Gujarat Technological University

Master of Pharmacy

Semester – II

Paper code -2920107

Specialization paper – III

PHARMACEUTICAL ANALYSIS SPECIALISATION

PHARMACEUTICAL ANALYSIS II

Theory

(Six hours per week, 7 credits)

1. Preparation of drug samples for analysis: Pharmaceutical samples, fundamental theories controlling preparation techniques, specific sample preparation techniques. **04 Hrs**

2. A detailed study of the principles, instrumentations and applications in drug analysis of: GC-MS, LC-MS with reference to drug metabolism, toxicologic and forensic studies, diagnosis of disease state, quantification of drugs in biological samples, counter current chromatography; Super critical fluid chromatography and size exclusion chromatography **20Hrs**

3. Analytical methods for the analysis of protein and its product: Amino acid sequence analysis, HPLC,Tryptic maping, ion exchange amino acid analysis, isoelectric focusing and other electrophoretic techniques. **7 Hrs**

4. A detailed study of the various principles and procedure involved in the quantitative analysis of pharmaceutical preparations and dosage forms containing the following groups of drugs included in I.P. (Biological and microbiological methods excluded)
   (a) Analgesics and Antipyretics (b) Sedatives & Tranquillizers
   (c) Antihypertensives (d) Antihistaminics
   (e) Cardiovascular drugs (f) Antidiabetics **7 Hrs**

5. Solid state analysis of drug substance including a detailed study on related substances and impurities present in drugs and their effect on drug stability and therapeutic action.
   ICH guidelines for impurity and related substances determination in drugs. **6Hrs**

6. Methods of systematic phytochemical analysis including extraction and identification of plant constituents using chromatographic techniques.
   Quality control of crude drugs : proximate analysis including ash and extractive values, crude fibre content, U.V. and fluorescence analysis of powdered drugs.
   WHO guidelines for the quality control of raw materials used in herbal formulations.
   Analysis of official formulations derived from crude drugs including some Ayurvedic preparations. **14 Hrs**

7. Automated analysis **02Hrs**

Specialization paper – III
Pharmaceutical Analysis II
Practical
(Six hours per week, 8 credits)

1. Determination of active constituents in crude drugs. e.g. Caffiene from tea powder, curcumin from curcuma longa, quinine from cinchona bark etc.
2. Determination of extractive values of crude drugs.
3. Determination of Rf values of different amino acids and alkaloids.
4. Assay of Ibuprofen Tablet I.P., Tolbutamide Tablet I.P., Calcium Lactate and Ferrous Fumerate I.P.
5. Quality control Tests for Tablets, Capsules, Injections, Ointments and Suppositories.
7. Determination of related substances in Albendazole, Amiloride, Metronidazole, Betamethazone, Carbamazepine, Diclofenac, Ephedrine, Ibuprofen, Paracetamol, Eucalyptus oil, Phenylbarbitone and Sulphafurazone, Rifampicin as per I.P.
8. Quality Control tests for some herbal formulations.

References Books:

1. Harry G Brittain, Spectroscopy of Pharmaceutical Solids, Drugs and Pharm Sci.Series, Vol. 160, Taylor and Francis, 2006 N.Y.
2. Lena Ohannesian and Anthony J. Streeter, Hand Book of Pharmaceutical Analysis, Pharm Sci. series, Vol. 117, Maarcel Dekker Inc., N.Y
3. Peptide and Protein Drug Analysis, by Reid,(Marcel Dekker).
4. Pharmaceutical Analysis – Modern Methods – Part A, Part B, James W. Munson – 2001.
5. A text book of Pharmaceutical analysis by K.A.Conners (John Wiley)
6. Indian Pharmacopoeia,Vol. I and Vol. II - 2010.The Controller of Publications; New Delhi, Govt. of India,
7. The International Pharmacopoeia Vol 1,2,3,4, 3rd Edition General methods of analysis and quality specifications for pharmaceutical substances, excipients, dosage forms.
8. Quality Assurance of Pharmaceuticals – A compendium of guidelines and related materials Vol.1 and Vol.2, WHO, (1999)
9. Basic tests for pharmaceutical substances – WHO (1988)
10. Basic tests for pharmaceutical dosage forms – WHO (1991)
11. Phytochemical Methods by J.B.Haroborne
12. Pharmacopoeial standards for Ayurvedic Formulation (Council of Research in Indian
13. Medicine & Homeopathy)
14. ICH guideline for impurity determination and stability studies.
15. WHO guide lines for the quality control of Herbal plant materials.
16. The Practical evaluation of phytopharmaceutical by Brain & Turner.
17. Indian Herbal Pharmacopoeia, Vol.1&2, RRL, IDMA, 1998, 2000.
18. Ayurvedic Formulary of India.
19. British Herbal Pharmacopoeia.