SYLLABUS

M.S.(Pharm)/ M.Tech.(Pharm)/ M.B.A.(Pharm)

HYDERABAD

राष्ट्रीय औषधीय शिक्षा एवं अनुसंधान संस्थान

NATIONAL INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH

(Dept. of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Govt. of India)

रसायन एवं अर्वरक मंत्रालय, भारत सरकार

Mentor Institute
CSIR-INDIAN INSTITUTE OF CHEMICAL TECHNOLOGY
Hyderabad

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CONTENTS

SUMMARY OF ORDINANCE & REGULATIONS FOR MASTERS AND DOCTORAL PROGRAMMES

1. Students of all programmes have to renew the registration every semester till submission of the dissertation (for masters) and thesis (for Ph.D.). Teaching in the Institute will be organized around the credit system. Each course will have a certain number of credits which will describe its weightage. The letter grades and their equivalent grade points are:

   A (Outstanding) = 10

   A (-) (Excellent) = 9

   B (Very Good) = 8

   B (-) (Good) = 7

   C (Average) = 6

   C (-) (Below Average) = 5

   D (Marginal) = 4

   E (Poor) = 2

   F (Very Poor / Absent / Short of Attendance) = 0

2. A student (of Master Programme) is not entitled to avail more than two repeat examinations in each semester in courses in which he/she has obtained E or F grade(s) or where he/she has scored a CGPA of less than 6.00.

3. Due to lack of fulfillment of all the requirements for the course on account of extra ordinary circumstances subject to having 50% attendance, a candidate can be put under I-grade and shall be permitted to appear second time in a course(s).

4. The minimum credit requirement for masters degree is 50 valid credits including a minimum of 28 credits of course work and balance credits of the project work. The credit requirement for M.B.A.(Pharm) degree is 100 valid credits including a minimum of 75 credits course work and balance credits of project work.

5. The minimum CGPA required for the award of Masters Degree is 6.00 The maximum period for completion of the Master Programme will be 3 years from the date of joining the programme.

6. The Masters Degree holders of the Institute getting into the Ph.D programme will have to complete doctoral courses of minimum 12 credits and all other students will have to complete minimum of 28 credits (not less than 16 credits from the specialization)

7. The minimum CGPA requirement for Ph.D. is 6.50. If CGPA is above 6.00 but below 6.50, student will be asked to take more courses in order to make up the required CGPA. If CGPA is below 6.00 at the end of any semester he/she will have to discontinue the Ph.D. programme.
8. A Ph.D. student will be required to clear the comprehensive examination before the beginning of sixth semester, after completing course work. A maximum of two attempts will be allowed to a student to clear the comprehensive examinations. The student will be required to be registered for a period of not less than 3 years and submit the thesis within 5 years from the date of registration.
9. Students (of all Programmes) are required to attend every lecture and practical class during the semester. However, in the case of the late registration, sickness and other contingencies, the attendance required will be a minimum 75% of the classes actually held.
10. For Masters Programme: A student is entitled to a maximum of 45 days leave in addition to general holidays during the four semester of their stay at the Institute. 10 days of medical leave every year besides 45 days leave can be granted. A student is not entitled to any vacation. For Ph.D. degree programme, a student is entitled to 30 days leave in each year in addition to the general holidays. Women student will be entitled to 3 months maternity leave besides the 30 days leave, once during their tenure. Leave with scholarship may be granted to students for attending academic meetings/conferences/symposia

NOTE: This is the summarized form of Ordinance and Regulations of the Institute for the benefit of the students. For details, original documents on Ordinances and Regulations shall be referred to.

Cancellation of Registration:

The registration shall be cancelled under any of the following conditions:

a) Where the student absent for a continuous period of four weeks without prior intimation/sanction of leave;

b) Where the student fails to renew registration;

c) Where the student fails to clear the examination;

d) Where the student has committed an act of misconduct/indiscipline;

e) Where academic performance of the student is unsatisfactory; and

f) Where the student resigns from the programme and his or her resignation has been accepted.

Provided the student will be given an opportunity of being heard before invoking sub-section (a) to (e)

Mid Term Examination

If a student in case of any exigency or otherwise remains absent in the Mid Term Examination, the course coordinator shall assign 0 marks to the student.

Repetition of Examination

The student shall be permitted repetition of examination in theory courses in the following cases:

a) Where the student earns E or F or both grade(s) in not more than two courses, he or she shall be required to repeat the examination. The examination shall be held within 10 days of last day of the Mid Term examination in the following semester;

b) Where the student has attendance of 75% or more but is unable to appear in the examination in the course(s) on account of the reasons specified for awarding the 'I' grade, student shall be required to appear in the End Semester examination in the semester when the examination for the course is held. The student shall not be required to attend the classes again and shall pursue course(s) of subsequent semester(s)/dissertation;

c) Where the attendance of the student is less than 75% and is not permitted to appear in the examination, he/she shall have to repeat the course(s) in the semester when such course(s) is/are offered;

d) Where the student earns 'F' grade in more than two courses in any semester, he or she shall have to discontinue the studies and shall cease to be the student of the Institute;

e) Where a student otherwise wants to improve his or her Cumulative Grade Point Average (CGPA), such student shall be permitted to repeat the examination in not more than two theory courses of the semester;

f) Grade points awarded in repeat examination shall be final;

g) Grade obtained on account of improvement examination shall be specified in the award list; and

h) The student opting for grade improvement examination shall not be eligible for merit awards. Such student shall rank in merit list below the students who cleared the examination in first attempt.

LABORATORY SAFETY

The following safety rule applies **at all times** in the laboratory rooms.

- No open food or drink is permitted at any time, whether a lab is in progress or not.
- No eating, drinking, or chewing of gum or tobacco is permitted.
- Never taste anything at all while in the lab rooms.

The following additional rules apply **while a laboratory session is in progress.**

- The lab is restricted to the students enrolled in the course. Visitors, especially children, are not allowed.
- You must wear goggles for eye protection during every laboratory period, until all students have completed all their experiments. Even if you wear prescription glasses or contact lenses, you need to wear goggles as well.
- Report all accidents to your laboratory instructor immediately.
- Know the location of the two main exits from the room, eye washes, safety shower, fire alarms, fire blanket and fire extinguishers. (First Aid box, nearest hospital)
- If a chemical comes in contact with your eye, immediately flush the eye with a gently flowing source of water from the eyewash. If you wear contact lenses, remove them. Continue flushing for at least 15 minutes. Use your thumb and forefinger to hold your eyelids away from the eyeball, move your eyes continuously—up and down and sideways—to flush out thoroughly behind the eyelids and behind the eyeball. Notify the laboratory instructor immediately. Promptly seek medical attention. If someone else in the lab has a chemical in their eye, help them get to the eyewash and help them operate it!
- Clothing must offer you good protection against chemical spills and splashes.
- No high heeled shoes open toed shoes, sandals, or shoes made of loosely woven material not allowed.
- Legs must be covered by your clothing.
- No smoking is allowed in chemical laboratories.
- Every student must wear protective eye shields at all times in the laboratory. This is to protect you from your neighbour's mistakes as well as your own.
- Carry out experiments which produce toxic chemicals or vapours, and/or are likely to be violent, in a fume cupboard.
- Fire is a serious hazard in the laboratory and is usually caused by the careless handling of organic solvents. These must not be heated using a Bunsen burner.
- Do not peer into the mouth of a test tube which is being heated or in which a reaction may be occurring.
- If the clothing is splashed by a corrosive liquid, strip the clothing and treat the skin immediately. As a first treatment washing with water is generally appropriate, call a demonstrator to assist you.

- Wear a laboratory coat at all times in the practical laboratory to protect you and your cloths.
- Always carry a small towel to the laboratory to assist you in handling hot objects in addition to tongs.
- Bunsen burners may only be used in the fume cupboard or keep it away from the inflammable solvents.
- Most organic compounds are combustible. Those with low boiling points and high vapor pressure at room temperatures may present a serious fire hazard. Ether, for example, which has a boiling point of 35°C, may be ignited by a flame removed by sixteen feet. Hence, it is never permissible to heat over an open flame any substance in an open vessel containing such volatile liquids. Steam bath is ideal for this purpose.

• Fire

Fire is one of the most serious and most likely hazards to occur in a laboratory. The most generally useful fire extinguisher in the laboratory is the Carbonodioxide cylinder which can be safely used with most chemicals and electric equipment, and is clean.

Asbestos blankets are useful for smoothening small fires and burning clothings.

• Chemical Hazards

Most compounds are highly toxic when injected orally. Many chemicals are poisonous, corrosive, carcinogenic or explosive.

- Corrosive chemicals such as acids and alkalis are stored in low shelves and opened with care.
- One should never taste any compound and odors of substances should be detected with extreme care.
- Mouth pipetting is always potentially dangerous and some form of safety pipette must be used instead.
- Sensitive tissues, for example, the eye should not be needlessly exposed to vapours. One should never place his/her face directly over a reaction mixture.
- It is mandatory that each student study each experiment prior to undertaking any laboratory procedure in order to understand the implications of the particular experiment.
- Dangers chemicals obtained from commercial sources usually carry a warning printed in the bottle. These warnings should be followed.
- It is the duty of all members of laboratory staff to co-operate in the prevention of accidents.
- In addition to the welfare of the staff of the laboratory there is concern for preservation of the building, equipment, furnishing and apparatus.

Medicinal Chemistry

M.S.(Pharm)

Course Code	Course Name	Credits	Page No.
I Semester			
MC-510	Basics of Drug Action	2	02
MC-511	Spectral Analysis	2	03
MC-520	Logic in Organic Synthesis-I	3	04
NP-510	Separation Techniques	1	14
PC-540	Chemotherapy of Parasitic and Microbial Infections	1	26
PT-510	Industrial Process and Scale-up Techniques	1	51
GE-510	Biostatistics	2	15
GE-511	Seminar	1	17
LG-510	General Lab Experience	3	06
	Total Credits	**16**	
II Semester			
MC-610	Drug Design	2	06
MC-620	Logic in Organic Synthesis-II	3	07
MC-630	Structure and Function of Biomolecules	2	09
MC-650	Stereochemistry and Drug Action	2	10
PC-610	Drug Metabolism	1	29
PC-611	Pharmacological Screening and Assays	1	30
GE-611	Seminar	1	23
LS-610	General Lab Experience in the area of Specialization	2	11
	Total Credits	**14**	
III Semester			
	Project 22 (Weeks)		
TH-598	Synopsis	5	
TH-599	Presentation	3	
	Total Credits	**8**	
IV Semester			
TH-698	Thesis	9	
TH-699	Defence of Thesis	3	
	Total Credits	**12**	
	Grand Total (I to IV Semesters)	**50**	

Pharmaceutical Analysis

M.S.(Pharm)

Course Code	Course Name	Credits	Page No.
I Semester			
PA-510	Topics in Pharmaceutical Analysis	2	13
MC-511	Spectral Analysis	2	03
NP-510	Separation Techniques	1	14
PE-510	Dosage Form Design Parameters	1	42
BT-510	Biotechnology in Pharmaceutical Sciences	1	28
GE-510	Biostatistics	2	15
GE-520	Fundamentals of Intellectual Property (IP) and Technology Management	1	16
GE-511	Seminar	1	17
LG-510	General Lab Experience	3	18
	Total Credits	**16**	
II Semester			
PA-610	Pharmacopoeial Methods of Analysis	2	18
PA-620	Instrumental Techniques for Evaluation of APIs and Drug Products	2	19
PA-630	Stability Testing	1	20
PA-640	Quality Control and Quality Assurance	2	21
NP-640	Structure Elucidation	2	22
PC-611	Pharmacological Screening and Assays	1	30
PE-630	Pharmaceutical Product Developmemt-I	2	46
PE-660	Solid State Pharmaceutics	1	48
GE-611	Seminar	1	23
LS-610	General Lab Experience in the Area of Specialization	2	23
	Total Credits	**14**	
III Semester			
	Project 22 (Weeks)		
TH-598	Synopsis	5	
TH-599	Presentation	3	
	Total Credits	**8**	
IV Semester			
TH-698	Thesis	9	
TH-699	Defence of Thesis	3	
	Total Credits	**12**	
	Grand Total (I to IV semesters)	**50**	

