SEMESTER-III (Pool-B)

COURSE NAME : Drug Analysis

(CHOI-B17)

Number of Credit: - 02 **Maximum marks: 50**

Paper… : CHOI-B… : Drug Analysis

Contact Hours/Week	**:** 04 Hours/Week	**Maximum Marks**	**:** 50 Marks
Total Hours/Semester	**:** 60 Hours/Semester	**Minimum Pass Marks**	**:** 20 Marks
Duration of Examination	**:** 04 Hours/Paper	**Nature of Examination**	**:** Practical

Conduction of Examination: End semester examination will not be conducted at university level. It will be conducted internally at the department/college level after completion of the semester. Marks/grades will be filled by the concern department/college and hard copy of the same will be sent to the University for declaration of result.

Distribution of Marks:

S. No.	Name of Exercise	Marks
1.	Exercise No. 1	15
2.	Exercise No. 2	15
3.	Practical Record	05
4.	Good Laboratory Skills and Regularity in Practicals	05
5.	Comprehensive Viva-voce	10
	Total Marks	**50**

Theory:

Purity of Substances/Products: Introduction, official standards, official compendia, description of drugs/products, sampling procedures. Hierarchy of analytical methodology (technique, method, procedure, protocol).

Errors: Errors in chemical analysis, classification of errors, rejection of results, presentation of data.

Limit Tests: Introduction, types, limit tests for metallic, non-metallic and acid radical impurities.

Validation Process: Selectivity, linearity, accuracy, precision, sensitivity, range, limit of detection, limit of quantification, ruggedness or robustness.

Quality Assurance: Control charts, documenting and archiving, proficiency testing, laboratory accreditation. Regulatory control.

Quantitative Analysis: Volumetric analysis, gravimetric analysis and biomedical analysis.

Chemical Methods: Titrimetric Methods: Aqueous and Non-aqueous titrations. Redox Methods: Iodimetry, Iodometry. Precipitation Methods: Argentometry. Complexometric

Methods: Complexometry. Gravimetric Methods: Gravimetry. Thermoanalytical Methods: DSC, TGA, DTA, TT.

Electrochemical Methods: Potentiometry, Amperometry.

Optical Methods: Refractometry, Polarimetry, Nephelometry and Turbidimetry, Flame photometry.

Separation Methods: Liquid-liquid extraction, Thin Layer Chromatography, Column Chromatography, Gas Chromatography, High Performance Liquid Chromatography, Size Exclusion Chromatography.

Spectral Methods: AAS, UV-VIS, IR, NMR, LC-MS.

Miscellaneous Methods: Radioimmunoassay.

Practical:

1. Calibration of glassware and instruments.
2. Separation of various active pharmaceutical ingredients by chromatographic techniques.
3. Structure elucidation of various active pharmaceutical ingredients by using spectral techniques.
4. Limit tests for metallic (Pb, As, Fe), non-metallic (boron, free halogen, selenium) and acid radicals (chlorides, sulfates, arsenates, cyanides, nitrates, carbonates, oxalates, phosphates) impurities.
5. Complete assay some drugs like paracetamol, phenacetin, aspirin, ibuprofen, diclofenac, fluconazole, chloroquine, diazepam, quetiapine, propranolol, losartan, tamoxifen, zidovudine, sulphadiazine, *etc*.
6. Assay of sodium, potassium and calcium in blood serum and water.
7. Assay of barium, potassium and sodium in calcium acetate.
8. Assay of total zinc in insulin zinc suspension.
9. Assay of palladium in carbenicillin sodium.
10. Estimation of mixture of benzoic acid/salicylic acid/iron in pharmaceutical preparation.
11. Estimation of sodium hydroxide, sodium bicarbonate and sodium carbonate in drugs by using various titrimetric techniques.
12. Estimation of ascorbic acid.
13. Estimation of benzoic acid in ointment.
14. Estimation of isoniazid and sodium benzoate.
15. Estimation of riboflavin/quinine sulphate.
16. Determination of salicylic acid in aspirin.
17. Determination of 4-aminophenol in paracetamol.
18. Determination of digitonin in digitoxin.
19. Determination of aspirin, phenacetin and caffeine in drug tablets.
20. Determination of copper(I), lead(I), Ni(II), Iron(III) and molybdenum(VI) by solvent extraction method.
21. Determination of moisture in drug samples by Karl-Fischer titration.
22. Determination of viscosity of ointment / syrup / liquid, *etc*.
23. Determination of dissociation constant of indicators.
24. Determination of chlorides and sulphates in calcium gluconate.

25. Determination of pKa using pH meter.
26. Determination of Na/K by Flame Photometry.
27. Determination of refractive index of various pharmaceutical substances.
28. Determination of optical rotation of various pharmaceutical substances.
29. Study of effect of pH and solvent on the UV spectrum of given compound.
30. Simultaneous estimation of two drugs presents in the given formulation.
31. Radioimmunoassay of morphine, clonazepam, flurazepam, chlordiazepoxide, barbiturates in human plasma.

Books:

- Quantitative Drug Analysis by Garrot. D, Chapman & Hall Ltd., London.
- Textbook of Pharm. Analysis (Practical) by Beckett &Stenlake, CBS Publishers, Delhi.
- Textbook of Drug Analysis by P.D. Sethi, CBS Publishers, Delhi.
- Pharmaceutical Drug Analysis by Ashutosh Kar, New Age International (P) Ltd., New Delhi.