ACADEMIC PROGRAMMES, ELIGIBILITY CRITERIA AND NUMBER OF SEATS FOR 2015-17

NIPER-A conducts educational programmes at postgraduate and doctoral level. Currently NIPER-A is offering only one Masters Program i.e. M. S. (Pharm.). The details of discipline, eligibility criteria and No of seats is appended below:

M.S. (Pharm.)		
Discipline	**Eligibility for Application**	**No. of Seats**
Biotechnology	B.Pharm; M.Sc.(Biological Sciences)	07
Medicinal Chemistry	B.Pharm.; M.Sc.(Organic chemistry)	08
Medical Devices	B.Pharm	07
Natural Products	B.Pharm.; M.Sc.(Organic chemistry)	06
Pharmaceutical Analysis	B.Pharm; M.Sc. (Organic/Analytical Chemistry)	08
Pharmaceutics	B. Pharm	12
Pharmacology & Toxicology	B.Pharm; B.V.Sc.; M.B.B.S.	07

Note:

1. One seat is reserved for Physically Handicapped (PH) candidates in M.S. (Pharm.) program and will be adjusted in any discipline in NIPER, Ahmedabad.
2. Provision for reservation for Kashmiri migrants (KM) shall be made as per Govt. of India Order.
3. Number of seats mentioned above is including SC/ST/ OBS/ Gen category and provisions for reservation shall be made as per Govt. of India in force.

SUMMARY OF ORDINANCE & REGULATIONS FOR MASTERS PROGRAMME

1. Teaching in the institute will be organized around the credit system. Each course has a certain number of credits which will describe its weightage. The performance/ progress of the student will be measured by the number of credits that he/she has completed satisfactorily. A minimum grade point average will be required to qualify for the degree. The letter grades and 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) = 0

Grade Point Average (GPA) = (Number of Credits x Grade Points) divided by Credits.
For calculating GPA only those course(s) including projects will be taken into account in which the student has been awarded A,B,C or D Grade.

Grading scale

% of Marks	≥ 80	75-79	70-74	65-69	60-64	55-59	50-54	40-49	<40
Letter grade	A	A(-)	B	B(-)	C	C(-)	D	E	F
Grade point	10	9	8	7	6	5	4	2	0

2. The student shall be required to take two written examinations for each theory course, one Mid-Term Examination and other End-Term Examination; For any course the distribution of marks will be 20% for Mid-term, 20% for internal assessment and 60% for end of semester examination;
3. When a student of Masters Programme earns 'E' or 'F' grade 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 the last day of the mid term examination in following semester.
4. Where the student does not get E or F grades in any theory course but scores CGPA of less than 6.00, he/she shall be allowed to repeat examination in maximum of two courses to improve the grade. Grades awarded in repeat exam will be final.
5. Due to lack of fulfillment of all the requirements for the course on account of extraordinary circumstances subject to having 50% attendance, a candidate can be put under I- grade and shall be permitted to appear in examination within 10 days of mid-term exam for conversion in to a regular grade subject to fulfillment of other criteria as per ordinance and approval of the project director
6. The minimum credit requirement for master degree is 50 valid credits including a minimum of 30 credits of course work and balance credits of project work.
7. The minimum CGPA required for the award of the master degree is 6.00.
8. The maximum period for completion of the Masters Programme is 3 years from the date of joining.
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 is a minimum 75% of the classes actually held.
10. For Masters programme: a student is entitled to a maximum of 45 day's 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.

Summarized rules governing conduct and maintenance of discipline for students

Every student shall at all times maintain absolute integrity and devotion to studies and research and conduct him/her in a manner conducive to the best interest of the institute and shall not commit any act which is unbecoming of him/her or is prejudicial to the interest of the institute.

- Conform to and abide by the provisions of the rules made by the institute from time to time.
- Comply and abide by all lawful orders which may be issued to him/her from time to time in the course of his/her studies and research by the institute or by any person or persons to whom he/she may be reporting in his/her department.

Recognition of Exemplary Conduct:

- A teacher or an officer of the institute may at any time make a confidential report through the Registrar to the Director about an act of exemplary good conduct by a student which in his/her opinion deserves recognition. The recommendation shall only be made if the conduct of the student is otherwise satisfactory.
- The report recommending recognition shall precisely state the facts of the case and the reasons for the recommendation.
- The recommendation for the recognition of exemplary good conduct shall be considered by the Director if he is satisfied that the conduct deserves a recognition, may award a certificate of exemplary conduct with or without monetary reward.
- Any certificate granted aforesaid may be withdrawn for sufficient cause but only after giving recipient an opportunity to be heard.

Acts of indiscipline:

- An act punishable under any law for the time being force.
- Willful insubordination or disobedience (whether or not in combination with others) of any lawful and reasonable instructions of his faculty, willful negligence, commission of any act, subversive to discipline or good behavior.
- Misconduct (including ragging) or an act which violates any rule of discipline or any other provision of the rules and regulations of the institute.
- Fraud/theft/bribery/dishonesty or acting under the influence of outsiders in connection with the research and studies or the property of the institute or to another student.
- Unauthorized custody and/or use of the institute equipment, tools, hostel or any other property of the institute.
- An act in breach of agreement or undertaking or direction or failure or refusal to obey instruction or direction of any authority.
- Resorting to mass cuts of classes, tests or examinations and /or other compulsory activities of the institute.
- Absence without leave or overstaying the sanctioned leave for more than seven consecutive days without sufficient grounds or satisfactory explanation.

- Falsification of institute record, impersonation or forgery.
- Furnish at the time of admission or thereafter incomplete or wrong information or suppressing any information including dismissal removal or rustication by previous institute/university or any punishment of any court of law.
- Conviction by court of law by any criminal offense involving moral turpitude or conviction by court of law for a serious criminal offence.
- Willful slowing down of performance in research and studies or abetment or instigation thereof.
- Smoking or consumption of intoxicating drinks within the institute. Sleeping while at work within laboratory or classroom.
- Making direct representation or sending grievances petitions to persons or bodies outside the institute except through proper channel.
- Non-payment of institute and other dues including Cafeteria charges.
- An act which interferes with personal liberty of anther or subjects another indignity or involve physical violence or use of abusive language.
- Collection of funds for any student programme, project or activity without the permission of the appropriate authority.
- Organizing a procession or meeting without the permission of the appropriate authority or participation therein.
- Use of agitational means including strikes, picketing Gheraos, fast arousing the sentiments of the student's body and the public or use outside agency for the redressal of grievances.
- Demanding or defacing of institute property and breaking into any institute building or premises.
- An act which disrupts the running of the institute or environment conducive to pursuit of knowledge and harmonious relationship between different people in the institute campus.
- An act which brings the institute (and its teachers, officers or authorities) into disrepute.
- Refusal to give evidences or establish or reveal identity where require.
- Proxy registering of attendance or abetting the act or registering the attendance of another student.
- Spreading, broking or encouraging Casteism, Regionalism, Communalism, or Untouchability.
- Refusal to accept and acknowledge, Charge-sheet, orders or any other communication addressed to student(s).
- Habitual late arrival or early departures or irregular attendance.
- Induiging in an act of sexual harassment of girls/women within or outside the Institute.
- Such other acts as may be notified by the authorities from time to time.

