**IKG PUNJAB TECHNICAL UNIVERSITY, JALANDHAR**
**M. Pharm. (Pharmaceutical Analysis)**
**Scheme and Syllabus**

**FIRST SEMESTER**

| S. No. | Subject Code | Subject Title | Teaching Load Allocation (hr) | | | Marks Distribution | | | Exam. (hr) | Credit |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | L | T | P | Int | Ext | Total | | |
| 01 | PHANL 131 | Pharmaceutical Analytical Techniques | 4 | 1 | - | 20 | 80 | 100 | 3 | 5 |
| 02 | PHANL 133 | Spectral Analysis | 4 | 1 | - | 20 | 80 | 100 | 3 | 5 |
| 03 | PHANL 135 | Advanced Spectroscopic Techniques | 4 | 1 | - | 20 | 80 | 100 | 3 | 5 |
| 04 | PHANL 137 | Pharmaceutical Analysis Laboratory – I | - | | 14 | 20 | 80 | 100 | 8 | 7 |
| | | **Total** | **12** | **03** | **14** | **80** | **320** | **400** | | **22** |

**SECOND SEMESTER**

| S. No. | Subject Code | Subject Title | Teaching Load Allocation | | | Marks Distribution | | | Exam. (hr) | Credit |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | L | T | | Int | Ext | Total | | |
| 01 | PHANL 132 | Advanced Pharmaceutical Techniques | 4 | 1 | - | 20 | 80 | 100 | 3 | 5 |
| 02 | PHANL 134 | Biological Standardization | 4 | 1 | - | 20 | 80 | 100 | 3 | 5 |
| 03 | PHANL 136 | Quality Control & Quality Assurance | 4 | 1 | - | 20 | 80 | 100 | 3 | 5 |
| 04 | PHANL 138 | Pharmaceutical Analysis Laboratory-II | - | | 14 | 20 | 80 | 100 | 8 | 7 |
| | | **Total** | **12** | **03** | **14** | **80** | **320** | **400** | | **22** |

**THIRD AND FOURTH SEMESTER [Credits 12+12=24]**

Research Work for one year
The thesis shall be presented by the candidate at the end of record academic year
The thesis shall be evaluated as under:
Evaluation of written thesis : MM 200
Presentation of seminar on thesis : MM 100 and viva-voce
Total : 300 marks
**[Note: L- Lecture – Tutorial, P – Practical]**

**M. PHARM. (Pharm Analysis) SEMESTER-I**

| S. No. | Subject Code | Subject Title | Teaching Load Allocation | | | Marks Distribution | | | Credit |
|---|---|---|---|---|---|---|---|---|---|
| | | | L | T | P | Int | Ext | Total | |
| 01 | PHANL 131 | Pharmaceutical Analytical Techniques | 4 | 1 | - | 20 | 80 | 100 | 5 |

**Module 01 and Module 02**

**Separation Techniques:** Chromatography general Principles, Classification, Chromatographic techniques, normal and reversed phase, column chromatography, TLC, counter current chromatography, droplet chromatography, Ion exchange chromatography.

**Gas Chromatography:** Theory & Principles, column operation, instrumentationand Applications in Pharmaceutical analysis.

**High Performance liquid Chromatography:** Theory and Principle, columnoperation instrumentation and application in Pharmaceutical analysis.

**Module 03**

**Electrometric methods of analysis :** Principle, Procedure of Pharmaceutical applications of Conductometric titrations, Amperometric titrations and Controlled potential electrolysis

**Module 04**

**Light scattering methods in quantitative analysis:** Nephelometry and Turbidometry

**Quantitative analysis based on molecular luminescence:** Flourimetry and Phosphorimetry

**Module 05**

**Statistical Analysis Methods**

**Probability:** Introduction, Definition, Importance of the concept of probability, Experiments & Events, Mutually exclusive events, Independent & Dependent events, exhaustive events, complementary events, theoremson Probability, conditional probability, binomial distribution and poison distribution.

**Module 06**

**Correlation:** Introduction, significance, Types of correlation, Karl Pearson'scoefficient of correlation, Rank correlation, merits & limits of the Rank Method.

**Regression:** Introduction, Regression equation of Y on X and Regression equation of X on Y.

**Chi square:** Introduction, definition, conditions for applying chi square & uses of chi square. **F-Test :** Assumptions and Applications.