Pharmacology & Toxicology

M.S.(Pharm)

Course Code	Course Name	Credits	Page No.
I Semester			
PC-511	Pathophysiology	1	25
PC-520	General Pharmacology	2	25
PC-530	Experimental Pharmacology	1	26
PC-540	Chemotherapy of Parasitic and Microbial Infections	1	26
NP-510	Separation Techniques	1	14
PE-520	Biopharmaceutics and Pharmacokinetics	2	42
BT-510	Biotechnology in Pharmaceutical Sciences	1	28
GE-510	Biostatistics	2	15
GE-520	Fundamentals of Intellectual Property (IP) and Technology Management	1	16
GE-511	Seminar	1	17
LG-510	General Lab Experience	3	29
	Total Credits	**16**	
II Semester			
PC-610	Drug Metabolism	1	29
PC-611	Pharmacological Screening and Assays	1	30
PC-620	CNS and Respiratory Pharmacology	2	30
PC-630	Autonomic, CVS, Blood, Renal and GI Pharmacology	2	31
PC-640	Autocoid and Endocrine Pharmacology	1	31
PC-650	Clinical Pharmacology and Regulatory Toxicology	2	32
PC-660	Chemotherapy and Immunopharmacology	2	33
GE-611	Seminar	1	23
LS-610	General Lab Experience in the area of Specialization	2	34
	Total Credits	**14**	
III Semester			
	Project 22 (Weeks)		
TH-598	Synopsis	5	
TH-599	Presentation	3	
	Total Credits	**8**	
IV Semester			
TH-698	Thesis	9	
TH-699	Defence of Thesis	3	
	Total Credits	**12**	
	Grand Total (I to IV Semesters)	**50**	

Regulatory Toxicology

M.S.(Pharm)

Course Code	Course Name	Credits	Page No.
I Semester			
RT-540	Principles and Methods in Toxicology	1	36
RT-550	Introduction to Regulatory Toxicology	2	36
PC-511	Pathophysiology	1	25
PC-520	General Pharmacology	2	25
PC-530	Experimental Pharmacology	1	26
PE-520	Biopharmaceutics and Pharmacokinetics	2	42
GE-510	Biostatistics	2	15
GE-520	Fundamentals of Intellectual Property (IP) and Technology Management	1	16
GE-511	Seminar	1	17
LG-510	General Lab Experience	3	37
	Total Credits	**16**	
II Semester			
RT-630	Molecular Toxicology	2	38
RT-640	Target Organ Toxicology	2	38
RT-650	Good Laboratory Practice in Regulatory Toxicology	2	39
RT-660	Bioethics	1	39
PC-610	Drug Metabolism	1	29
PC-611	Pharmacological Screenings and Assays	1	30
PC-650	Clinical Pharmacology and Regulatory Toxicology	2	32
GE-611	Seminar	1	23
LS-610	General Lab Experience in the area of Specialization	2	40
	Total Credits	**14**	
III Semester			
	Project 22 (Weeks)		
TH-598	Synopsis	5	
TH-599	Presentation	3	
	Total Credits	**8**	
IV Semester			
TH-698	Thesis	9	
TH-699	Defence of Thesis	3	
	Total Credits	**12**	
	Grand Total (I to IV Semesters)	**50**	

Pharmaceutics

M.S.(Pharm)

Course Code	Course Name	Credits	Page No.
I Semester			
PE-510	Dosage Form Design Parameters	1	42
PE-520	Biopharmaceutics and Pharmacokinetics	2	42
MC-510	Basics of Drug Action	2	02
MC-511	Spectral Analysis	2	03
NP-510	Separation Techniques	1	14
BT-510	Biotechnology in Pharmaceutical Sciences	1	28
GE-510	Biostatistics	2	15
GE-520	Fundamentals of Intellectual Property (IP) and Technology Management	1	16
GE-511	Seminar	1	17
LG-510	General Lab Experience	3	44
	Total Credits	**16**	
II Semester			
PE-620	Drug Delivery Systems	2	45
PE-630	Pharmaceutical Product Developmemt-I	2	46
PE-640	Pharmaceutical Product Developmemt-II	2	46
PE-650	Biomaterials	2	48
PE-660	Solid State Pharmaceutics	1	48
PC-610	Drug Metabolism	1	29
PC-611	Pharmacological Screening and Assays	1	30
GE-611	Seminar	1	23
LS-610	General Lab Experience in the area of Specialization	2	49
	Total Credits	**14**	
III Semester			
	Project 22 (Weeks)		
TH-598	Synopsis	5	
TH-599	Presentation	3	
	Total Credits	**8**	
IV Semester			
TH-698	Thesis	9	
TH-699	Defence of Thesis	3	
	Total Credits	**12**	
	Grand Total (I to IV Semesters)	**50**	

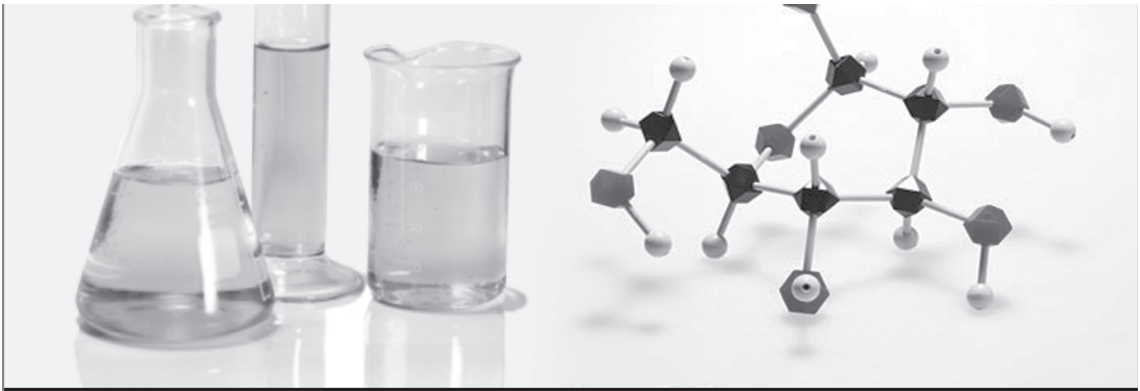
Pharmaceutical Technology (Process Chemistry)

M.Tech.(Pharm)

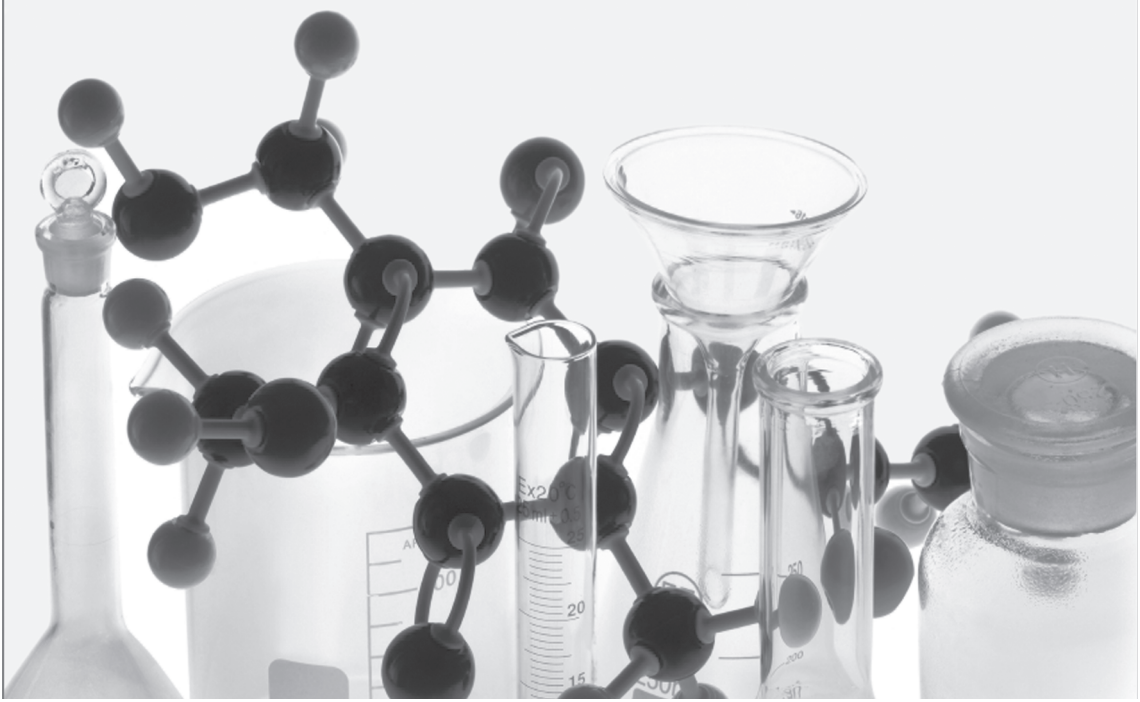
Course Code	Course Name	Credits	Page No.
I Semester			
PT-510	Industrial Process and Scale-up Techniques	1	51
PT-560	Synthetic Aspects of Process Chemistry	2	51
MC-511	Spectral Analysis	2	03
MC-520	Logic in Organic Synthesis-I	3	04
NP-510	Separation Techniques	1	14
GE-510	Biostatistics	2	15
GE-520	Fundamentals of Intellectual Property (IP) and Technology Management	1	16
GE-511	Seminar	1	17
LG-510	General Lab Experience	3	53
	Total Credits	**16**	
II Semester			
PT-610	Topics Relevant to Drugs and Pharmaceutical Industry	1	53
PT-630	Synthetic Bulk Drug Technology	2	54
PT-690	Downstream Processing of Biological Products	1	55
MC-620	Logic in Organic Synthesis-II	3	07
MC-650	Stereochemistry and Drug Action	2	10
PA-620	Instrumental Techniques for Evaluation of APIs and Drug Products	2	19
GE-611	Seminar	1	23
LS-610	General Lab Experience in the area of Specialization	2	56
	Total Credits	**14**	
III Semester			
	Project 22 (Weeks)		
TH-598	Synopsis	5	
TH-599	Presentation	3	
	Total Credits	**8**	
IV Semester			
TH-698	Thesis	9	
TH-699	Defence of Thesis	3	
	Total Credits	**12**	
	Grand Total (I to IV Semesters)	**50**	