Disciplinary Action:

Category-1:

- An order rusticating a student for stated period under intimation to other universities/institutions in India.
- An order expelling a student from the Institute whether for all time to come or for a stated period under intimation to other universities/institutions in India.
- An order suspending a student for a period exceeding 15 days whether from all activities of the institute, Departments or Hostels or only from specific activities.
- An order to directing a student to pay fine exceeding Rs. 1000/- (Rupees one thousand only).

Category-2:

- An order to suspending a student for a period not exceeding 15 days whether from all activities the Institute, Departments or Hostels or only from specific activities.
- An order directing a student to pay a fine up to but not exceeding Rs. 1000/- (Rupees one thousand only).
- An order to directing entry of adverse remarks in the character role of the student.

Category-3:

- An order directing a student to vacate the premises and prohibiting him from re-entering the same for period not exceeding three days.
- An order directing a student to cease and desist from indulging in any act of indiscipline.
- An order warning a student.

FEES PAYABLE

Students who desire to take admission to NIPER-Ahmedabad and wish to avail the Hostel facility will have to pay **Hosteller Fees** and who do not wish to avail the hostel facility will have to pay the **Non-hosteller fees** applicable to the respective course/discipline and category.

FEES AND PAYMENTS
M. S. (Pharm.)

One time payment of charges	**General/OBC (Rs.)**	**SC/ST (Rs.)**	**Govt. /Indus. Spons. (Rs.)**
Admission fee	2000	2000	
Alumni Fund	2000	2000	
Hostel Admission	1500	1500	
Group Insurance (for 2 years)	1500	1500	
Caution money (Refundable)	10000	10000	
Total (A)	**17000**	**17000**	**33400**

Charges payable for each semester

Tuition Fee	13200	—	
Examination/Evaluation Fee	500	500	
Registration Fee	500	500	
Sports	500	500	
Computer Contingency	500	500	
Medical Charges	300	300	
Hostel Seat Rent	2500	2500	
Electricity Charges	1250	1250	
Benevolent fund	250	250	
Total (B)	**19500**	**6300**	**37900***

Total charges Payable

Payable on admission [Sem-1 (A+B)]	**36500**	**23300**	**71300***
Payable for Semester-2-4 (B)	**19500**	**6300**	**37900**

*Group Insurance and caution money in case of Govt. /Industry Sponsored candidate will be same as in case of other students**.**

Note: Non hostellers will not be required to pay hostel admission, hostel seat rent and electricity charges. However in case of NRI category even if a student does not avail hostel facility, he/she will not be declared a non hosteller.

REFUND OF SECURITY

If the student does not join the programme after paying the dues and leaves the Institute, only security deposit as applicable to each category shall be refunded, provided a written application is made by the student to the Director. No other amount shall be refunded.

FINANCIAL ASSISTANCE

All the admitted candidates of M.S. (Pharm.) except candidates Sponsored by Public/Private Sector undertaking, Govt. Department, Research and Development Organization, will be provided with stipend of Rs. 8,000 per month. Where at any stage, the progress and conduct of awardee student is not satisfactory, the fellowship shall be suspended/terminated. However the student will be given an opportunity to be heard before any adverse action is initiated against him/her.

REGISTRATION/ORIENTATION

Every student is required to register before the commencement of each semester in the period mentioned in the Academic Calendar of the institute. The student shall deposit the fee and other charges at the time of renewing the registration. The courses offered by the departments will be made known to the students at the time of orientation.

The student has to register in person. A student, who fails to get himself/herself registered, will no longer be considered as a student of the Institute. If a student is unable to appear for registration personally on account of illness or similar circumstances which are beyond his/her control he/she may appear for late registration. In genuine cases the Registrar may approve late registration on payment of late fee. Registration in absentia may be allowed only in exceptional circumstances at the discretion of the Registrar.

SUBJECT CO-ORDINATOR

Every department will be co-ordinated by a faculty member of the department offering the course in a given semester. This faculty member will be called the subject co-ordinator. The co-ordinator will have the full responsibility of, co-ordinating the work of the other members of the faculty involved in that course, holding tests and assignments and awarding the grades. In case of any difficulty the student is expected to approach the subject co-ordinator for advice and clarification. However, the overall academic activities will be supervised by the Project Director.

LEAVE RULES

Every student will be assigned a mentor within first four weeks of joining the course. Student who wants to take leave will have to approach the mentor with filled in leave application. Mentor will forward the application to Registrar. Registrar will be the approving authority of leave. Student will avail the leave, only after approval of the Registrar. In case of sickness or some unforeseen reason if a student is not able to come to institute then he/she will take the permission of his/her mentor on telephone and submit the leave application on joining the institute. If a student fails to do so then suitable disciplinary action will be taken by the institute.

QUALIFYING CRITERIA FOR AWARD OF DEGREE

Students are required to attend every lecture and practical class during the semester: provided that in the case of the late registration, sickness and other contingencies, the attendance required will be a minimum of 75% of the classes actually held. If the student falls short of 75% of mandatory attendance in a course, he/she will not be permitted to appear in the end-semester examination of that course in that semester and the student will have to complete all requirements of that course in the subsequent year.

The minimum credit requirement for masters degree will be 50 credits including a minimum of 30 credits of course work and balance credits of project work. The minimum CGPA required for the award of the degree will be 6.00. If the CGPA is more than 5.50 but below 6.00 in any semester, the candidate may be permitted to continue in the programme with certain conditions. If CGPA is below 5.50 in any semester, the student shall be permitted to improve his/her CGPA by repeating in a maximum of 2 theory courses irrespective of the grade earned.

If a student after availing the maximum number of repeat examinations as per rules, fails to clear the course(s) or fails to secure minimum CGPA shall have to discontinue the

programme. The maximum period for completion of the Masters Programe will be 3 years from the date of joining the programme.

When the student earns 'F' grade in more than two courses in any semester, he/she shall have to discontinue the studies and shall cease to be the student of the institute.

FACULTY

The faculty will include scientists of B.V.Patel PERD Centre who have rich experience in various disciplines of Pharmaceutical Sciences

Dr. Manish Nivsarkar	Dr. Viral Shah	Dr. Anshu Srivastava
Dr. Kamala Vasu	Dr. Bhagwati Saxena	Dr. Priti Desai
Dr. Neeta Shrivastava	Dr. Govind Kapusetti	Dr. Milee Agarwal
Dr. Anita Mahapatra	Dr. Shankar Katekhaye	Dr. Rahul Tripathi
Dr. Vinod Jairaj	Dr. Bhagyashree Kamble	Dr. Anirban Samantha
Dr. Manju Misra	Dr. Anurag Maheshwari	Ms. Rajeshwari Rathod
Dr. Neelam Chauhan	Mr. Amit Shard	Ms. Sweta Patel
Dr. Mukty Sinha	Dr. Amita Joshi	

Moreover, about twenty eminent persons from the industry and other academic institutes have been providing their expertise as visiting faculty.