**ANOVA:** Assumptions, Techniques of Analysis of variance. (one way & two way)

**Calculation of $ED_{50}$, $LD_{50}$ & Probit analysis**

**Reading Material Recommended**


1. K. A. connors, Text book of Pharmaceutical Analysis, 3rd Ed. Johnwiley & sons, New York.
2. Beckett & stanlake, Practical Pharmaceutical Chemistry Part-I & II, 4th Ed.
3. Gerhard Schomburg, Gas Chromatography, VCH, Weinheim, New York.
4. R V Smith, J T Stewart, Textbook of Bio Pharmaceutical Analysis.
5. S P Gupta, Statistical Methods, Sultanchand & Sons, Education Publishers, New Delhi.

| S.No. | Subject Code | Subject Title | Teaching Load Allocation | | | Marks Distribution | | | Credit |
|---|---|---|---|---|---|---|---|---|---|
| | | | L | T | P | Int | Ext | Total | |
| 02 | PHANL 133 | Spectral Analysis | 4 | 1 | - | 20 | 80 | 100 | 5 |

**Module 01**

**Ultraviolet and Visible spectroscopy :** Introduction, energy levels, selection rules; Woodward Fieser, Fieser Kuhn and Nelson rule, Influence of substituents, ring Size and strain on spectra characteristics, solvent effect, methodology, spectral correlation with structure.

**Module 02**

**Infrared Spectroscopy:** Introduction, types of vibrations, characterstics regions of the spectrum, influence of substituents, ring size, hydrogen bonding, vibrational coupling, field effects on frequency, methodology, spectral interpretation with example.

**Module 03 and 04**

**Nuclear Magnetic Resonance spectroscopy:** Introduction, magnetic nuclear, chemical shift, shielding, relaxation process, chemical & magnetic non equivalence, local dia magnetic shielding and magnetic anisotropy, spin splitting, Pascal triangle, coupling constant, mechanism of coupling, quadrapoule broadening and decoupling. Effect of stereochemistry on the spectrum, shift reagent, application of $^{1}$HNMR with some examples. Introduction to the following techniques would be covered DEPT, APT, COSY, NOESY and INADEQUATE.

**Module 05 and 06**

**Mass Spectrometry:** Introduction, Essential components of a mass spectrometer, types of ions, molecular ion, fragment ion, rearrangement ion, metastable ion, Isotopic ions and their corresponding peaks, rules of fragmentation Mc Lafferty rearrangement, Retro Diels Alder and other fragmentation patterns**.** Introduction to FAB, LC-MS, and GC-MS.

**Reading Material Recommended**


1. R. M. Silverstein and F. X. Webster, Spectrometric identification of Organic compounds, John Wiley & Sons, New York. (Latest edition).
2. William kemp, Organic Spectroscopy, ELBS Mac millan, Hampshire, (U. K).
3. D. L. Pavia, G. M. Lampman and G. S. Kriz, Introduction to spectroscopy- A guide for students of Organic chemistry, Harcourt college publishers. (Latest edition).
4. D. H. Williams and I. Fleming, Spectroscopic methods in Organic chemistry, Tata Mc Graw Hill publishing company Ltd, New Delhi, India.

| S. No. | Subject Code | Subject Title | Teaching Load Allocation | | | Marks Distribution | | | Credit |
|---|---|---|---|---|---|---|---|---|---|
| | | | L | T | P | Int | Ext | Total | |
| 03 | PHANL 135 | Advanced Spectroscopic Techniques | 4 | 1 | - | 20 | 80 | 100 | 5 |

**Module 01**

**Atomic Absorption Spectroscopy:** Introduction, Principle, Instrumentation, Differences between Atomic Absorption & Flame Emission Spectroscopy, Advantages & Disadvantages and Applications of Atomic Absorption Spectroscopy.

**Module 02 and Module 03**

**$^{13}$C Nuclear Magnetic Resonance ($^{13}$C – NMR):** Natural abundance of $^{13}$C, resolution and multiplicity FT mode, RF mode, uses of proton coupled, decoupled and off resonance decoupling techniques, deuterium substitution, chemical equivalence in peak assignment, chemical shift, Effect of substitution on chemical shifts, position of alkanes, alkenes, alkynes and benzene spin coupling and $C^{13}$- $H^{1}$ coupling

**Module 04**

**ESR :** Principle and correlation with proton magnetic resonance, derivative curves, g-values, hyperfine splitting, Applications.

**Module 05**

**Raman Spectroscopy:** Introduction, Principle and application of Raman Spectroscopy.

**Module 06**

**Flame Photometry:** Introduction, Instrumentation, Effect of Solvent in Flame Photometry, Applications of Flame Photometry, Interferences in Flame Photometry and Limitations of Flame Photometry

