

5 Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.

**References:**


6 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.

7 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.

8 WHO, The International Pharmacopeia, Vol. 2: Quality Specifications, 3rd ed. World Health Organization, Geneva, 1981.

9 WHO, Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999.

10 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.

11 WHO, Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.


**Suggested Theory Distribution:**

The suggested theory distribution as per Bloom's taxonomy is as follows. This distribution serves as guidelines for teachers and students to achieve effective teaching-learning process

| Distribution of Theory for course delivery | | | | | |
|---|---|---|---|---|---|
| **Remember / Knowledge** | **Understand** | **Apply** | **Analyze** | **Evaluate** | **Higher order Thinking / Creative** |
| 20.00 | 30.00 | 25.00 | 15.00 | 10.00 | 0.00 |

**Instructional Method:**

1 The course delivery method will depend upon the requirement of content and the need of students. The teacher in addition to the conventional teaching method by the blackboard may also use any tools such as demonstration, role play, quiz, brainstorming, MOOCs etc

2 The internal evaluation will be done based on continuous evaluation of students in the laboratory and classroom.

3 Students will use supplementary resources such as online videos, NPTEL videos, MOOCs/ e-courses, virtual laboratories.

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