HOSTEL FACILITIES

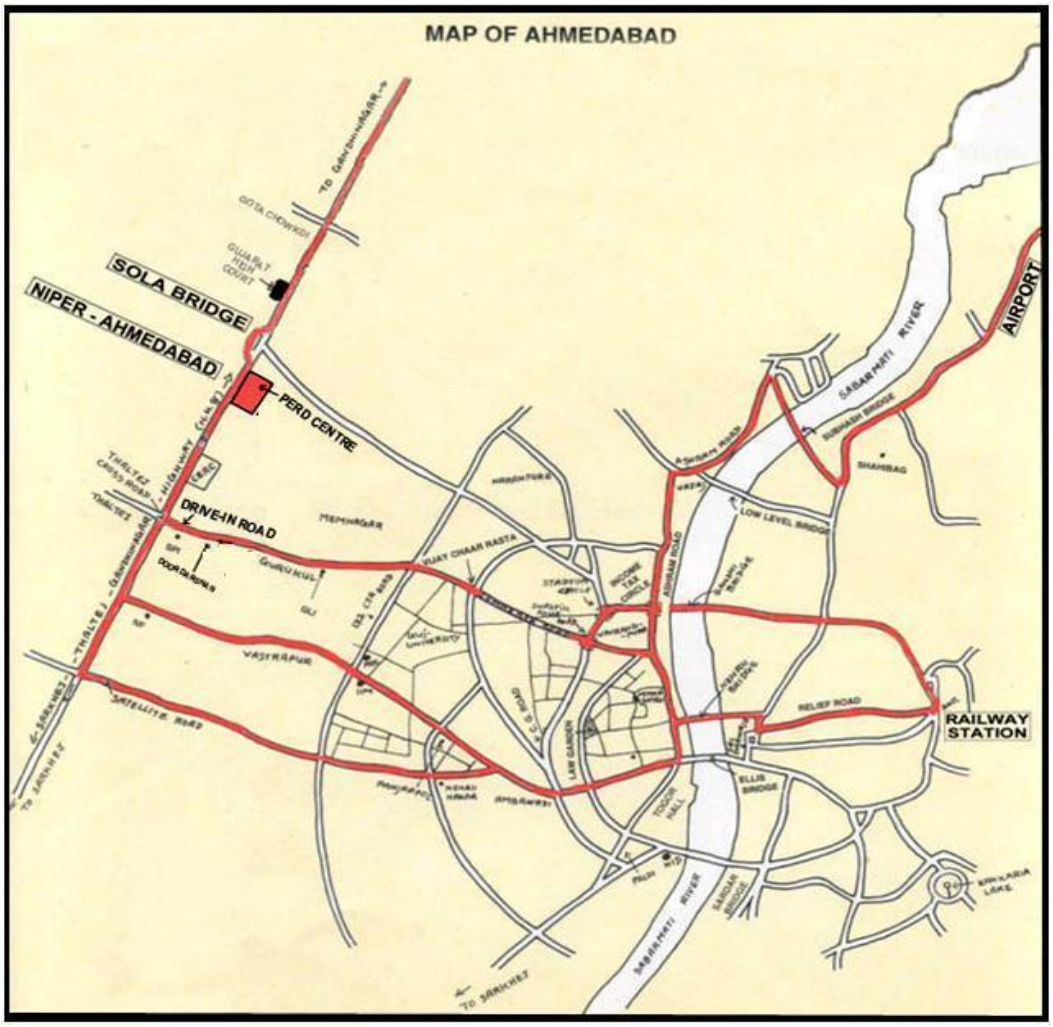
Permanent Hostel facility is not available. The facility for the student shall be provided as per availability.

HOW TO REACH NIPER-AHMEDABAD

Ahmedabad is well connected to major cities of India by rail and air. PERD Centre, where NIPER-Ahmedabad is housed, is situated along the Sarkhej-Gandhinagar highway, near Thaltej cross-roads, about 16 kilometres from Ahmedabad airport and the main railway station at Kalupur.

Pre-paid taxis are available at the airport, and the taxi driver can be instructed to go to Thaltej cross-roads (or chaar-rasta, in local parlance). Similarly you can hire an auto rickshaw from the railway station and ask for the same destination.

Map of Ahmedabad with location of NIPER- Ahmedabad (PERD)



SYLLABUS

- **Biotechnology**
- **Medicinal Chemistry**
- **Medical Devices**
- **Natural Products**
- **Pharmaceutics**
- **Pharmaceutical Analysis**
- **Pharmacology & Toxicology**

BIOTECHNOLOGY

M. S. (Pharm.)

Course no.	Course Name	Credits
Semester I		
BT-520	Cell Biology	2
BT-530	Microbial Genetics	1
BT-550	Biochemistry	2
MC-511	Spectral Analysis	2
NP-510	Separation Techniques	1
PT-520	Microbiology	1
PT-530	Biochemical Engineering Fundamentals	2
GE-510	Biostatistics	2
GE-511	Seminar	1
LG-510	General Laboratory Experience	3
	Total Credits	**17**
Semester II		
BT-610	Molecular Biology	2
BT-620	Recombinant DNA Technology	2
BT-630	Immunology and Immunotechnology	2
BT-650	Analysis, Diagnostics and Cell Based screening	2
BT-660	Sequence Analysis	2
GE-611	Seminar	1
LS-610	General Lab Experience in the Area of Specialization	2
	Total Credits	**13**
Semester III Project (22 weeks)		
TH- 598	Synopsis	5
TH- 599	Presentation	3
	Total Credits	**8**
Semester IV		
TH-698	Thesis	9
TH-699	Defence of Thesis	3
	Total Credits	**12**
TOTAL CREDITS (I TO IV SEMESTERS)		**50**

BIOTECHNOLOGY - SEMESTER I

BT-520

Cell Biology (2 Credits)