M.B.A.(Pharm) Pharmaceutical Management

Course Code	Course Name	Credits	Page No.
I Semester			
PM-501	Fundamentals of Management	3	58
PM-502	Accounting for Management	3	58
PM-503	Managerial Economics	3	59
PM-504	Pharmaceutical Marketing	3	60
PM-505	Quantitative Techniques and Management Techniques	3	61
PM-506	Information Technology and MIS	3	61
PM-507	Human Behaviour in Organization	2	62
PM-508	IPRs in Pharmaceutical Management	1	63
PM-511	Seminar	1	64
	Total Credits	**22**	
II Semester			
PM-601	Pharmaceutical Business Environment	3	64
PM-602	Financial Management	3	65
PM-603	Marketing Research	3	66
PM-604	Materials and Operations Management	3	67
PM-605	Business Communication	3	68
PM-606	Human Resource Management	2	69
PM-607	Supply Chain Management in Pharmaceutical Sector	3	69
PT-610	Topics Relevant to Drugs and Pharmaceutical Industry	1	70
PM-611	Seminar	1	71
	Total Credits	**22**	
III Semester			
PM-551	Project Management	3	71
PM-552	Entrepreneurial Development	3	72
PM-553	National Regulatory Environment	2	73
PM-554	International Marketing	3	74
PM-555	Sales Management and Sales Promotion	3	74
PM-556	Industrial and Service Marketing	3	75
PM-557	Contemporary Issues in Pharmaceutical Marketing	2	76
PM-558	Fundamentals of R & D Management - I	2	76
PM-581	Project Summer Training	2	-
	Total Credits	**23**	
IV Semester			
PM-651	Management Control System	3	77
PM-652	Strategic Management	3	78
PM-653	International Regulatory Environment	2	79
PM-654	Pharmaceutical Product Management	3	80
PM-655	Pharmaceutical Brand Management	3	81
PM-656	Consumer Behaviour	2	81
PM-657	Advertising in Pharmaceutical Sector	3	82
PM-658	Fundamentals of R&D Management-II	2	82
PM-680(a)	Major Research Project (Thesis)	9	-
PM-680(b)	Defence of Thesis	3	-
	Total Credits	**33**	
	Grand Total (I-IV Semesters)	**100**	



Medicinal Chemistry



I Semester

MC-510 Basics of Drug Action (2 credits)

1. Structure: 2D vs 3D. Structure vs. Electronic structure. Electronic structure of ketenes and its importance in reactivity. Diels-Alder reaction, Symmetry using group theory. Graph theory and 2D structure.
2. Energy: Energy concept and its importance in drug action. First, Second and Third laws of thermodynamics and the principles derived from these laws which are of significance to drug action.
3. Thermodynamics: Free energy and Relationship between thermodynamics and statistics. Importance of chemical potential in drug action. Thermodynamic cycle. Statistical thermodynamics in predicting the structure of biomolecules and their interaction with drug molecules. Macromolecular vs. micromolecular correlation using thermodynamics and statistical thermodynamics.
4. Interactions: Inter- and intramolecular interactions. Weak interactions in drug molecules. Chirality and drug action. Covalent, ion-ion, ion-dipole, Hydrogen bonding, C-H hydrogen bonding, dihydrogen bonding, Van derWaals interactions and the associated energies.
5. Receptorology: Drug-receptor interactions, Receptor theories and drug action: Occupancy Theory, Rate Theory, Induced Fit Theory, Macromolecular perturbation theory, Activation-Aggregation theory. Topological and stereochemical consideration.
6. Enzyme Kinetics: enzyme kinetics in drug action. Do all molecules of an enzyme have same kinetics? Mechanisms of enzyme catalysis, Electrostatic catalysis and desolvation. Covalent catalysis, Acid-base catalysis, Strain / distortion in enzyme catalysis. Coenzyme catalysis.
7. Enzyme Inhibition: Drug action through enzyme inhibition. Examples based on PDE4, GSK3, etc. Theories of enzyme inhibition and inactivation. Enzyme activation of drugs prodrugs.
8. Nucleic acids: NA as targets for drug action. NA-interactive agents. Classes of drugs that interact with nucleic acids. Intercalation, NA-alkylation, NA-strand breaking and their importance in drug action.
9. Drug likeness: Drug like molecules and theories associated with the recognition of drug like properties. Physical organic chemistry of Drug metabolism, drug deactivation and elimination.
10. Drug action after Metabolism: Phase I and Phase II transformations. Concept of hard and soft drugs. Chemistry of ADME and Toxicity properties of drugs.

Recommended Books:

1. The Organic Chemistry of Drug Design and Drug Action by R.B. Silverman
2. C.J. Coulson, Molecular Mechanism of Drug Action by C.J. Coulson
3. A primer of Drug Action by R.M. Julien
4. Drug-Receptor Thermodynamics by R.B. Raffa
5. Principles of Drug Action by W.B. Pratt, P. Taylor
6. Medicinal Chemistry How Drugs Act and Why by A. Gringauz
7. Principles of Molecular recognition by A.D. Buckingham

8. Quantitative molecular pharmacology and Informatics by M. Lutz
9. Physical Biochemistry by K.E.V. Holde
10. Free energy calculations in rational drug design by M. Rami Reddy

MC-511 Spectral Analysis (2 credits)

1. Ultra Violet (UV) and visible spectroscopy:
   a) Energy levels and selection rules: Definitions, molecular orbital approach for energy absorption, various modes of transitions.
   b) Correlation of structural variation with UV absorption: Factors influencing the position and intensity of absorptions, Inductive and resonance effects, effect of ring size, influence of stereochemical factors.
   c) Predicting UV absorption: Woodward- Fieser, Fieser-Kuhn and Nelson rules;
   d) Other factors: Non-conjugative effect, solvent effect, S-Cis band.
2. Infrared (IR)spectroscopy:
   a) Characteristic regions of the spectrum: Various modes of vibrations, Energy levels
   b) Correlation of structure with IR spectra: Influence of substituents, ring size, hydrogen bonding, vibrational coupling and field effect on frequency.
   c) Applications: Determination of stereochemistry. Spectral interpretation with examples.
3. Nuclear Magnetic Resonance (NMR) Spectroscopy:
   a) Fundamentals: Physical basis, magnetic nuclei, resonance, relaxation processes, signal-sensitivity.
   b) Instrumentation: Continuous-Wave (CW) instrument, Pulsed Fourier Transform (FT) instrument, Functions, Relation with sensitivity, Sampling.
   c) 1H NMR, correlation of structure with spectra: Chemical environment and shielding, chemical shift and origin of its concept, reference compound, local diamagnetic shielding and magnetic anisotropy, relation with chemical shift, chemical and magnetic non-equivalence, spin-spin splitting and its origin, Pascal's triangle, coupling constant, mechanism of coupling, integral, NMR solvents and their residual peaks, protons on heteroatoms, quadrupole broadening and decoupling, effect of conformations and stereochemistry on the spectrum, Karplus relationship, diastereomeric protons, Heteronuclear coupling to 19F and 31P, virtual coupling, long range coupling-epi, peri, bay effects. Shift reagents-mechanism of action, spin decoupling and double resonance. Explanation of spectra of some compounds and drugs.
   d) 13C NMR, correlation of structure with spectra: Chemical environment, shielding and carbon-13 chemical shift, calculation, proton-coupled C Spetra, Proton-decoupled C spectra, Nuclear Overhauser Enhancement (NOE), Problem with integration, Distortionless Enhancement by Polarization Transfer (DEPT), Heteronuclear coupling for carbon to deuterium, carbon to 19F, carbon to 31P. Explanation of spectra of some compounds and drugs.

4. Mass spectrometry (MS): Molecular ion and metastable peak, fragmentation patterns, nitrogen and ring rules, McLafferty rearrangement, electron and chemical ionization modes, applications.

Recommended Books:

1. Spectroscopy by Donald L Pavia, Gary M Lampman, George S Kriz, James A Vyvyan
2. Organic spectroscopy by William Kemp
3. Spectroscopic Methods in Organic Chemistry by Dudley H. Williams & Ian Fleming
4. Spectrometric Identification of Organic Compounds by Robert M. Silverstein, Francis X. Webster & David J. Kiemie
5. Applications of Absorption Spectroscopy of Organic Compounds by Dyer
6. Fundamentals of Molecular Spectroscopy by Colin N. Banwell & Elaine M. McCash
7. Spectroscopy by Pavia, Donald L. Lampman, Gary M. Kriz, George S.

MC-520 Logic in Organic Synthesis-I (3 credits)

1. Organic reaction mechanism:
   a) Methods of determining reaction mechanisms: kinetic and non-kinetic methods; Energy profile diagrams, reaction intermediates, crossover experiments and isotopic labelling; order of reactions; Reversible, consecutive and parallel reactions; Solvent, ionic strength and salt effects; Acid-base catalysis.
   b) Nucleophilic substitution reactions: Uni- and bimolecular reactions; Attacking and leaving groups; Steric and electronic effects; Neighboring group participation; Formation and hydrolysis of esters, amides and acyl halides different mechanisms.
   c) Electrophilic substitution reactions: Aromatic electrophilic substitutions including Friedel-Crafts reactions.
   d) Addition and elimination reactions: Addition to C=C and C=O; Mechanism; Dehydrohalogenation, dehydration, etc; E1, E2 and Syn-elimination mechanism.
2. Principles of synthetic planning: Logic-centered molecular synthesis; Dislocation, synthetic tree, synthons, logical imposition of boundary conditions, direct associated approach; Structure-functionality relationships, functionality and unsaturation levels; Polar reactivity analysis; Control elements, consonant and dissonant circuits; Protocol for synthetic design.
3. Alkylation:
   a) Enolates: Regio- and stereo-selective enolate generation, "O" versus "C"- alkylation, effects of solvent, counter cation and electrophiles; Symbiotic effect; Thermodynamically and kinetically controlled enolate formations; Various transition state models for stereoselective enolate formation.
   b) Enamines and metalloenamines: Regioselectivity in generation, applications in controlling the selectivity of alkylation.
4. Reaction of ylides:
   a) PhosphorSemester-Ious ylides: Structure and reactivity, stabilized and Non-stabilized ylides, effects of ligands on reactivity, Wittig reaction, Schlosser modification, Wittig-Horner and Horner-Wadsworth-Emmons olefination reactions, Mechanism reactions and synthesis of various scaffolds.

b) Sulphur Ylides: Stabilized and non-stabilized ylides; thermodynamically and kinetically controlled reactions with carbonyl compounds, regio- and stereo-selective reactions.

5. Hydroboration: Control of chemo-, regio- and stereo-selectivity, rearrangement of alkylboranes; Alkylboranes as organometallic reagents, e.g., 9-BBN, thexylboranes, siamylborane, chiral boranes- Ipc2BH IpcBH2 etc.

Recommended Books:

1. March's Advanced Organic Chemistry: Reactions, Mechanisms, and Structure by Michael B. Smith, and Jerry March
2. Designing Organic Syntheses by Stuart Warren
3. Organic Synthesis: the Disconnection Approach by Stuart Warren
4. Advanced Organic Chemistry: Reactions and Synthesis, Part A: Structure & Mechanism by Francis A. Carey; Richard J. Sundberg
5. Advanced Organic Chemistry: Reactions and Synthesis, Part B: Reaction & Mechanism by Francis A. Carey; Richard J. Sundberg
6. Modern Synthetic Reactions by Herbert O. House
7. Modern Methods of Organic Synthesis by Carruthers, William Coldham, Iain
8. Mechanism and Structure in Organic Chemistry by Gould
9. Advanced Inorganic Chemistry by Cotton , Wilkinson, Murillo and Bochmann
10. Fundamentals of Medicinal Chemistry by Thomas ISBN047084307

In each case the treatment of the topic starts from the entry level discussion from the above text/ reference books followed by relevant research articles from the original research work as well as review articles. Such suggested readings are provided along with the progress of the lectures.

NP-510 Separation Techniques (1credit)
(Refer to Page No. 14)

PC-540 Chemotherapy of Parasitic and Microbial Infections
(Refer to Page No. 26) **(1 credit)**

PT-510 Industrial Process and Scale up Techniques (1 credit)
(Refer to Page No. 51)

GE-510 Biostatistics (2 credits)
(Refer to Page No. 15)

GE-511 Seminar (1 credit)
(Refer to Page No. 17)

LG-510 General Laboratory Experience - 15 hours / week (3 credits)

1. Analytical techniques: (75 hours)
   a) Spectral analysis workshop (45 hours)
   b) Separation Techniques (30 hours)
2. Computer and application in pharmaceutical sciences (100 hours): Introduction to computers, basic unit and functions, H/W and S/W, operating systems, word processing, spread sheet, graphic programs, dbase, windows, statistical S/W programs and packages. Steps involved in S/W development, computer languages with emphasis to FORTRAN language and programming, hands on experience in pharmaceutical software systems. Use of computers in information retrieval systems.
3. Specialization (95 hours): Two to three step synthesis. Purification by chromatographic technique and identification by IR, NMR, and MS.

