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

FIRST SEMESTER

S.No.	Subject Code	Subject Title	Tea	ching	Load	Mark	s Distr	ibution	Exam.	Credit
			Allocation (hr)					(nr)		
			L	Т	Р	Int	Ext	Total		
01	PHANL 131	Pharmaceutical Analytical	4	1	-	20	80	100	3	5
		Techniques								
02	PHANL 133	Spectral Analysis	4	1	-	20	80	100	3	5
03	PHANL 135	Advanced Spectroscopic	4	1	-	20	80	100	3	5
		Techniques								
04	PHANL 137	Pharmaceutical Analysis	-		16	20	80	100	8	5
		Laboratory – I								
		Total (31)	12	03	16	80	320	400		20

SECOND SEMESTER

S.No.	Subject Code	Subject Title	Tead	ching	Load	Mark	s Distr	ibution	Exam.	Credit
			Allo	Allocation					(hr)	
			L	Т		Int	Ext	Total		
01	PHANL 132	Advanced Pharmaceutical	4	1	-	20	80	100	3	5
		Techniques								
02	PHANL 134	Biological Standardization	4	1	-	20	80	100	3	5
03	PHANL 136	Quality Control & Quality	4	1	-	20	80	100	3	5
		Assurance								
04	PHANL 138	Pharmaceutical Analysis	-		16	20	80	100	8	5
		Laboratory-II								
		Total (31)	12	03	16	80	320	400		20

THIRD AND FOURTH SEMESTER

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 200Presentation of seminar on thesis: MM 100and viva-voce: MM 100

Total : 300 marks

[Note : Credit System : 1 credit = 20 marks, L- Lecture – Tutorial, P – Practical]

S.N	Subject Code	Subject Title	Teac	hing L	Load	Marks	Credit		
0.			L	T	Р	Int	Ext	Total	
01	PHANL 131	Pharmaceutical Analytical Techniques	4	1	-	20	80	100	5

M. PHARM. (Pharm Analysis) SEMESTER-I

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 ED₅₀, LD₅₀ & 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.N	Subject Code	Subject Title	Teac	hing L	Load	Marks	Credit		
0.			Allocation						
			L	Т	Р	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, characteristics 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 ¹HNMR 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.

- 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. (Latest edition).

S.N o.	Subject Code	Subject Title	Teac Allo	hing L cation	load	Marks	Credit		
			L	Т	Р	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

¹³C Nuclear Magnetic Resonance (¹³C – NMR) :

Natural abundance of ¹³C, 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} - H¹ 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

- 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. 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.N	Subject Code	Subject Title	Teac	hing L	Load	Marks	Credit		
0.			Allo	cation					
			L T P			Int	Ext	Total	
04	PHANL 137	Pharmaceutical Analysis	-		16	20	80	100	5
		Laboratory – I							

- 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.

S.N	Subject Code	Subject Title	Teac	hing L	.oad	Marks	bution	Credit	
0.			Allocation						
			L	Т	Р	Int	Ext	Total	
01	PHANL 132	Advanced Pharmaceutical	4	1	-	20	80	100	5
		Techniques							

M.PHARMACY (Pharm. Analysis)- SEMESTER II

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, B₁, B₂, B₁₂, 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, P₄, S₈,Cl₂.

- 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.N	Subject Code	Subject Title	Teac	hing L	Load	Marks	Credit		
о.			Allo	cation					
			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 effically 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).

of

Module 06

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

- 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).

S.N o.	Subject Code	Subject Title	Teac Allo	hing L cation	load	Marks	Credit		
			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, Nonclinical 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.

- 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. <u>http://www.patentinoffice.nic.in</u>
- 4. <u>http://www.patentmatics.com</u>
- 5. http://www.iprlawindia.org
- 6. http://www.indianpatent.org.in
- 7. http://www.wipo.int

S.N	Subject Code	Subject Title	Teac	hing L	Load	Marks	Credit		
0.			Allo	cation					
			L T P			Int	Ext	Total	
04	PHANL 138	Pharmaceutical Analysis	-		16	20	80	100	5
		Laboratory-II							

- 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.