1. **Cell structure and organization:** Cells as a unit of life, prokaryotic and eukaryotic cells, biomembranes, structure and basic functions of various cell organelles i.e. nucleus, ribosomes, ER, golgi, lysosomes, peroxisomes, exosomes, cytoskeleton
2. **Tools and Techniques of Cell Biology:** Histology, staining, fluorescence, confocal microscopy, TEM and SEM, Fluorescent dyes and GFP tagged proteins in visualization, FACS, cell fractionation, cell culture.
3. **Organization of tissues:** Cell-cell and cell-matrix interactions, cell adhesion molecules, components of the extracellular matrix, cellular junctions and role.
4. **Cell cycle:** G1, G2, S and M Phase of the cell cycle. Cell cycle analysis and its applications, programmed cell death apoptosis versus necrosis. Role of telomeres in the cell cycle.
5. **Cell signaling:** Receptor concept, receptor signaling and expression, orphan receptors, extracellular signals and cell functions, hormones, second messengers and hormone actions, growth factors.
6. **Transport across membranes:** Osmosis, active and passive transport. Protein transporters ion channels, antiporters, symporters. Applications in the field of medicine.
7. **Cellular movement and Molecular motors:** Types of movement, extravasation, role of cytoskeletal proteins in movement, molecular motors, the movement of cilia and flagella, muscle contraction, myosin and kinesins in the movement of vesicles.
8. **Protein Synthesis and Targeting:** Ribosome and endoplasmic reticulum, Secretory pathway, targeting and sorting of proteins, nuclear localization signal, organelle specific signal sequence, ATP driven translocation, glycosylation, transport of protein, endocytosis, exocytosis, macropinocytosis.
9. **Relevance of Cell Biology:** Stem cells, Tissue engineering, infectious disease.
10. **Cancer:** Tumor cells, cell lines and models, proto-oncogenes and oncognese, oncogenic mutations, loss of cell cycle control, carcinogens.

Reading Material

1. Molecular Cell Biology by Harvey Lodish
2. Molecular Biology of the Cell by Bruce Alberts
3. Principles of Biochemistry: Lehgninger
4. Biochemistry by L Stryer
5. Lehninger Principles of Biochemistry, Fourth Edition, 2007

   D. L. Nelson and M. M. Cox

W. H. Freeman and Company

6. Biochemistry, Third Edition, 2004
   D. Voet and J. G. Voet
   John Willey and Sons
7. Kuby – Immunology, Sixth Edition, 2007
   T. J. Kindt et.al.
   W. H. Freeman and Company
8. Immunology, Seventh Edition, 2006
   David Male et.al.
   ASM Press

BT- 530

Microbial Genetics (1 Credit)

1. **Classical genetics:** 'Transforming factor', Hershey and Chase's experiment, Replica plating, Types and selection of mutants.
2. **Mechanisms of genetic exchange:** Transformation, Genetic mapping using transformation.
3. **Mechanisms of genetic exchange:** Transduction (generalized, specialized), Genetic mapping using transduction, Triple cross experiments, Cis-trans complementation.
4. **Mechanisms of genetic exchange:** Conjugation (Hfr strains; Interrupted mating, time-of-entry mapping), Lederberg-Tatum experiment, Resistance plasmids.
5. **Transposition:** Mechanism and models. Insertion sequences. Composite transposons. Transposon-generated *in vitro* mutagenesis.
6. **Gene regulation in prokaryotes:** Principles of regulation in *E. coli*, Differences between prokaryotes and eukaryotes. Regulation of transcription and processing (*lac* operon, tryptophan operon, etc.); Translational control, feedback inhibition. Blue-white screening. Different models and mechanisms of transcriptional attenuation.
7. **Gene regulatory proteins:** Different types of motifs. Structures of repressors. Mechanism of *lac* repressor. Concept of 'immunity'
8. **Viruses:** Structure, classification, genome, replication and growth, purification, quantification. Mechanism of infection by retroviruses. HAART. Life cycle of viruses: Lytic and Lysogenic phage. Detail of lambda genome.
9. **Other infectious agents:** Koch's postulates Viroids, satellites, prions. Replication species barrier.
10. **Yeast:** Model organism, Importance as a genetic tool. Mating type switch. Types of yeast vectors. Important genes. Red-white screening.
11. **Applications of yeast genetics:** Two-hybrid system, Yeast artificial chromosomes. *In vivo* recombination

READING MATERIAL

1. Microbiology (4/e) by Lansing Prescott, John Harley and Donald Klein, McGraw hill.
2. Lewin's Genes X by Jocelyn E. Krebs. Elliott S. Goldstein and Stephen T. Kilpatrick. Jones and Bartlett.
3. Molecular Biotechnology: Principles and Applications of Recombinant DNA (4/e) by Bernard R. Glick , Jack J. Pasternak and Cherly L. Patten, ASM press
4. Relevant research and review papers.
5. Gene Cloning and DNA Analysis, Fourth Edition, T. A. Brown
   Blackwell Science
6. Principles of Gene Manipulation, Sixth Edition, 2004
   S. B. Primrose et.al.
   Blackwell Science, Atul Prakashan
7. Pharmaceutical Statistics: Practical and Clinical Applications, Fourth Edition, 2004
   Sanford Bolton
8. Biometry, Third Edition, 1995
   Robert R. Sokal and F. James Rohlf
9. Introduction to the Practice of Statistics, Fifth Edition, 2004
   David S. Moore and George P. McCabe
10. Experimental Design in Biotechnology, 1989
    Perry D. Haaland
11. Probability Statistics and Queueing Theory, 2005
    P. Kandasamy, K. Thilagavathi and K. Gunavathi

BT-550
Biochemistry (2 Credits)

1. **Biomolecules:** Carbohydrates, Lipids, chemistry and classification, structures of biomolecules, biochemical properties, pharmaceutical importance.
2. **Protein and Nucleic acids:** Structure (primary, secondary, tertiary and quaternary), properties, pharmaceutical importance
3. **Enzymes:** Classification, mode of action (activation, specificity), enzyme kinetics, enzyme inhibitors and regulators, allosteric enzymes, isoenzymes, multienzyme system, pharmaceutical importance.
4. **Coenzymes and cofactors:** Coenzymes, classification of vitamins, role and mechanism of action of some important coenzyme (NAD^+/$NADP^+$, FAD, lipoic acid, tetrahydrofolate, B_{12}- coenzyme), role of cofactors with specific examples.
5. **Biochemical energetics Part I:** free energy, concept of standard free energy, laws of thermodynamics, exergonic and endergonic reactions.
6. **Biochemical energetics Part II:** energy rich compounds, coupling of reaction, biological oxidation-reduction
7. **Carbohydrate metabolism:** Glycolysis, gluconeogenesis, pentose phosphate

pathways (PPP), glycolysis, TCA cycle, glyoxylic acid cycle, regulation of carbohydrate metabolism, electron transport chain and oxidative phosphorylation, disorders of carbohydrate metabolisms.

8. **Lipid metabolism:** Hydrolysis, absorption and transport of lipids, catabolism of lipids, α-β- and ω- oxidation of fatty acids, ketone bodies formation, biosynthesis of fatty acids, disorders of lipid metabolisms.
9. **Protein metabolism:** Hydrolysis, of proteins, pathways of amino acid degradation, urea cycle and formation of uric acid, assimilation of ammonia, biosynthesis of amino acids, inborn error of protein metabolism
10. **Nucleic Acid Metabolism:** Purine and pyrimidine biosynthesis, salvage pathway, degradation of nucleotides, role of ribonucleotide reductase, pharmaceutical importance, disorders of purine and pyrimidine metabolisms.