II Semester

MC-610 Drug Design (2 credits)

1. Electronic Structure methods: Quantum chemical methods semi-empirical and ab initio methods. Conformational analysis, energy minimization, comparison between global minimum conformation and bioactive conformation. Predicting the mechanism of organic reactions using electronic structure methods. Complete and constrained conformational search methods, their advantages and disadvantages. Theoretical aqueous solvation calculations for design of ligands. Conformational interconversion, transition-state determination and their role in designing rigid analogs.
2. Quantum chemical methods of analyzing drugs: Metformin, its comparison to carbones, rapid racemization in glitazones, metabolism and toxicity of troglitazone, conversion of proguanil to cycloguanil.
3. Molecular modeling: Energy minimization, geometry optimization, conformational analysis, global conformational minima determination; approaches and problems. Bioactive vs. global minimum conformations. Automated methods of conformational search. Advantages and limitations of available software. Molecular graphics. Computer methodologies behind molecular modeling including artificial intelligence methods.
4. Structure Activity Relationships in drug design: Qualitative versus quantitative approaches-advantages and disadvantages. Random screening, Non-random screening, drug metabolism studies, clinical observations, rational approaches to lead discovery. Homologation, chain branching, ring-chain transformations, bioisosterism. Insights into molecular recognition phenomenon. Structure based drug design, ligand based drug design.
5. QSAR: Electronic effects: Hammett equation, lipophilicity effects. Hansch equation, steric effects. Taft equation. Experimental and theoretical approaches for the determination of physico-chemical parameters, parameter inter-dependence; case studies. Regression analysis, extrapolation versus interpolation, linearity versus nonlinearity. Descriptor calculation. The importance of biological data in the correct form; 2D QSAR; 3D-QSAR examples of CoMFA and CoMSIA.

6. Molecular docking: Rigid docking, flexible docking, manual docking. Advantages and disadvantages of Flex-X, Flex-S, Autodock and Dock softwares, with successful examples.
7. Molecular dynamics: Dynamics of drugs, biomolecules, drug-receptor complexes, Monte Carlo simulations and Molecular dynamics in performing conformational search and docking. Estimation of free energy from dynamical methods.
8. Pharmacophore concept: Pharmacophore mapping, methods of conformational search used in pharmacophore mapping. Comparison between the popular pharmacophore methods like Catalyst/HipHop, DiscoTech, GASP with practical examples.
9. De Novo drug design techniques: Receptor/enzyme cavity size prediction. Predicting the functional components of cavities, designing drugs fitting into cavity.
10. Informatics methods in drug design: Informatics methods in drug design: Brief introduction to bioinformatics, chemoinformatics. Their relation to drug design as per the topics discussed in items 1-9 above.

Recommended books:

1. Molecular Modelling, by A. R. Leach
2. Organic Chemistry of Drug Design and Drug Action, by R.B. Silverman
3. Practical Applications of computer aided drug design, by P.S. Charifson
4. Molecular modeling in Drug Design, by C. Cohen
5. Chemical Applications of Molecular modeling, by J. Goodman
6. Pharmacophore perception, by O.F. Guner

MC-620 Logic in Organic Synthesis-II (3 credits)

1. Metal/ammonia reduction: Reduction of mono-, bi- and tri-cyclic aromatic systems and various functional groups, reductive alkylation, regio- and stereoselectivity; Reduction of alkynes; Complex metal hydrides and selectrides.
2. Reaction of electron-deficient intermediates: Carbene, nitrene and free radical, their stabilities and modes of generation; Addition and insertion reactions of carbenoids and nitrenoids - regio- and stereoselectivity, role of the metal catalysts in the transitionmetalcatalyzed reactions, other types of reactions of carbenoids, e.g., ylide generation, 1,3- dipolar addition, rearrangement, etc.; Intra-molecular radical trapping process leading to ring annulation - Baldwin's rule.
3. Organometallics: Applications of organo-lithium, cadmium and cerium reagents, heteroatom directed lithiation; Oxy- and amido-mercurations; Gilman reagent, mixed and higher order cuprates, uses in nucleophilic substitution, cleavage of epoxides and conjugate addition reactions; Mechanism of action; Spiro-annulation; Wacker oxidation, Wilkinson's catalyst, carbonylation/hydroformylation reactions; Heck arylation; Role of metal- ligands in controlling regio- and stereo-selectivity; Catalytic and stoichiometric oxidation reactions; Homogeneous and heterogenous processes; Chemo-selective reactions; Bio-mimicking processes.
4. Umpolung and umpoled sythons: Concept, acyl and glycine cation/anion, homoenolate anion, vicinyl dicarbanion, carbonyl dication equivalence, etc.

5. Asymmetric synthesis: Chiral induction-factors controlling facial selectivity; Chiral reagents/ catalysts, auxiliaries, enzymes and antibodies; Kinetic resolution, double asymmetric induction, acyclic diastereoselection, asymmetric amplification; Asymmetric synthesis of amino acids and beta lactams.
6. Concerted reactions and photochemistry: Molecular orbital symmetry, frontier orbitals of 1,3-butadiene, 1,3,5- hexatrienes, allyl system, classification of pericyclic reactions; FMO approach, Woodward-Hoffman correlation diagram method and PMO approach to pericyclic reactions; Electrocycli-creactions-conrotatory and disrotatory motions, [4n], [4n+2] and allyl systems, secondary orbiatl interaction; Cycloaddition- antarafacial and the suprafacial additions, [4n] and [4n+2] sytems with stereo chemical effects, 1,3 -dipolar cycloadditions, chelotropic reactions; Sigmatropic rearangements-supra and antarafacial shifts of H, sigmatropic shifts of carbon moiety, retention and inversion of configuration, [3,3] and [3,5] sigmatropic rearrangements, fluxional tautomerism, ene reactions; Franck-Condon principle, Jablonski diagram, singlet and triplet states, photosensitization, quantum effeciency; Photochemistry of carbonyl compounds, Norish type-I and type-II cleavages, Paterno-Buchi reaction, photoreduction, photochemistry of enones and parabenzoquinones.
7. Synthesis of complex molecules: Various approaches for the systhesis of Taxol, Forskolin, FK-506, Gibberellines, Prostaglandins, Spatol, Aphidicolin, etc. on the basis of disconnection and direct associative approaches.

Recommended books:

1. March's Advanced Organic Chemistry: Reactions, Mechanisms, and Structure by Michael B. Smith, and Jerry March
2. Advanced Organic Chemistry: Reactions and Synthesis, Part A: Structure & Mechanism by Francis A. Carey; Richard J. Sundberg
3. Advanced Organic Chemistry: Reactions and Synthesis, Part B: Reaction & Mechanism by Francis A. Carey; Richard J. Sundberg
4. Modern Synthetic Reactions by Herbert O. House
5. Modern Methods for Organic Synthesis, W. Carruthers and Iain Coldham
6. Asymmetric Synthesis, Vol 3, Editor: J. D. Morrison Advanced Organic Chemistry by March
7. Mechanism and Structure in Organic Chemistry by Gould
8. Advanced Inorganic Chemistry by Cotton , Wilkinson, Murillo and Bochmann
9. Fundamentals of Medicinal Chemistry by Thomas
10. Web resources

In each case the treatment of the topic starts from the entry level discussion from the above text/ reference books followed by relevant research articles from the original research work as well as review articles published in peer reviewed journals of international repute. Such suggested readings are provided along with the progress of the lectures.

MC-630 Structure and Function of Biomolecules (2 credits)

1. Methods for the determination of structure of biomolecules: Biological crystallography-crystallisation data collection, refinement, identification of active site, phase determination heavy atom derivatives, electron density maps; Differences in the small molecule and biomolecules crystallography; spectrofluorimetry- basic principles of fluorescence, intensity of fluorescence, fluorescent group, sensitivity of fluorescence to environment and biological applications; Optical activity measurements, ORD/CD applications to nucleic acids and proteins; Differential scanning calorimetry (DSC) and thermogravimetric analysis (TA) of biomolecules and other thermodynamics based instrumental methods estimating the structural features of biomolecules.
2. Properties of amino acids and peptide bond: End group determination of peptides, sequencing of peptides using various chemical and analytical techniques; A techniques with case studies like LHRH and TRH peptides.
3. Protein structure building block to quaternary structure of proteins: Ramachandran plots; Peptidomimetics; Protein-ligand interactions; multiple binding modes.
4. Structure of lipoproteins and glycoproteins in relation to their function.
5. Structure of lipids, polysaccharides and carbohydrates: Relation-ship between their physico-chemical properties and their biological function.
6. Detailed structure of nucleic acids and protein-nucleic acid interactions: Nucleic acid and small molecule interactions;DNA damage and repair.
7. Structure and function of biomolecules pertaining to different thearapeutic areas: Cancer-tubuline-role in cell proliferation, various binding sites, the chemistry and biology of tubuline inhibitors; farnesyl transferase- X-ray structure, ras protein and its role; Inflammation- COX-1 and COX-2 their structures and physiological role; Hyperlipidimia-HMG-CoA its structure and role in cholesterol manipulation.
8. Biological crystallography: Crystallisation data collection, refinement, identification of active site, phase determination heavy atom derivatives, electron density maps. Differences in the small molecule and biomolecule crystallography.
9. Spectrofluorimetry and Optical methods: Basic principles of fluorescence, intensity, fluoresent group, sensitivity of fluorescence to environment, biological applications. Optical activity measurements, ORD/CD applications to nucleic acids and proteins.
10. Thermodynamical methods: Differential Scanning Calorimetry (DSC) and Thermogravimetric analysis (TA) of biomolecules, Isothermal Titration Calorimetry (ITC). Various thermodynamics based instrumental methods for estimation of structural features of biomolecules, enthalpy vs entropy contribution to free energy.

Recommended books:

1. Physical Biochemistry: Applications to Biochemistry and Molecular Biology by David Freifelder
2. Methods in Modern biophysics, by B. Nolting
3. Introduction to Biophysical methods in Protein and Neucleic Acid research, by J.A. Glasel

4. Monosaccharides. Their Chemistry and Their Roles in Natural Products
5. Essentials of Glycobiology by Varki
6. Carbohydrates by Osborn
7. Modern Methods in Carbohydrate Synthesis by Khan and O'Neill
8. Organic Synthesis with Carbohydrates by Boons and Hale
9. Enzymes in Synthetic Organic Chemistry by Wong and Whitesides
10. Methods in Modern Biophysics by B. Nolting
11. Introduction to Biophysical Methods in Protein and Neucleic Acid Research by J.A. Glasel.

MC-650 Stereochemistry and Drug Action (2 credits)

1. Molecular isomerism: Molecular motion, time scales and energy; Conformation of open chain and saturated cyclic systems.
2. Chirality and molecular symmetry: Nomenclature and representations; Macromolecular stereochemistry; Dynamic stereochemistry.
3. Group theoretical interpretation of chirality group: Laws of group theory, symmetry elements and operations, classification of symmetry operation into groups, chiral and achiral point groups, determination of molecular structures into symmetry point groups, platonic solids, disymmetrisation.
4. Conformational analysis:
   a) Definitions: Internal coordinates, distinction between conformation and configuration.
   b) Conformational analysis of cyclic compounds: carbocycles and heterocycles, bi- and tri-cyclic compounds.
   c) Conformational analysis of acyclic compounds: potential energy diagrams of various acyclic systems, gauche effect, generalized anomeric effect.
5. Assignment of configuration: Various projectional formulae, molecular with chiral center, axis and plane.
6. Front on projectional formula of conformers and configurational isomers: rational with specific examples.
7. Resolution procedures: Biological and chemical; Analytical chiral integrity determinations; Pfeiffer rule and its violations; Recent attempts to develop continuous scale for chirality; Chiral ligands.
8. Chirality and drug action: Realization that stereoselectivity is a pre-requisite for evolution; Role of chirality in selective and specific therapeutic agents; Case studies; Enantioselectivity in drug absorption, metabolism, distribution and elimination.