**Reading Material Recommended**


1. R. M. Silverstein and F. X. Webster, Spectrometric identification of Organic compounds, John Wiley & Sons, New York.
2. William kemp, Organic Spectroscopy, ELBS Mac millan, Hampshire, (U. K).
3. D. L. Pavia, G. M. Lampman and G. S. Kriz, Introduction to spectroscopy- A guide for students of Organic chemistry, Harcourt college publishers. (Latest edition).
4. J. March, Advanced Organic Chemistry, Reaction Mechanisum and Structure, John Wiley and Sons, New York.
5. M.E. Wolff, Burger's Medicinal Chemistry, John Willey and Sons. New York.
6. K. A. connors, Text book of Pharmaceutical Analysis, 3rd Ed. Johnwiley & sons, New York.
7. Beckett & stanlake, Practical Pharmaceutical Chemistry Part-I & II, 4th Ed.
8. Kealey and Haines, Analytical Chemistry, Viva Books Pvt. Ltd., New Delhi.

| S. No. | Subject Code | Subject Title | Teaching Load Allocation | | | Marks Distribution | | | Credit |
|---|---|---|---|---|---|---|---|---|---|
| | | | L | T | P | Int | Ext | Total | |
| 04 | PHANL 137 | Pharmaceutical Analysis Laboratory – I | - | | 14 | 20 | 80 | 100 | 7 |

1. Interpretation of spectra of organic compounds- Workshop involving interpretation of IR, NMR and Mass spectra of Organic compounds to elucidate their chemical structure.
2. Basic chromatographic techniques
3. Experiments Based on HPLC and GC
4. Simultaneous estimation of combination formulations.
5. Use of spectrophotometer for analysis for pharmaceutical compounds &their formulations.

**M.PHARMACY (Pharm. Analysis)- SEMESTER II**

| S. No. | Subject Code | Subject Title | Teaching Load Allocation | | | Marks Distribution | | | Credit |
|---|---|---|---|---|---|---|---|---|---|
| | | | L | T | P | Int | Ext | Total | |
| 01 | PHANL 132 | Advanced Pharmaceutical Techniques | 4 | 1 | - | 20 | 80 | 100 | 5 |

**Module 01**

Detection and quantitative determine of preservatives antioxidants, colouring materials, emulsifiers and stabilizers in Pharmaceutical formulations.

**Module 02**

Principles and Procedures involving the use of the following regents in the Pharmaceutical analysis with suitable examples.

- MBTH reagent
- FC (folin-ciocalteu) reagents
- PDAB reagent
- Ninhydrin reagent
- Carr-price reagent
- PDAC reagent
- 2,4-DNP.

**Module 03**

Principle & Procedure involved in quantitative determine of the following functional groups : hydroxyl, carboxyl, aldehyde, Ketone, methoxyl, ester, amine

**Module 04 and 05**

Principle & Procedure involved in the analysis of Preparations & dosage forms containing.

- Alkaloids: Cinchona, Ergot
- Glycosides : Digitoxin & Digoxin
- Vitamins : Vitamin A, $B_1$, $B_2$, $B_{12}$, and C
- Steroids : Esterogen, Androgens and cholesterol
- sulphonamides.

**Module 06**

Validation of analysis methods, calibration of instruments & equipments, quality assurance & raw materials. Elemental analysis such as determine of Na, K, Ca, $P_4$, $S_8$,$Cl_2$.

**Reading Material Recommended**


1. Indian Pharmacopoeia, 2007 Controller of Publications, Govt. of India, New Delhi.
2. Beckett & stanlake, Practical Pharmaceutical Chemistry Part-I & II, 4th Ed.
3. Bochmman & Hassan, Pharmaceutical Analysis, edited by: Higuchi.
4. D C Garrott, Quantitative Analysis of drugs. CBS Publishers, New Delhi.
5. R V Smith, J T Stewart, Textbook of Bio Pharmaceutical Analysis.
6. P D Sethi Quantitative Analysis of Drugs in Pharmaceutical formulations
7. Howard C.Ansel, Michelle J. Stoklosa, Lippincott Williams & Wilkins, Pharmaceutical Calculations.

| S. No. | Subject Code | Subject Title | Teaching Load Allocation | | | Marks Distribution | | | Credit |
|---|---|---|---|---|---|---|---|---|---|
| | | | L | T | P | Int | Ext | Total | |
| 02 | PHANL 134 | Biological Standardization | 4 | 1 | - | 20 | 80 | 100 | 5 |

**Module 01**

Detailed study of principles & procedures involved in bio assay of Heparin, insulin, posterior pituitary, Diphtheria, typhoid

**Module 02**

Principles and Procedures involved in Biological tests of the following:

- Living contaminants in vaccines.
- Absence of Pyrogens.
- Histamine like substances
- Determine of toxic elements

**Module 03**

Study of method procedure, drugs of formulations standard requirements of herbal medicines, traditional and folk remedies, preparation & their quality, safety and efficaly assessment & use for acceptance by FDA.

**Module 04**

Radioimmuno assay: Gen principles, scope of limitations R.I.A of Insulin and digitalis. Introduction to Bio equivalence studies & their importance.