READING MATERIAL

1. Principles of Biochemistry by Lehinger.
2. Biochemistry by L. Stryer
   Atul Prakashan
3. Pharmaceutical Statistics: Practical and Clinical Applications, Fourth Edition, 2004
   Sanford Bolton
4. Biometry, Third Edition, 1995
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7. Probability Statistics and Queueing Theory, 2005
   P. Kandasamy, K. Thilagavathi and K. Gunavathi

MC-511

SPECTRAL ANALYSIS TOPICS (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-conjugated interactions, 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) ^{1}H 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 ^{19}F and ^{31}P, 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)^{13}C NMR, correlation of structure with spectra: Chemical environment, shielding and carbon-13 chemical shift, calculation, proton-coupled ^{13}C spectra, Proton-decoupled ^{13}C spectra, Nuclear Overhauser Enhancement (NOE), Problem with integration, Distortionless Enhancement by Polarisation Transfer (DEFT), Heteronuclear coupling for carbon to deuterium, carbon to ^{19}F, carbon to ^{31}P, Explanation of spectra of some compounds and drugs.

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

READING MATERIAL

1. Introduction to Spectroscopy: A Guide for Students of Organic Chemistry
   Donald L. Pavia, Gary M. Lamlma and George S. Kriz
   Thomson
2. Spectroscopy of Organic Compounds, 6th edition
   P. S. Kalsi
   New Age Internation United Publication
3. Instrumental Methods of Analysis,7th edition
   Hobart H. Willard, Lynne L. Merrit, John A. Dean and Frank A. Settle
   CBS Publishers
4. Spectrometric Identification of Organic Compounds, 6th edition
   Robert M. Silverstein and Webster Fransis, Wiley-VCH

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 reversed phase, bonded phase chromatography, stationary phases, activity of stationary phases, elutropic series, and separation mechanisms.
3. **Column chromatography and 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 Pressure Liquid Chromatography (HPLC):** 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. **Planer 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. **Gas chromatography:** Introduction to GC-MS and LC-MS techniques and their application in natural products.

READING MATERIAL

1. Applied Thin Layer Chromatography, 2nd edition
   Elke Hahn Deinstrop
   Wiley-VCH
2. HPLC Made to Measure: A Practical Handbook for Optimization
   Stavros Kromidas
   Wiley-VCH
3. Thin Layer Chromatography: A Modern Practical Approach
   Practical HPLC method development

Lloyd R. Snyder, Joseph J. Kirkland and Joseph L. Glajch
John Wiley and Sons

PT- 520

MICROBIOLOGY (1 CREDIT)

1. **Introduction aims and scope***:* Organization and function of prokaryotic and eukaryotic cells; Structure and function of cell organelles-surface structure, special organelles, cellular reserve materials.
2. **Distinguishing features of various groups of micro organisms:** Actinomycetes, bacteria, moulds, yeasts and algae and their broad classification.
3. **Characteristics of selected groups of microbes:** Archaebacteria and microorganisms of extreme environment; Control of micro organisms by physical and chemical agents; Pure culture concept and cultural characteristics.
4. **Microbial nutrition and growth principles:** Growth measurement techniques: assimilation of carbon, nitrogen and sulphur. Various growth media for the cultivation of organisms. Cultivation of anaerobes, rare actinomycetes etc.
5. **Isolation and preservation:** Isolation, development and preservation of industrial microorganisms; isolation of microorganisms from various sources and long term preservation and improvement of cultures.
6. **Biochemical pathways:** Energy transduction in microbial systems, phosphoketolase, Enter-doudruff and glyoxalate pathways; Anaerobic respiration; Microbial pathogenicity.
7. **Recycling of energy sources:** Bioassays, recycling of carbon, nitrogen and sulphur: Role of microbes in agriculture, public health, medicine and industry.
8. **Control of microorganisms:** Rate of death of bacteria; conditions influencing antimicrobial action; Mode of action of antimicrobial agents; control of microorganisms by physical agents; control of microorganisms by chemical agents; Antibiotics and other chemotherapeutic agents.
9. **Microbiology in the treatment of effluent:** Primary, secondary and tertiary treatment of effluent, aerobic and anaerobic system of treatment, sludge generation, definitions of total solids, soluble solids, fixed solids, volatile solids etc. kinetics of waste treatment.
10. **Microorganisms and disease:** Microbial flora of the healthy human host; natural resistance and nonspecific disease mechanisms; Basis aspects of the immune response; Bacterial agents of disease.

READING MATERIAL

1. Prescott, Harley and Klein's Microbiology, Seventh Edition - 2008
   J. M. Willey et.al.
   McGraw Hills Publication
2. Microbiology: An Introduction, VIIIth Edition - 2006

Tortora et.al.
Pearson Education

3. General Microbiology, Fifth Edition - 2007
R. Stanier et.al.
Macmillan Press

4. Microbial Biotechnology : Fundamentals of Applied Microbiology
Alexander N. Glazer, Hiroshi Nikaido
W. H. Freeman and Company

PT-530
Biochemical Engineering Fundamentals (2 Credits)

1. **Homogenous reactions**: Reaction thermodynamics; Reaction yield; Reaction rate; Reaction kinetics; Calculation of reaction rates from experimental data; General reaction kinetics for biological systems; Zero-order kinetics; Michaelis-Menten kinetics; Determining enzyme kinetic constants from batch data.
2. **Microbial growth**: Kinetics of microbial growth; substrate utilization and product formation; Structured and unstructured model for growth; Equations for substrate utilization and product formation and related numericals.
3. **Reactor design:** bioreactor configurations; Stirred tank; Airlift reactor; Packed bed; Monitoring and control of bioreactors; Ideal reactor operation; Batch operation of a mixed reactor; Total time for batch reaction cycle; Fed-batch operation of a mixed reactor; Continuous operation of a mixed reactor; Chemostat cascade; Continuous operation of a plug flow reactor; Detailed studies on the batch, continuous and fed-batch bioreactors.
4. **Agitation:** Need of agitation in aerobic fermentation; Effect of agitation; How agitation helps aeration; different types of agitational methods; impeller design and relationship with the characteristics of the fluid; flow behaviour etc.
5. **Aeration:** Need of aeration in aerobic fermentation; Effect of aeration; How aeration helps agitation; different types of aeration methods; aeration in high density fermentation; aeration in qualescence and non-qualescence medium; flow behaviour etc.
6. **Sterilization of air and medium:** Different methods of sterilization; Kinetics of sterilization; batch and continuous sterilization; advantages and disadvantages thereof; Calculation of del factor and solving of numerical.
7. **Mass transfer:** Mass and energy balance in microbial processes; Resistance encountered in fermentation medium by the oxygen molecule; Role of dissolved oxygen concentration in mass transfer; Determination of mass transfer co-efficient (KLa), Factors affecting KLa and their relationship.
8. **Heat transfer in bioreactors:** Mechanisms of heat transfer; heat transfer between fluids; Calculation of heat transfer co-efficients; Heat transfer equipment; Steady state conductance; LMTD calculation; Relationship between heat transfers; Cell concentration and stirring conditions.