Recommended books:

1. StereoChemistry of Organic Compounds by Ernest L. Eliel, Samuek H. Wilen, Lewis N. Mander
2. StereoChemistry of Carbon Compounds by Ernest L. Eliel

3. Chemical Application of Group Theory by F. Albert Cotton
4. Relevant research articles as suggested time to time during the progress of class room teaching.

PC-610 Drug Metabolism (1 credit)

(Refer to Page No. 29)

PC-611 Pharmacological Screening and Assays (1credit)

(Refer to Page No. 30)

GE-611 Seminar (1 credit)

(Refer to Page No. 23)

LS-610 General Laboratory Experience 10 hours/week (2 credits)

Synthesis of a drug that includes 4 to 5 reaction steps; Isolation of each product by chromatographic and other techniques; Identification of structure of products by spectral and other analytical techniques; Report of yield; Understanding the correlation between theoretical and practical aspects of chemistry. Study of theoretical organic chemistry using computation methods for the same reactions and learning the techniques of molecular modeling.

Pharmaceutical Analysis

I Semester

PA-510 Topics in Pharmaceutical Analysis (2 credits)

1. Introduction to pharmaceutical analysis and techniques: Scope and range of modern pharmaceutical analysis. Listing of various techniques, with broad discussion on their applications.
2. Material and product specifications: Definition of specifications, study of Q6 guidelines and understanding of specifications through study of pharmacopoeial monographs on drug substances and products.
3. Reference standards: Types, preparation, containers, labeling, storage and use.
4. Documentation-STPs, certificate of analysis, laboratory books: Typical documents used in a GLP laboratory including standard test protocols, COA and laboratory notebooks.
5. Introduction to method development: Method development concepts, steps involved, intricacies at each step, use of software.
6. Methods validation: Definition and methodology, discussion on each parameter with examples.
7. Calibration and qualification of equipment: Difference of definitions, calibration standards, calibration frequency, examples of calibration of pH meter, FTIR and a UV spectrophotometer. Definition of qualification process involving DQ, IQ, OQ, CQ and PQ. Brief discussion on protocol of each.
8. Bioanalysis and bioanalytical method validation: Types of body fluids, requirement of analysis, matrix effects, sample preparation, non-biological analytical samples. Acceptance criteria in comparison to non-biological samples.
9. Impurity profiling: Types of impurities in drug substances and products. Method development for impurity analysis, techniques, identification and quantitation.
10. Automation and computer-aided analysis, LIMS: The concept of auto samplers and high-throughput analysis, computer controlled instrumentation, and networked laboratory. Peculiarities of laboratory information management systems (LIMS).
11. Management of analytical laboratory: Organization of laboratories based on their types, staffing, skill development and training, budgeting and financing, purchase of costly equipment, qualities of laboratory manager and management styles.
12. Laboratory inspections: Internal inspection, external audit, concepts, preparing for inspections and audits.

Recommended books:

1. Chemical Analysis: Modern Instrumentation Methods and Techniques' by Francis Rouessac and Annick Rouessac
2. Principles of Analytical Chemistry by Miguel Valcarcer

3. Analytical Method Development and Validation by Michael E. Swartz, Ira S. Krull
4. Good Laboratory Practices by Jurg P. Seiler
5. Principles of Instrumental Analysis by Douglas A. Skoog, F. James Holler, Timothy A. Nieman
6. Handbook of Modern Pharmaceutical Analysis by Satinder Ahuja, Stephen Scypinski
7. Principles and Practice of Bioanalysis by Richard F. Venn

MC-511 Spectral Analysis (2 credits)

(Refer to Page No. 03)

NP-510 Separation Techniques (1 credit)

1. Separation Techniques: Need for learning separation techniques, separation techniques in natural product research and drug discovery, extraction techniques.
2. Chromatography: General principles, classification of chromatographic techniques, normal and reverse phase, bonded phase chromatography, stationary phases, activity of stationary phases, elutropic series, and separation mechanisms.
3. Column Chromatography and Short column chromatography: Column packing, sample loading, column development, detection.
4. Flash chromatography and Vacuum liquid chromatography: Objectives, optimization studies, selecting column and stationary phases, selecting suitable mobile phases, automated flash chromatography, and reverse phase flash chromatography.
5. High performance liquid chromatography: Principles, instrumentation, peak shapes, capacity factor, selectivity, plate number, plate height, resolution, band broadening, pumps, injector, detectors, columns, column problems, gradient HPLC, HPLC solvents, trouble shooting, sample preparation, method development.
6. Planar Chromatography - TLC/HPTLC/OPLC: Basic principles, sample application, development of plates, visualization of plates, 2D TLC, densitometry, Over pressure layer chromatography.
7. Counter current chromatography: Basic principles, droplet counter current chromatography, centrifugal partition chromatography, choice of solvents for SP and MP.
8. Gas Chromatography: Principles, instrumentation, split-splitless injector, head space sampling, columns for GC, detectors, quantification.
9. Biochromatography: Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases.
10. Hyphenated techniques: Introduction to GC-MS and LC-MS techniques and their applications in natural products.

Recommended Books:

1. Methods in Biotechnology, Natural Product Isolation by Sarker, Latif, Gray
2. Methods in Biotechnology, Natural Product Isolation by Richard Canell
3. Various Reviews and Research Papers

PE-510 Dosage Form Design Parameters (1 credit)

(Refer to Page No. 42)

BT-510 Biotechnology in Pharmaceutical Sciences

(Refer to Page No. 28) **(1 credit)**

GE-510 Biostatistics (2 credits)

1. Statistics: Introduction, its role and uses. Collection; Organization; Graphics andpictorial representation of data; Measures of central tendencies and dispersion. Coefficient of variation.
2. Probability: Basic concepts; Common probability distributions and probability distributions related to normal distribution.
3. Sampling: Simple random and other sampling procedures. Distribution of sample mean and proportion.
4. Estimation and Hypothesis testing: Point and interval estimation including fiducial limits. Concepts of hypothesis testing and types of errors. Student- t and Chi square tests. Sample size and power.
5. Experimental design and analysis of variance: Completely randomized, randomized blocks. Latin square and factorial designs. Post- hoc procedures.
6. Correlation and regression: Graphical presentation of two continuous variables; Pearson's product moment correlation coefficient, its statistical significance. Multiple and partial correlations. Linear regression; Regression line, coefficient of determination, interval estimation and hypothesis testing for population slope. Introduction to multiple linear regression model. Probit and logit transformations.
7. Non-parametric tests: Sign; Mann-Whitney U; Wilcoxon matched pair; Kruskal wallis and Friedman two way anova tests. Spearman rank correlation.
8. Statistical techniques in pharmaceutics: Experimental design in clinical trials; Parallel and crossover designs. Statistical test for bioequivalence. Dose response studies; Statistical quality control.

Recommended books:

1. Fundamentals of Biostatistics by Bernard Rosner
2. Pharmaceutical Statistics: Practical and Clinical Applications by Bolton and Bon
3. Statistical Misconceptions by Huck

GE-520 Fundamentals of Intellectual Property (IP) and Technology Management (1 credit)

1. Intellectual property: Concepts and fundamentals; Concepts regarding intellectual property (IP), intellectual property protection (IPP) and intellectual property rights (IPR); Economic importance, mechanisms for protection of intellectual property-patents, copyrights, trademark; Factors effecting choice of IP protection; Penalities for violation; Role of IP in pharmaceutical industry; Global ramifications and financial implications.
2. Trade related aspects of intellectual property rights: Intellectual property and international trade; Concept behind WTO (World Trade Organisation), WIPO (World Intellectual Property Organisation) GATT (General Agreement on Tariff and Trade), TRIPs (Trade Related Intellectual Property Rights), TRIMS (Trade Related Investment Measures) andGATS (General Agreement on Trade in Services); Protection of plant and animal gentic resources; Biological materials; Gene patenting; Biotechnology / drug related IPR issues; Status in India and other developing countries; Case studies and examples; TRIPS issues on herbal drugs.
3. Nuts and bolts of patenting, copyright and trademark protection criteria for patentability, types of patents; Indian Patent Act, 1970; WTO and modifications under TRIPS: Filing of a patent application; Precautions before patenting-disclosures / non-disclosures, publication-article / thesis; Prior art search-published patents, internet search patent sites, specialized services-search requests, costs; Patent application-forms and guidelines, fee structure, time frames, jurisdiction aspects; Types of patent applications- provisional, non provisional, PCT and convention patent applications; International patenting-requirement procedures and costs; Financial assistance for patenting- introduction to schemes by NRDC and TIFAC; Publication of patents-gazette of India, status in Europe and US; Patent annuity; Patent attomeys technical aspects, criteria for selection, addresses, fee, rights and responsibilities of a patentee; Practical aspects regarding maintaining of a PATENT FILE; Patent infrigment- meaning, scope, litigation,case studies and examples; Patenting by research students, lecturers and scientists-University / organisational rules in India and abroad; Thesis research paper publication, credit sharing by workers, financial incentives; Useful information sources for patents related information-internet sites, brouchers, periodicals, CD roms; Significance of copyright protection for researchers; Indian Copyright Law and digital technologies-Beme convention, WIPO copyright treaty (WCT), WIPO performance and Phonogram Treaty (WPPT); Protection for computer data bases, multi media works; Trade marks legislation and registration system in India-an introduction, meaning of trademark criteria for eligibility; filling application for trademark registration; Trade secrets-scope modalities and protection; Case studies-drug related patents infringments.
4. Technology development / transfer / commercialisation related aspects: Technology development-meaning; Drug related technology development; Toxicological studies, bioequivalence (BU), clinical trials-phase-I, phase-II and phase-III; Approved bodies and agencies; Scale-up, semi-commercialisation and commercialisation-practical aspects and problems; Significance of transfer of technology (TOT), bottlenecks; Managing technology transfer-guidelines for research students, scientists and related personnal; TOT agencies in India-APCTD, NRDC, TIFAC, BCIL, TBSE/SIDBI; TOT related documentation-confidentiality agreements, licensing, MOUs, legal issues; Compulsary licensing excess to medicine issues;

DOHA declaration, POST WTO product patent regime from 2005; Challenges for Indian pharmaceutical industry in the context of globalisation of IP; Drug registration and licensing issues-national and global; Drug master file submissions, SOPS; Related registration and marketing issues; Case studies- antiretroviral drugs and others.

5. Funding sources for commercialization of technology: Preparation of a project report, financial appraisal, business models; GOI schemes and incentives; NRDC, TePP, HGT, TDB schemes. PATSER; Venture capitalists, banks. Incubator concept-Case studies with respect to IIT, CCMB, IMTECH, NIPER. Documentation and related aspects.
6. Ethics and values in IP: IP and ethics-positive and negative aspects of IPP; Societal responsibility; Avoiding unethical practices; Echo-responsibility-economic, social and environmental benifits of modern biotechnology; Voluntary adoption of pollution control strategies.