**Module 05**

Thermal Methods of Analysis: Theory, Instrumentation and applications of Thermo Gravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC) and Thermo Mechanical Analysis (TMA).

**Module 06**

Various types of raw material used in the cosmetic industry for the manufacture of finished products. General method of analysis to determine the quality of raw materials used in cosmetic industry.

**Reading Material Recommended**


1. Indian Pharmacopoeia, 2007 Controller of Publications, Govt. of India, New Delhi.
2. Bochmman & Hassan, Pharmaceutical Analysis, edited by: Higuchi.

3. D C Garrott, Quantitative Analysis of drugs. CBS Publishers, New Delhi.
4. R V Smith, J T Stewart, Textbook of Bio Pharmaceutical Analysis.
5. Pulok K Mukherjee: Quality Control of Herbal Drugs, Business Horizons Pharmaceutical Publishers, New Delhi.
6. British Pharmacopeia, Department of Health U.K.
7. Classification of cosmetic raw materials and adjuncts IS 3958 of Indian standards institution (BIS).

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|---|---|---|---|---|---|---|---|---|---|
| | | | L | T | P | Int | Ext | Total | |
| 03 | PHANL 136 | Quality Control & Quality Assurance | 4 | 1 | - | 20 | 80 | 100 | 5 |

**Module 01 and Module 02**

**Drug Regulatory Affairs:** Harmonization of regulatory requirements including ICH activity. Regulatory requirements of different regions applicable to pharmaceutical developments, manufacturing, quality control on finished products, extended release products, biopharmaceutical and bioequivalence assessment and good clinical practices and Comparison with regulation in India. Filing of INDA, NDA and ANDA for approval and registration.

**Module 03**

**Stability Testing :** Role of stability testing, stability test guidelines. Protocol of stability testing including testing under different climatic zones and conditions. Conduct of stability testing. Presentation and recording of stability data, determination of shelf life. Stability test equipment and recent developments in this area.

**Module 04**

**Documentation :** Importance of documentation, statutory requirements and procedure for documentation, critical examination of documents.

**Module 05**

**GMP of Pharmaceuticals :** Current GMP in manufacturing, processing, packaging of drugs. GMP for finished products. General provision, organization and personnel, building and facilities, equipment, control of components and drug product, container and closures, production and process, packaging and labeling, laboratory and control of records and reports.

**Module 06**

**Good Laboratoy Practice :** Current GLP in manufacturing, responsibilities. General provision, organization and personnel, building and facilities, equipment, control of components and drug product, laboratory and control of records and reports, Non-clinical testing, Controls on animal house, Application of Computers in Quality control Laboratory.

Regulatory aspects of Pharmaceuticals and Bulk Manufacturing, WHO Certification Globalisation of Drug Industry, Patent regime.

**Reading Material Recommended**

1. Pharmaceutical product development 2006, edited by N.K. Jain, CBS publishers and distributors.

New Delhi, and references there in.
2. Good manufacturing practices for pharmaceuticals: A plan for total quality control from manufacturer to customer, Vth edition, revised and expanded by Sidney H. Willig, Marcel and Dekker.
3. http://www.patentinoffice.nic.in
4. http://www.patentmatics.com
5. http://www.iprlawindia.org
6. http://www.indianpatent.org.in
7. http://www.wipo.int

| S. No. | Subject Code | Subject Title | Teaching Load Allocation | | | Marks Distribution | | | Credit |
|---|---|---|---|---|---|---|---|---|---|
| | | | L | T | P | Int | Ext | Total | |
| 04 | PHANL 138 | Pharmaceutical Analysis Laboratory-II | - | | 14 | 20 | 80 | 100 | 7 |

1. Assay of calcium gluconate
2. Assay of amoxicillin
3. Assay of Phenylhydrazine HCl
4. Assay of frusemide tablets
5. Assay of Lignocaine HCl injection
6. Assay of vitamin $B_{12}$/folic acid in vitamin preprations
7. Estimation of cotrimazole tablets
8. Determination of hardness of water
9. Drug analysis by U.V.& I.R
10. Analysis of Drugs in blood & urine sample
11. Estimation of Quinine Sulphate
12. Assay of rifampicin
13. Bio assay of acetylcholine.
14. IR, NMR, Graphs interpretation
15. Based on topic covered in theory with emphasis on analysis of cosmetics and their adulteration with reference to Drugs and Cosmetic rules 1945.
16. Quality control tests for some cosmetics.

**M. PHARM. SEMESTER-III and IV [Credits 12+12=24]**

Research Work

The thesis shall be presented by the candidate at the end of record academic year. The thesis shall be evaluated as under:

Evaluation of written thesis : MM 200
Presentation of seminar on thesis and viva-voce : MM 100
**Total : 300 marks**