9. **Dimensional analysis:** Various types of dimensionless analysis in terms of mass transfer; Heat transfer and momentum transfer; Importance of dimensionless number in designing the bioreactors; heat exchangers etc.
10. **Scale-up**: Principles and criteria; Different methods of scale up and the detailed analysis with case studies; Instrumentation and control of bioprocesses.

READING MATERIAL

1. Bioprocess engineering: Basic concept by Michael L. Shuler, Fikret Karg
2. Bioprocess engineering Principles by Pauline M. Doran
3. Biochemical Engineering Fundamentals by James Edwin Bailey, David F. Ollis
4. Principles of Fermentation Technology by Peter F. Stanbury, Allan Whitaker, Stephen J. Hall
5. Biotol series (This series has many books pertaining to all fields of Biotechnology, students have to select the books as per the topic of interest)

GE-510

BIOSTATISTICS (2 CREDITS)

1. **Statistics:** Introduction and its role and uses, Collection, Organization, Graphics and pictorial 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 andregression:** Graphical presentation of two continuous variables, Pearson's product moment correlation coefficient, its statistical significance, Multiple and partial correlations, Linearregression, 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

READING MATERIAL

1. Mathematics and Biostatistics, Second Edition, 2007-2008
   G. K. Jani
   Atul Prakashan
2. Pharmaceutical Statistics: Practical and Clinical Applications, Fourth Edition,
   2004 Sanford Bolton
3. Biometry, Third Edition, 1995
   Robert R. Sokal and F. James Rohlf
4. Introduction to the Practice of Statistics, Fifth Edition, 2004
   David S. Moore and George P. McCabe
5. Experimental Design in Biotechnology, 1989
   Perry D. Haaland
6. Probability Statistics and Queueing Theory, 2005
   P. Kandasamy, K. Thilagavathi and K. Gunavathi

GE-511

SEMINAR (1 CREDIT)

1. Introduction, Information retrieval systems.
2. Writing term papers and reports.
3. Organization of scientific material, thesis, dissertation and references.
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, Step 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. **Biotechnology for pharmaceutical sciences (20 hours)**

   Preparation for plasmid miniprep, Plasmid miniprep and restriction digestion, Gel electrophoresis and molecular weight calculation. Discussion of result and viva.

4. **Biotechnology Specialization (75 hours)**

   Cell biology: Sterilization by autoclaving and filtration, media preparation and cell counting, subcellular fractionation by homogenization, solubilization, sonication and protein estimation, Running SDS-PAGE and Viva.

   Enzyme kinetics: Assay of trypsin, Thermal stability of trypsin, Lineaweaver-Burk plot for trypsin, plotting of graphs and discussion of result.

   Enzyme biochemistry: enzyme kinetics, time course; Effect of pH and temperature, Inhibition studies and characterization, Ionic strength effect and Viva.

   Bacterial culture and Growth Kinetics: Direct and indirect methods to measure bacterial growth, media preparation, setting up of primary cultures, monitoring growth kinetics, effect of different parameters on growth, plotting of growth curves, calculation of mean generation time and growth rate constant, analysis of results, discussion of results and viva.

BIOTECHNOLOGY - SEMESTER II

BT 610

Molecular Biology (2 Credits)

1. **Genome Organization:** Organization of bacterial genome, structure of eukaryotic Chromosomes, role of nuclear matrix in chromosome organization and function, matrix binding proteins, heterochromatin and euchromatin, DNA reassociation kinetics (Cot curve analysis), repetitive and unique sequences, satellite DNA, DNA melting and buoyant density, nucleosome phasing, DNase I hypersensitive regions, DNA methylation & imprinting.

2. **DNA Structure:** Structure of DNA- A-, B-, Z-, P- and triplex DNA, measurement of properties-spectrophotometric, CD, AFM and electron microscope analysis of DNA Structure.

3. **Replication:** replication initiation, elongation and termination in prokaryotes and eukaryotes, enzymes and accessory proteins, fidelity, replication of single stranded circular DNA, gene stability.

4. **Repair & Recombination:** DNA repair-enzymes, photoreactivation, nucleotide excision repair, mismatch correction; SOS repair, recombination, homologous and non-homologous, site specific recombination, chi sequences in prokaryotes.

5. **Prokaryotic & Eukaryotic Transcription:** Prokaryotic transcription, transcription unit, Promoters- constitutive and inducible, operators, regulatory elements, initiation, attenuation, termination-Rho-dependantand independent, anti-termination, transcriptional regulation-positive and negative, Regulation of gene expression, negative and positive, trans acting products and cis acting sequences, control of structural gene clusters, induction and repression of genes, role of antisense RNA in gene inactivation, regulator RNA's and micro RNA's as regulators in eukaryotes.

6. **Eukaryotic transcription and regulation:** RNA polymerase structure and assembly, RNA polymerase I, II, III, eukaryotic promoters and enhancers, general transcription factors, TATA binding proteins (TBP) and TBP associated factors (TAF), activators and repressors, transcriptional and post transcriptional gene silencing.

7. **Post Transcriptional Modifications:** Processing of hnRNA, tRNA, rRNA, 5'-cap formation; 3'-end processing and polyadenylation, Splicing, RNA editing, mRNA stability, catalytic RNA.

8. **Translation & Transport:** Translation machinery; Ribosomes, composition and assembly, universal genetic code, degeneracy of codons, termination codons, Isoaccepting tRNA, Wobble hypothesis, Mechanism of initiation, elongation and termination, Co-and post translational modifications, genetic code in mitochondria, protein stability, protein turnover and degradation.

9. **Mutations, Oncogenes and Tumor suppressor genes:** Nonsense, missense and point mutations, Intragenic and Intergenic suppression, Frame shift mutations, Physical, chemical and biological mutagens. Viral and cellular oncogenes, Tumor suppressor genes from humans, structure, function and mechanism of action of PRB and p53 tumor suppressor proteins, activation of oncogenes and dominant negative effect, suppression of tumor suppressor genes, oncogenes as transcriptional activators.

10. **Transposable elements:** Transposition Transposable genetic elements in prokaryotes and eukaryotes, mechanisms of transposition, role of transposons in mutation.

READING MATERIAL

1. Genes VIII by Benjamin Lewin
2. Principles of Genetics by Gardner, Simmons and Snustard
3. Molecular Biology of the Cell, Fourth Edition, 2002
   Bruce Alberts et.al.
   Taylor and Francis Group
4. Molecular Cell Biology, Sixth Edition, 2008
   H. Lodhish et.al.
   W. H. Freeman and Company
5. Gene Cloning and DNA Analysis, Fourth Edition
   T. A. Brown
   Blackwell Science
6. Principles of Gene Manipulation, Sixth Edition, 2004
   S. B. Primrose et.al.
   Blackwell Science
7. Gene IX
   Benjamin Lewin
   Jones and Bartlett Publishers

BT-620

Recombinant DNA Technology (2 credits)

1. **Basic techniques in Gene analysis:** Purification and analysis of nucleic acids: Isolation of DNA and RNA, Plasmid purification, agarose, polyacrylamide and pulse field gel electrophoresis, southern, northern and western blotting.