Recommended books:

1. Law Relating to Intellectual Property by B.L.Wadhera
2. IPR Handbook for Pharma Students and Researchers by P.Bansal
3. The Patents Act, 1970 (Bare Act with Short Notes) (New Delhi: Universal Law Publishing Company Pvt. Ltd. 2012)
4. Patent Agent Examination by Sheetal Chopra and Akash Taneja
5. Making Innovation Happen- A simple and Effective Guide to Turning Ideas into Reality by Michael Morgan.
6. Making Breakthrough Innovation Happen by Porus Munshi
7. Innovation X- Why a Company's Toughest Problems are its Greatest Advantage by Adam Richardson
8. Legal Drafting for the Layman by Nabhi Kumar Jain
9. How to Write and Publish a Scientific Paper by Rober A Day
10. Concise Law Dictionary-with Legal Maxims, Latin Terms and Words and Phrases by Justice Y.V.Chandrachud
11. Biomedical Research- From Ideation to Publication by G.Jagadeesh and others

GE-511 Seminar (1 credit)

1. Introduction, Information retrieval systems.
2. Writing term papers and reports.
3. Organization of scientific material, thesis, dissertation and refernces.
4. Reading research papers
5. Skills in oral presentation.

Each student has to present a seminar before end of the semester.

LG-510 General Laboratory Experience-15 hours/week (3 credits)

1. Analytical techniques (75 hours)

   a) Spectral analysis workshop (45 hours):

   b) Separation techniques (30 hours):

2. Computer and application in pharmaceutical sciences (100 hours): Introduction to computers, basic unit and functions, H/W and S/W, operating systems, word processing, spread sheet, graphic programs, dbase, windows, statistical S/W programs and packages. Steps involved in S/W development, computer languages with emphasis to FORTRAN anguage and programming, hands on experience in pharmaceutical software systems. Use of computers in information retrieval systems.
3. Pharmacology (25 hours) : Animal handling, route of administration of drugs, dose response relationship,acute toxicity testing of drugs, analgesic activity of a compound, estimation of protein and haemological parameters.
4. Biotechnology for pharmaceutical sciences (20 hours)

   Day-1: Preparation for plasmid miniprep.

   Day-2: Plasmid miniprep and restriction digesion.

   Day-3: Gel electrophoresis. and molecular weight calculation.

   Day-4: Discussion of result and viva.

5. Specialization (50 hours)

   a) To Calibrate thermometer

   b) To Calibrate the common glassware (Volumetric flask, burette and pipette) found in an analytical laboratory.

   c) Calibration of pHmeter

   d) To determine water content in the given sample by Karl Fisher reagent

   e) To determine moisture content in the given sample using infrared moisture balance

   f) To Construct calibration curve for a drug by UV spectrophotometer

   g) To perform dissolution test on the given sample.

   i) Determination of pKa of given sample by spectrophotometric method.

II Semester

PA-610 Pharmacopoeial Methods of Analysis (2 credits)

The course shall cover critical comparative analysis of the following selected tests in IP, BP/ EP and USP:

1. Physical tests: Viscosity, melting point, boiling point/range, water content, osmolality/ osmolarity, refractive index, loss on drying, loss on ignition, optical rotation, pH and specific gravity.
2. Limit tests: Tests for arsenic, lead, chloride, sulfate, and heavy metals.
3. Special tests: Inorganic impurities, residual solvents, etc.

4. Microbiological assays: Antimicrobial effectiveness testing, microbial limit tests, sterility test.
5. Biological tests: Antibiotics-microbial assays, bacterial endotoxins test.
6. Dissolution tests: Types of dissolution apparatus, dissolution test requirements for immediate release, delayed release, extended release dosage forms; coated, uncoated and enteric-coated tablets; gelatin capsules, etc.
7. Miscellaneous tests: Test for epianhydrotetracycline and epitetracycline (USP).

Recommended books:

1. The Indian Pharmacopoeia, Indian Pharmacopoeia Commission, Ghaziabad, 2010.
2. The British Pharmacopoeia, Stationary Office British Pharmacopoeia Commission, London, 2008.
3. The United States Pharmacopeia-National Formulary, Board of Trustees, Rockville, 2006.
4. The European Pharmacopoeia, Directorate for Quality of Medicines of the Council of Europe, 2007.

PA-620 Modern Instrumental Techniques for Evaluation of APIs and Drug Products (2 credits)

1. Spectroscopic techniques: Specific discussion on the following shall be preceded by overview on many newer techniques that allow non-destructive analysis and visualization. Also students shall be made aware of the concepts of chemometrics, lasers, and charged coupled devices.
   a) FT-NIR: Principle (overtones, combinations, fermi resonance, interferences etc.), instrumentation (dispersion spectrometer and FT-NIR), advantage and disadvantage, qualitative and quantitative applications, including PAT and non-destructive analysis.
   b) ATR: Principle (total internal reflection, evanescent wave, etc.), instrumentation (ATR crystal, IR beam), advantages and disadvantages, pharmaceutical applications.
   c) FT-Raman: Principle (absorption, diffraction, scattering and emission of wave, molecular interaction), instrumentation (Dispersive Raman, FT-Raman), advantage and disadvantage, pharmaceutical applications including detection of counterfeits.
2. Thermal techniques:
   a) DSC: Principle, thermal transitions, instrumentation (Heat flux and power- compensation designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, ources of errors) and their influence, advantages and disadvantages, pharmaceutical applications.
   b) DTA: Principle, instrumentation, advantage and disadvantage, pharmaceutical application, derivative differential thermal analysis (DDTA).
   c) TGA: Principle, instrumentation, factors affecting results, advantages and disadvantages, pharmaceutical application.
3. Particle sizing: Light interaction methods: Rayleigh or static laser light scattering, photon correlation spectroscopy or dynamic laser light scattering, single particle light scattering, multi-angle light scattering.
4. Electrophoresis: Capillary electrophoresis: Basic principle (zeta potential), instrumentation, different modes of CE, advantages and disadvantages, pharmaceutical applications.

5. Chromatographic techniques:
   a) HPLC: Principle, instrumentation, pharmaceutical applications.
   b) UPLC: Principle and applications.
   c) LC-MS and LC-NMR: Nature of interfaces, applications.

Recommended books:

1. Principles of Instrumental Analysis by Dougla A. Skoog, F. James Holler, Timothy A. Nieman
2. Instrumental Method of Analysis by Hobart H. Willard, Lynne L. Merrit, John A. Dean, Frank A.Settle
3. Fundamentals of Fourier Transform Infrared Spectroscopy by Brian C. Smith
4. Modern Raman Spectroscopy: A Practical Approach by Ewen Smith, Geoffery Dent
5. Chemical Analysis: Modern Instrumental Methods and Techniques by Franscis Rouessac and Annick Rouessac
6. Handbook of Pharmaceutical Analysis by Lena Ohannesian, Antony J. Streeter
7. HPLC for Pharmaceutical Scientists, Edited by Yuri Kazakevich and Rosario LoBrutto
8. Introduction to Thermal Analysis Techniques and Applications by Michael E. Brown
9. Modern Methods of Particle Size Analysis, Edited by Howard G. Barth
10. Electrophoresis: The Basics by David M. Hawcroft

PA-630 Stability Testing (1 credit)

1. Drug development cycles and stability testing: Role and types of stability studies during different stages of drug and product development.
2. Stress testing: Role, regulatory aspects, protocols/approaches, practical considerations.
3. Stability-indicating methods: Definition, regulatory requirement, steps in development, practical considerations.
4. Role of kinetics studies: Important mechanistic and stability-related information provided by results of study of factors like temperature, pH, buffering species, ionic strength, dielectric constant, etc. on the reaction rates.
5. Stability testing protocols: Selection of batches, container orientation, test parameters, sampling frequency, specifications, storage conditions, recording of results, concept of stability commitment, etc.
6. Retest period/shelf life determination: Evaluation of stability data. .
7. Photostability: Photostability testing of new active substances and medicinal products, light sources and options, types of chambers, presentation of samples, practical considerations, confirmatory testing.
8. Stability testing of biotechnological products: Typical stability testing issues of biotechnological vis-à-vis conventional products, considerations in ICH Q5C guideline.
9. Stability testing of phytopharmaceuticals: Regulatory requirements, protocols, HPTLC/HPLC finger printing, Interactions and complexity.
10. Post-approval changes: Nature of post-approval changes. Regulatory requirements of stability re-workup.

11. Reduced stability-testing plans: Bracketing and matrixing designs for multiple strength, packaging, etc.
12. Ongoing and follow-up stability testing: Definitions, applicability, requirements in WHO 2009 stability testing guideline.
13. Stability test equipment: Types of stability chambers (walk-in, stand-alone, photostability), design considerations, qualification and other critical issues.

Recommended books:

1. Stability and Characterization of Protein & Peptide of Drugs by Y. John Wang
2. Peptide and Protein Drug Analysis by Ronald Reid
3. Pharmaceutical Stress Testing (Predicting Drug Degradation) by Steven Baertschi and Karen Alsante
4. Drug Stability (Principles and Practices) by S. James, Jens Thurø Carstensen
5. Stability-indicating HPLC Methods for Drug Analysis by Quanyun A. Xu , Lawrence A. Trissel
6. Stability of Drugs and Dosage Forms by Sumic Yoshioka, Valentino Stella
7. Physical Pharmacy and Pharmaceutical Sciences by Patrick Sinko, Alfred Martin
8. New Drug Approval Process (Chapter 7) by Richard Guarino
9. Handbook of Stability Testing in Pharmaceutical Development: Regulations, Methodologies, and Best Practices by Kim Huynh-Ba

PA-640 Quality Control and Quality Assurance (2 credits)

1. Good manufacturing practices and its applications to pharmaceutical industry.
2. Basic principles and concepts of quality management viz. quality control, quality assurance, quality auditing and ISO system etc.
3. Sampling, finished products labeling, distribution records.
4. Document control: Issuance, storage and retrieval.
5. Standard operating procedures: Change control procedure and annual product review.
6. Basic principles of validation: Validation protocols, analytical method validation and process validation.
7. Technology transfer from R & D to manufacturing.
8. Product change over, basic requirements of cleaning and its validation.
9. Market complaint and handling of returned goods.

Recommended books:

1. Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials
2. Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials by D.H. Shah, Q.A. Manual
3. Good Pharmaceutical Manufacturing Practice: Rationale and Compliance by John Sharp

NP-640 Structure Elucidation (2 credits)

1. Structure elucidation of natural products: General strategies for structure elucidation of natural products with few examples.
2. Chemical methods: Determination of carbon skeleton, dehydrogenation, oxidative methods in structure elucidation, reductive methods in structure elucidation.
3. Chemical methods: General methods for structure elucidation of steroids, terpenoids, alkaloids with few examples.
4. Ultraviolet spectroscopy: Basic principles, rules to calculate max, applications in structure elucidation with examples.
5. Infra red spectroscopy: Basic principles, various factors affecting frequency, functional group identification, applications in structure elucidation with examples.
6. Mass Spectrometry: Basic principles, various ionization modes EI, CI, FAB etc. fragmentation patterns, HRMS, applications in structure elucidation with examples.
7. 1H and 13C NMR Spectroscopy: basic principles, chemical shift, factors affecting chemical shift, prediction of chemical shifts, coupling constants, Karplus curve, advanced 1D NMRexperiments such as NOE, DEPT etc.
8. 2D NMR: 1H-1H COSY, HSQC, HMBC, NOESY experiments: Their use in structure elucidation.
9. Structure elucidation: Examples from alkaloids, flavaonoids, and sterols.
10. Structure elucidation - examples from coumarins, triterpenes, and xanthones.

Recommended books:

1. Spectroscopy by Pavia, Lampman, Kriz, Vyvyan
2. Spectrometric Identification of Organic Compounds by RM Silverstein
3. Organic Spectroscopy by William Kemp
4. Spectral Data for Structure Elucidation

PC-611 Pharmacological Screening and Assays (1 credit)
(Refer to Page No. 30)

PE-630 Pharmaceutical Product Development-I (2 credits)
(Refer to Page No. 46)

PE-660 Solid State Pharmaceutics (1 credit)
(Refer to Page No. 48)

GE-611 Seminar (1 credit)

Students are required to submit written record and present details of the project to be pursued in semester-III & IV. This should include the purpose and basis of the project, stating aims, objectives and probable outcomes, be able to supplement these with necessary information, literature review towards it and process for the project itself.

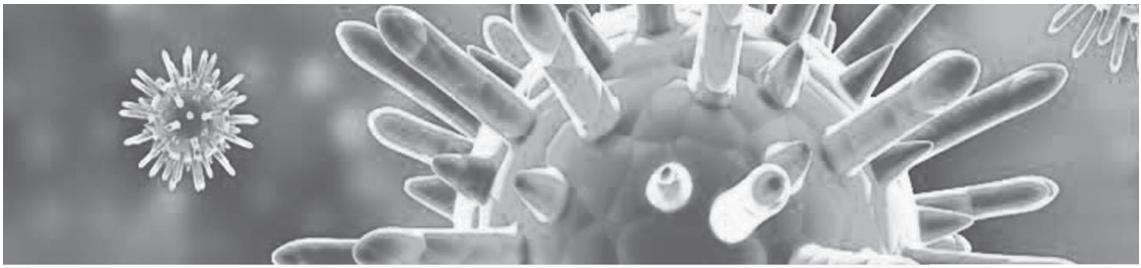
LS-610 General Laboratory Experience-10 hours/week (2 credits)

Practicals in Lab:

1. Analysis of a drug sample by a pharmacopoeial method and preparation of its certificate of analysis.
2. Determination of viscosity of given samples using Ostwald viscometer and rotoviscometer.
3. Estimation of the given drug in urine and blood samples using HPLC and identification of metabolites.
4. Stress study of a drug sample in proposed conditions and etablishment of a stability indicating assay using HPLC.
5. Separation of an impurity in a sample on a preparative HPLC.
6. Establishment of dissolution characteristics of a given controlled release preparation using an automated dissolution tester.
7. Particle size and shape analysis using of an automated particle size ana yzer.
8. Determination of tapped and bulk density.
9. Study of different packaging materials and their evaluation.
10. Determination of osmolality of given solutions.
11. Moisture determination of given substances using infrared moisture balance.

Practicals in CIL:

1. Determination of instrument calibration, melting behaviour and polymorphic beheviour of various compounds by DSC.
2. Spectrofluorimetric analysis of a given sample.
3. Study of hydrate forms of ampicillin trihydrate using TGA.
4. Study of the given sample by AAS.
5. Freeze drying of a sample.
6. Separation of impurities of betamethasone velerate on LC-MS using BP method and study the mass values of impurities.
7. Study of a given mixture by GC-MS.
8. Study of given sample on polarimeter.
9. ATR analysis of a given drug sample.
10. Conduct of a titration using an autotitrator.



Pharmacology & Toxicology

I Semester

PC-511 Pathophysiology (1 credit)

1. Factors influencing the disease conditions such as sex, age, nutritional status, genetic make up etc.
2. Pathogenesis, symptoms and signs, laboratory findings and complications of respiratory, urinary tract, venereal and meningial infections.
3. Pathogenesis, symptoms and signs, laboratory findings and complications of Congestive heart failure, hypertension, cardiac arrhythmias.
4. Pathogenesis, symptoms and signs, laboratory findings and complications of Ulcer, pancreatitis.
5. Pathogenesis, symptoms and signs, laboratory findings and complications of hepatitis and cholecystitis.
6. Pathogenesis, symptoms and signs, laboratory findings and complications of Bronchial asthma.
7. Pathogenesis, symptoms and signs, laboratory findings and complications of depression, schizophrenia, epilepsy.
8. Pathogenesis, symptoms and signs, laboratory findings and complications of Parkinsonism and Alzheimer's disease.
9. Pathogenesis, symptoms and signs, laboratory findings and complications of Hypo and hyper thyroidism, diabetes mellitus and other endocrine diseases.
10. Pathogenesis, symptoms and signs, laboratory findings and complications of Rheumatoid arthritis, gout and anemia.

PC-520 General Pharmacology (2 Credits)

1. Drug receptor interaction theories, occupation theory, rate theory.
2. Receptor occupation and response relationship, spare receptors, silent receptors, orphan receptors, presynaptic and postsynaptic receptors.
3. Receptor characterization methods: Pharmacological characterization, radio ligand methods, monoclonal anti-bodies, receptor subtypes, IUPHAR nomenclature, clinical significance of receptor subclassification.
4. Receptor down regulation and upregulation.
5. Structure activity relationships, pharmacodynamic and pharmacokinetic aspects of chiral drugs, allosteric binding, thermodynamics of drug interactions with the receptors.
6. Transmembrane signal mechanisms, second messengers, viz., cAMP, cGMP, calcium.
7. Dose response relationship and different types of antagonisms.
8. Desensitization and tachyphylaxis.
9. Drug dependence and withdrawal responses.
10. Non therapeutic uses of drugs.

Recommended books:

1. Pharmacotherapy: A Pathophysiologic Approach by Dipiro and others
2. The Pharmacological Basis of Therapeutics by Goodman and Gilman's.

PC-530 Experimental Pharmacology (1 Credit)

1. Common laboratory animals and their physiological parameters, breeding types, inbred strains, F1 hybrids; Random breeding, selective breeding, breeding methods, factors affecting the nature and degree of pharmacological responses; Handling and care of different animals; Bleeding and different routes of administration and chemical euthanasia.
2. Advantages and disadvantages; Physiological salt solutions, recording transducers, resting tensions, equilibrium, dose cycles; methods of stimulation, stimulating devices, operation of recording devices, superfusion, cascade superfusion, perfusion, some commonly used isolated preparations.
3. Advantages and disadvantages; Anaesthesia used in laboratory animals, common agents, dose calculations, cannulation methodology, ventilation rate, recording of arterial blood pressure, intestinal motility etc.
4. Conscious animal experimentation precautions to be taken in behavioural experiments.
5. Aseptic handling, cell counting and cell viability assays.
6. Western, northern, southern blot hybridization and PCRtechniques.
7. Protein purification and identification by RF-HPLC, LCMS-MS, MALDI.
8. Principle of radiation and radioactivity, decay of radioactivity, units, isotopes detection, scintillation detector (crystal and liquid), quenching, radioimmunoassay.
9. Storage, concentration expression,common solvents, stabilizing agents, storage conditions, reference standards, methods of procurement of reference standards.
10. Data reduction, data representation, cumulative and noncumulative dose response curves, transformation of data logit, probit, pAscale, pD scale.

Recommended Books:

1. The Pharmacological Basis of Therapeutics by Goodman & Gilman
2. Casarett & Doull's Essentials of Toxicology, edited by CD Klassen and JB Watkins

PC-540 Chemotherapy of Parasitic and Microbial Infections (1 Credit)

1. Introduction to parasitic and infectious diseases.
2. Biology of tuberculosis.
3. Mechanism of action of anti-tuberculosis drugs.
4. Targets for anti-tuberculosis drug development.
5. Mechanism of drug-resistance in tuberculosis.
6. Biology of human amoebiasis.
7. Mechanism of action of anti-amoebic drugs.
8. Biology of filarial infections.
9. Mechanism of action of anti-filarial drugs.
10. Targets of anti-filarial drug development.

11. Biology of HIV infection.
12. Mechanism of action of anti-HIV drugs.
13. Targets for anti-HIV drug development.
14. Biology of malaria.
15. Mechanism of action of anti-malarial drugs.
16. Targets for anti-malarial drug development.
17. Mechanism of drug-resistance in malaria.
18. Biology of leishmaniasis.
19. Mechanism of action of anti-leishmanial drugs.
20. Targets for anti-leishmanial drug development.
21. Drug-resistance in leishmaniasis.

Recommended books:

1. Chemotherapy by Frank Hawking
2. Parasitic Protozoa by Julius P. Kreier and Ristic
3. Malaria by Julius P. Kreier
4. Chemotherapy and Drug Resistance in Malaria by Wallace Peter
5. Atlas of Tropical Medicine and Parasitology by Wallace Peter and Geoffrey Pasvol
6. Manson's Tropical Diseases: Expert Consult Basic by Gordon C. Cook
7. Tropical Infectious Diseases: Principles, Pathogens and Practice by Richard L. Guerrant, David H. Walker and Peter F. Weller
8. Essentials of Tropical Infectious Disease by Richard L. Guerrant, David H. Walker, Peter F. Weller
9. History of Human Parasitology by F. E. G. Cox
10. Malaria Parasites and other Haemosporidia by P. C. C. Garnham
11. Diagnostic Microbiology by Bailey & Scott
12. Medical Microbiology by Samuel Baron
13. Textbook of Microbiology by P. C. Baveja
14. Human Parasitic Infections of Pharmaceutical & National Importance edited by Prati Pal Singh and V. P. Sharma
15. Quantitative Real-time PCR in Applied Microbiology edited by Martin Filion

NP-510 Separation Techniques (1 Credit)

(Refer to Page No. 14)

PE-520 Biopharmaceutics and Pharmacokinetics (2 credits)

(Refer to Page No. 42)

BT-510 Biotechnology in Pharmaceutical Sciences (1 credit)

1. Biotechnology in pharmaceutical Sciences perspective:Biology in drug discovery; Traditional drug discovery vs rational drug discovery; rational drug discovery pipeline; concept of target based drug design and target discovery; role of plant biotechnology in edible vaccine development.
2. Genomics in target discovery: Concept of genome, genes and gene expression; genome sequencing and sequence comparison methods (microarray); comparative genomics and expression genomics for target discovery of communicable disease and lifestyle disease.
3. Systems and methods of molecular biology:Isolation and validation of targets; PCR, RT-PCR nucleic acid isolation; cloning vectors (some examples), enzymes used in molecular cloning methods (some examples); cloning and characterization of biopharmaceuticals.
4. Protein expression systems:Gene expression in bacteria yeast, insect and mammalian cells.
5. Enzyme purification and assay: Various protein purification methods; enzyme based assay for small molecule screening.
6. Bioprocess technology: Upstream process: Introduction to microbial growth, media formulation; sterilization, inoculum preparation
7. Bioprocess technology:Fermentation: Fermentation process design, operation and characteristics of fermentation processes; batch, fed-batch and continuous culture systems, instrumentation and bioprocess control.
8. Downstream process:Introduction to various downstream process operations in biopharmaceutical manufacturing such as centrifugation, filtration, tangential flow filtration, cell disintegration, solvent-solvent extraction, supercritical fluid extraction etc.
9. Biotechnology in pharmaceutical industryMajor areas of biotechnology in the pharmaceutical industry such as antibiotics, vaccines, diagnostics, antibodies, biopharmaceuticals (insulin, interferon, GSF, CSF and therapeutic proteins etc.); commercial aspects, priorities for future biotechnological research.
10. Industrial enzymes in drug development: Penicillin amidase, lipase, oxidoreductase, nitrilase, protease etc.; use of all these enzymes for enantioselective synthesis of pharmaceutically important drugs/drug intermediates, future directions.