2. **DNA Modifying Enzymes:** Type I, II and III restriction enzymes, reverse transcriptases ligases, polymerases, kinases and phosphatases.

3. **PCR & Mutagenesis:** PCR enzymes, primer design, RT-PCR, Real time PCR cDNA synthesis, applications of PCR, random and site directed mutagenesis, primer extension, mutagenesis, strand selection mutagenesis, cassette mutagenesis PCR based mutagenesis, Quik Change mutagenesis.

4. **Vectors:** Cloning, and expression vectors, Plasmids, selectable markers, blue-white selection, phage, yeast vectors and YACs. Tags for purification and visualization bacterial transformation, manual and automated sequencing.

5. **Plant Biotechnology:** *Agrobacterium tumefaciens*, vectors, nuclear, chloroplast transformation, pest resistance, delay of fruit ripening, antibody generation in plants, edible vaccines. Ethics of rDNA products.

6. **Animal biotechnology:** Transformation of animal cells, stable and transient transfection, selection markers.

7. **Viral vectors:** Adenovirus, adeno-associated virus, baculovirus, herpes virus, retrovirus based expression systems.

8. **Gene targeting:** Random and specific, *Cre/lox Psystem,* knock-out mice.

9. **Transgenic animals:** Principal, nuclear transfer from somatic cells, stem cells, tests for pluripotency, mouse, frog, Drosophila.

10. **Protein 'pharm'ing:** Design of second generation therapeutic molecules, examples of engineered proteins of therapeutic potential, tools for protein engineering, library-based selection methods.

11. **Gene therapy:** Somatic cell gene transfer, autologous and non-autologous ex vivo genetherapy, prospects and limitations.

12. **Nucleic acid therapeutics:** Antisense technology, siRNA, trans-splicing, ribozymes, aptamers, case studies, advantages and challenges.

READING MATERIAL

1. Principles of Gene Manipulation and Genomics(7/e) by Sanday Primrose and Richard Twyman, Wiley-Blackwell

2. Analysis of Genes and Genomes by Richard J Reece, John Willey & Sons

3. Molecular Biotechnology:Principles and Applications of Recombinant DNA(4/e)by Bernard R. Glick, Jack J. Pasternak and Cheryl L. Patten. ASM Press
4. Relevant review & research papers
5. Molecular Cloning: A Laboratory Manual
   J. Sambrook et.al.
   Cold Spring Harbor Laboratory Press
6. Principles of Gene Manipulation
   S. B. Primrose et.al.
   Blackwell Science
7. Elements of Biotechnology
   P. K. Gupta

Rastogy Publishers

8. An Introduction to Genetic Analysis
   A. J. F. Griffiths et.al.
   W. H. Freeman and Company
9. Gene IX
   Benjamin Lewin
   Jones and Bartlett Publishers
10. Genetic Engineering Principles and Practice, 2007
    Sandhya Mitra
    Macmillan India Ltd.
11. Biotechnology in Healthcare : An Introduction to Biopharmaceuticals, 1998
    Eds. G. Brooks
    Pharmaceutical Press

BT-630

IMMUNOLOGY AND IMMUNO-TECHNOLOGY (2 CREDITS)

1. **Immunity:** Innate and adaptive, immune response memory, specificity and recognition of self and non-self, immunogenicity, antigenicity, physiology of immune response, epitope analysis, synthetic peptides and immune response, immunity to virus, bacteria, fungi.
2. **Cells and organs of the immune system**: Lymphoid cells, T cells, B cells, monocytes, phagocytes, mast cells and basophils, primary and secondary lymphoid organs, interplay between cells.
3. **Humoral immunity:** Antigen-antibody interactions, affinity, avidity, immunoglobulins, molecular mechanism of generation of antibody diversity, molecular biology of IgG.
4. **Cell mediated immunity:** T cell subset and surface marker, T cell-dependent and -independent markers, structure and function of MHC, association of MHC with disease susceptibility, structure of T cell antigen receptor
5. **Natural immunity:** Inflammation, stimuli, chemotaxis, arachidonic acid Metabolite and cytokines, vascular modifications, healing and fibrosis.
6. **Natural killer cells:** Functional definition, mechanism of lysis, recognition structures, phosphorylation.
7. **Immune memory:** B-cell memory significance, mutations and switches in memory cells, T -cell memory, lack of mutations and switches in T -cell memory, activation, super activation, loss of memory.
8. **Immune tolerance:** B-cell tolerance, reversible and irreversible tolerance, antigen induced tolerance, induction, T-cell tolerance, partial engagement of signal transducer, self-antigens, molecular consequence of tolerance.

9. **Disorders:** Hypersensitivity reaction, immunosuppression, autoimmune disorders, its molecular mechanism, immuno deficiency disorders (AIDS), tumor immunology.
10. **Immunobiotechnology:** Hybridoma, vaccines, viral, bacterial peptides, genetically engineered production of lymphokines, second generation antibodies a brief outline.

READING MATERIAL

1. Cellular and Molecular Immunology by A.K. Abbas, Andrew H. Lichtman and Shiv Pillai.
2. Kuby., Immunology by Thomas J. Kindt. Barbara A. Osborne, and Richard A. Goldsby
3. Kuby – Immunology, Sixth Edition, 2007
   T. J. Kindt et.al.
   W. H. Freeman and Company
4. Immunology, Seventh Edition, 2006
   David Male et.al.
   ASM Press

BT-650

Analysis, Diagnostics and Cell Based Screening (2 Credits)

1. **Total protein assay:** Quantitative amino acids analysis, Folin-Lowry protein assay, BCA assay, UV spectrophotometry etc.
2. **Purity:** Protein impurities, contaminants, electrophoretic analysis, HPLC based analysis, DNA content analysis, immunological assays for impurities, combined immunological and electrophoretic methods, host-cell impurities etc. ICH guidelines.
3. **Potency assays:** In-vitro biochemical methods MTYT assay, assay for apoptosis, cell-line derived assays, whole animal assays etc.
4. **Principles, methods and applications of immuno-diagnostics:** Principles and methods of some clinically used diagnostic immunoassays, e.g., homogeneous immunoassays, fluorescence, chemiluminescence and bioluminescence enzyme immunoassays, immunoblot, immunoaffinity, immunoprecipitation, biotinylation, immunosensors.
5. **Principles, methods and applications of DNA-based diagnostics:** DNA probe based diagnostics, sample preparation, hybridization, separation, detection, PCR-RFLP in paternity and forensic cases SNP detection MALDI and DHPLC.
6. **Diagnostics:** Cancer diagnostics, human retroviral diseases specially AIDS. Role of enzymes in diagnostics.
7. **High-throughput screening:** Requirements and parameters, Advantages and disadvantages of biochemical and cellular assays; miniaturization and automation.
   Cell-based screening assays: Advantages over in vitro assays. Different formats: radioactive, luminescence, fluorescence, etc. Assays compatible with cell membranes: GTPyS, cAMP accumulation.
8. **Yeast two-hybrid system:** Different Y2H systems, their advantages and

disadvantages, examples.