GE-510 Biostatistics (2 credits)
(Refer to Page No. 15)

GE-520 Fundamentals of Intellectual Property (IP) & Technology Management (1 credit)
(Refer to Page No. 16)

GE-511 Seminar (1 credit)
(Refer to Page No. 17)

LG-510 General Laboratory Experience-15 hours/week (3 credits)

1. Analytical Techniques Separation techniques.
2. Computer and application in pharmaceutical sciences (100 hours): Introduction to computers, basic unit and functions, H/W and S/W, operating systems, word processing, spread sheet, graphic programs, dbase, windows, statistical S/W programs and packages. Steps involved in S/W development, computer languages with emphasis to FORTRAN language and programming, hands on experience in pharmaceutical software systems. Use of computers in information retrieval systems.
3. Pharmacology (25 hours): Animal handling, route of administration of drugs, dose response relationship, analgesic activity of a compound, estimation of protein and haematological parameters.
4. Biotechnology in pharmaceutical sciences (20 hours):

   Day-1: Preparation for plasmid minirep.

   Day-2: Plasmid minirep and restriction digestion.

   Day-3: Gel electrophoresis and molecular weight calculation.

   Day-4: Discussion of result and viva.
5. Introduction to lab experience and animal experimentation,blood glucose estimation, IC50 determination, demonstration of motor coordination, microscopic techniques, to study effect of drug on food and water intake, histopathological study, SDSPAGE demonstration, cell culture demonstration, cell viability assay.

II Semester

PC-610 Drug Metabolism (1 Credit)

1. Biotransformation of drugs.
2. Enzymes responsible for bio-transformations, microsomal and non-microsomal mechanisms.
3. Factors influencing enzyme induction and inhibition.
4. Factors effecting drug metabolism.
5. Drug metabolism in fetus and new born.
6. Models to study drug metabolism.
7. Dose-effect relationships.
8. Excretion of drugs, biliary and fecal excretion.
9. Adverse drug reactions and drug interactions; Toxic reactions, allergic reactions, idiosyncracy.
10. Acute poisoning and its treatment.

Recommended books:

1. Introduction to Drug Metabolism, by G. Gordon Gibson and Paul Skett
2. Drug Metabolism Handbook Concepts and Applications Edited byAla F. Nassar, Wiley

PC-611 Pharmacological Screening and Assays (1 Credit)

1. General principles of screening, correlations between various animal models and human situations, animal ethics.
2. Pharmacological screening models for therapeutic areas such as hypertension, cerebral ischaemia, pain, epilepsy, depression, Parkinson's disease, Alzheimer's disease, diabetis, leishmaniasis etc.
3. Correlation between in-vitro and in-vivo screens; Special emphasis on cell based assay, biochemical assay, radioligand binding assay, high through put screening, high through put pharmacokinetic analysis, specific use of reference drugs and interpretation of results.

Recommended books:

1. Drug discovery and evaluation and pharmacological assays, by Gerhard Vogel
2. Screening Methods in Pharmacology by Turner
3. Drug screening Methods by Guptha
4. Screening Methods in Pharmacology by Parmar
5. Fundamentals of experimental Pharmacology by Ghosh

PC-620 CNS and Respiratory Pharmacology (2 Credit)

1. Chemical transmission and drug action in the central nervous system: CNS drug discovery and challenges.
2. Neurotransmitters: Dopamine, 5-HT, excitatory amino acids, GABA, glycine peptides as mediators.
3. Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of: Benzodiazepines and its antagonists. Barbiturates, local anesthetics.
4. Pharmadiacodynamic, pharmacokinetic, therapeutic and toxicological facets of 5-HT agonists and antagonists, tricyclic antidepressants, MAOI, atypical antidepressants, lithium.
5. Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of antiepileptics.
6. Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of drugs used in the treatment of Parkinsonism.
7. Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of centrally acting muscle relaxants.
8. Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of narcotic analgesics.
9. Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of psychomotor stimulants and psychotomimetic drugs, antipsychotic drugs.
10. Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of drugs used in Alzheimer's disease,
11. Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of: respiratory stimulants, bronchodilators and antiInflammatory agents used in asthma, cough

Recommended books:

1. The Pharmacological Basis of Therapeutics by Goodman and Gilman's
2. Pharmacology by Rang and Dale
3. Pharmacotherapy: A Pathophysiologic Approach by Dipiro and others
4. Pharmacology by Lippincott
5. Scientific journals (Trends in Pharmacological Sciences, Annual Reviews of Pharmacology and Toxicology, British Journal of Pharmacology, European Journal of Pharmacology, Pharmacology and Therapeutics, Nature Review Drug Discovery, Nature Review Neuroscience, Brain Research) Pharmacology by Lippincott suppressants.

PC-630 Autonomic, CVS, Blood, Renal, and GI Pharmacology (2 credits)

1. Chemical transmission of the autonomic nervous system.
2. Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of the followings: Muscarinic cholinergic receptor agonists and antagonists. Ganglionic stimulants and blocking agents, neuromuscular blocking agents, drugs acting and adrenoceptors.
3. Cardiac glycosides and other cardiotonic agents, Anti dysrhythmic drugs, antianginaldrugs.
4. Antihypertensives, Calcium channel antagonists, ACE inhibitors, endothelium derived relaxing factors, lipid lowering agents.
5. Diuretics, Drugs altering the pH of urine, excretion of organic molecules.
6. Oral anticoagulants, Factors increase / decrease the efficacy of oral anticoagulants, heparin.
7. Platelet adhesion and activation, Antiplatelet agents, thrombolytic agents and antifibrinolytic agents and hemostatic agents.
8. Factors necessary for erythropoiesis, Hematopoietic growth factors.
9. H2 receptor antagonists, Proton pump inhibitors, antacids, emetics, antiemetics and cancer chemotherapy, purgatives,
10. Drugs regulating the GI motility, Cholagogues and drugs used in cholelithiasis.

Recommended books:

1. The Pharmacological Basis of Therapeutics by Goodman and Gilman's
2. Scientific journals (Trends in Pharmacological Sciences, Annual Reviews of Pharmacology and Toxicology, British Journal of Pharmacology, European Journal of Pharmacology, Pharmacology and Therapeutics, Cardiovascular journals, Nature Review Drug Discovery)

PC-640 Autocoid and Endocrine Pharmacology (1 credit)

1. Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of the following Histamine and brady kinin agonist and antagonists.
2. Drugs acting through eicosanoids and platelet activating factor.
3. Adenohypophyseal hormones and related substances.

4. Thyroid and antithyroid drugs.
5. Insulin and oral hypoglycemic agents.
6. Endocrine pancreas.
7. Adrenocortical hormones: adrenocortical steroids and inhibitors of the synthesis.
8. Agents affecting the clarification, estrogens and progesterone and their antagonists.
9. Oral contraceptive.
10. Androgens.

Recommended books:

1. The Pharmacological Basis of Therapeutics by Goodman and Gilman's
2. Pharmacology by Rang and Dale
3. Basic and Clinical Pharmacology by Katzung

PC-650 Clinical Pharmacology and Regulatory Toxicology (2 credits)

1. Introduction to clinical pharmacology: Importance of clinical pharmacokinetics, therapeutic monitoring of important drugs.
2. Drug-drug interactions: Drug-food interactions; Drug-pollutant interaction.
3. Investigational new drug application, new drug application requirements; FDA requirements.
4. Preclinical testing strategy; Vis a-vis envisaged clinical studies; Experimental clarification of possible human risk; Technical details of experiments; Flow chart for development of preclinical testing.
5. Design and organisation of phase-I to phase-IV clinical studies
6. Single dose and repeat dose toxicity studies: Factors influencing such studies such asspecies, sex, size, route, dose level; Data evaluation and regulatory requirements.
7. Reproductive toxicology assessment of male reproductive toxicity: Spermatogenesis; Risk assessment in male reproductive toxicity; Female reproductive toxicology; Oocyte toxicity; alterations in reproductive endocrinology; relationship between maternal and developmental toxicity.
8. Mutagenicity: Mechanisms of mutagenesis, point mutations; Individual chromosomes and complete genome mutations, germ cell mutations, somatic cell mutation; Tests systems in vitro, test for gene mutation in bacteria, chromosome damage, gene mutation, in vivo micronucleus tests in rodent, metaphase analysis.
9. Carcinogenicity: Principles of carcinogenicity, prechronic studies for dose-setting, chronic study, transplacental carcinogenesis; Cocarcinogenisis/tumor promotion, estimation of carcinogenicity of complex mixtures.

10. Toxicokinetics, animals and dose groups:Exposure measurement; determination of metabolities complicating factors in exposure interpretation, analytical method, good laboratory practices; Stereoisomerism vis-a-vis regulatory requirements; Single enantiomers; Racemate enantiomer switch; Regulatory requirements.
11. Toxicokinetic methods validation:Assay development; Assay validation, study monitoring, calibration of standards; validation report.
12. Preclinical toxicological requirements for biologicals and biotechnological products: safety analysis; problems specific to recombinant products secondary pharmacology, antibodies, transmission of viral infections, residual DNA, etc.

Recommended books:

1. Clinical Pharmacology by Lawrence
2. Basic and Clinical Pharmacology by Katzung
3. ICH Guidelines
4. ScheduleY
5. OECD Guidelines
6. USFDAGuidelines

PC-660 Chemotherapy and Immunopharmacology (2 credits)

1. Introduction to immunopharmacology, immunomodulators, immunostimulants and immunosuppressants.
2. General considerations of antimicrobial agents.
3. Spectrum of activity, mechanism of action, ADME and therapeutic aspects of the following: Quinolones, sulphonamides, penicillins, cephalosporins, clavulanic acid aminoglycosides, broad spectrum antibiotics,
4. Spectrum of activity, mechanism of action, ADME and therapeutic aspects of the chemotherapeutic agents used in tuberculosis,
5. Spectrum of activity, mechanism of action,ADME and therapeutic aspects of the antifungal agents,
6. Spectrum of activity, mechanism of action, ADME and therapeutic aspects of the antiprotozoal agents,
7. Spectrum of activity, mechanism of action, ADME and therapeutic aspects of the antimalarial agents, antiparasitic drugs
8. Spectrum of activity, mechanism of action, ADME and therapeutic aspects of the antiviral drugs, drugs used in the treatment of AIDS
9. Spectrum of activity, mechanism of action, ADME and therapeutic aspects of the antineoplastic agents.

Recommended books:

1. Chemotherapy by Frank Hawking
2. Parasitic Protozoa by Julius P. Kreier and Ristic
3. Malaria by Julius P. Kreier
4. Chemotherapy and Drug Resistance in Malaria byWallace Peter
5. Atlas ofTropical Medicine and Parasitology byWallace Peter and Geoffrey Pasvol
6. Manson'sTropical Diseases: Expert Consult Basic by Gordon C. Cook
7. Tropical Infectious Diseases: Principles, Pathogens and Practice by Richard L. Guerrant, David H. Walker and Peter F.Weller
8. Essentials of Tropical Infectious Disease by Richard L. Guerrant, David H.Walker, Peter F.Weller
9. History of Human Parasitology by F. E. G. Cox
10. Malaria Parasites and other Haemosporidia by P. C. C. Garnham
11. Diagnostic Microbiology by Bailey &Scott
12. Medical Microbiology by Samuel Baron
13. Textbook of Microbiology by P. C. Baveja
14. Human Parasitic Infections of Pharmaceutical and National Importance edited by Prati Pal Singh and V.P. Sharma
15. Quantitative Real-time PCR in Applied Microbiology edited by Martin Filion

GE-611 Seminar (1 credit)

(Refer to Page No. 23)

LS-610 General Laboratory Experience in the area of Specialization- 10 hours/week (2 credits)

Ed50 calculation, working of stereotaxy apparatus, effect of drug on locomotor activity, demonstration of blood pressure recording, SDS PAGE, western blotting experiment, DNA Gel Electorphoresis experiment, MTT and LDH assay, effect of cyclophosphamide on neutrophil counts, Genotoxic effect of unknown drugs, histopathological evaluation with different target organ, microscopic techniques, blood cell counter.