9. **GPCRs as targets:** Identification of drug molecules; Important parameters: intracellular calcium, cAMP, β-arrestin, receptor internalization, reporter gene assays; orphan GPCRs; desensitization and internalization.

Reading Material

1. The immunoassay Handbook by David Wild
2. High Throughput Screening: The Discovery of Bioactive Substances by John P. Devlin
3. Practical Biochemistry: Principles and Techniques, Fifth Edition, 2005
   K. Wilson and J. Walker
4. Experimental Biochemistry, Third Edition, 1999
   R. L. Switzer and L. F. Garrity
   W. H. Freeman and Company
5. US Pharmacopeia, Vol. 1-3, 2007
   National Formulary 25, (Biotechnological drugs)
   The USP Convention
6. Indian Pharmacopoeia, Vol. 1-3, 2007
   (Biotechnology products)
   The IP Commission, Ghaziabad
7. Related Review Articles

BT-660
Sequence Analysis (2 Credits)

1. **Basics of Computational Biology:** Database concept; Protein and nucleic acid databases, structural databases.
2. **The NCBI:** publicly available tools, Resources at NCBI and EBI, DNA and protein information resources on the web.
3. **DNA Sequence Analysis Part I:** Analysis of sequencing chromatogram editing and contig building. Sequence-function relationship; Detection of protein-coding regions, promoters, transcription factor binding sites, restriction enzyme cleavage sites and intron-exon boundaries.
4. **DNA Sequence Analysis Part ll:** Databases and search tools; Biological background for sequence analysis. Retrieval of DNA sequences and searching of databases for similar sequence. Submitting DNA sequence to databases, where and how to submit.
5. **Protein sequence analysis:** Comparison of protein sequences and database searching. Predictive methods for protein sequences. Methods for discovering conserved patterns in protein sequences and structures and protein motifs.
6. **BLAST, various methods of DNA and protein BLAST and interpretation of output:** Sequence alignment, Pairwise alignment, Techniques, Multiple Sequence Alignment.
7. **Predicting secondary structure from protein sequences:** Protein structure prediction, homology modeling. Comparison of protein three-dimensional structures.

Protein family-based methods for homology detection and analysis.

9. **Phylogentic analysis sequence-based taxonomy:** Overview and assumptions from Multiple Alignment to phylogeny. Neighbour joining, maximum likelihood vs.parsimony. Computational tools for phylogentic analysis.
10. **Next generation sequencing and Realtime PCR:** Concept theory and applications in sequence detection and analysis.

READING MATERIAL

1. Essential Bioinformatics, by Jin Xiong
2. Bioinformatics: Sequence and Genome Analysis, by David W. Mount
3. Systems Biology by Bernhard Palsson
4. Systems Biology in Practice, Concepts, Implementation and Application by E. Klipp, R. Herwig, A. Kowald, C. Wieriing, H. Lehrach
5. Relevant Research and Review Papers
6. Systems Biology: Principle, Methods and Concepts. CRC Press. Taylor & Francis Group (2007).
7. An Introduction to System Biology. CRC Press. Taylor & Francis Group (2007).

GE-611

SEMINAR (1 CREDIT)

Students are required to submit written record and present details of the project to be pursued in semester-III and 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)

Cell Biology:

Expt-1: Cell proliferation / cytotoxicity assay (MTT)

Expt-2: Western transfer and immunoblotting

Recombinant DNA Technology:

Expt-1: Sequence retrieval and analysis

Expt-2: PCR primer generation

Expt-3: PCR and gel electrophoresis

Last day: Discussion of results and viva

Enzyme isolation:

Day 1-9: Extraction of a-amylase from wheat germ and its partial purification

Enzyme biochemistry:

Day 1-9: Expression, Partial purification and characterization of a recombinant enzyme

Bacterial Transformation:

Day 1-7: Commonly used methods for bacterial transformation, preparation of competent cells, comparison of transformation by electroporation and heat shock, estimation of transformation efficiency.

MEDICINAL CHEMISTRY
M.S. (Pharm.)

Course no.	Course Name	Credits
Semester I		
MC-510	Basics of Drug Action	2
MC-511	Spectral Analysis	2
MC-520	Logic in Organic Synthesis-I	3
NP-510	Separation Techniques	1
PC-540	Chemotherapy of Parasitic and Microbial Infections	1
PT-510	Industrial Process and Scale-up Techniques	1
GE-510	Biostatistics	2
GE-511	Seminar	1
LG-510	General Laboratory Experience	3
	Total Credits	**16**
Semester II		
MC-610	Drug Design	2
MC-620	Logic in Organic Synthesis-II	3
MC-630	Structure and Function of Bio-molecules	2
MC-650	Stereochemistry and Drug Action	2
PC-610	Drug Metabolism	1
PC-611	Pharmacological Screening and Assays	1
GE-611	Seminar	1
LS-610	General Lab Experience in the Area of Specialization	2
	Total Credits	**14**
Semester III Project (22 weeks)		
TH- 598	Synopsis	5
TH- 599	Presentation	3
	Total Credits	**8**
Semester IV		
TH-698	Thesis	9
TH-699	Defence of Thesis	3
	Total Credits	**12**
TOTAL CREDITS (I TO IV SEMESTERS)		**50**

MEDICINAL CHEMISTRY - SEMESTER I

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 der Waals 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 and prodrugs.
8. **Nucleic acids**: 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.

READING MATERIAL

1. An Introduction to Medicinal Chemistry, Fourth Edition

Graham L. Patrick
Oxford Press

2. Burger's Medicinal Chemistry, Drug Discovery and Development, 8 Volume Set (Burger's Medicinal Chemistry and Drug Discovery)
Donald J. Abraham and David P. Rotella

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-conjugated interactions, 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) ^{1}H 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 ^{19}F and ^{31}P, 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)^{13}C NMR, correlation of structure with spectra: Chemical environment, shielding and carbon-13 chemical shift, calculation, proton-coupled ^{13}C spectra, Proton-decoupled ^{13}C spectra, Nuclear Overhauser Enhancement (NOE), Problem with integration, Distortionless Enhancement by Polarisation Transfer (DEFT), Heteronuclear coupling for carbon to deuterium, carbon to ^{19}F, carbon to ^{31}P, 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.

READING MATERIAL

1. Organic Spectroscopic Analysis
   Rosaleen J. Anderson, David J. Bendell and Paul W. Groundwater
2. Spectrometric Identification of Organic Compounds
   Robert M. Silverstein, Francis S. Webster and David J. Kiemle

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 labeling, 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-eliminationmechanism.

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 un-saturation 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 to explain stereoselective enolate formation.

b) Enamines and metallo-enamines: Regioselectivity in generation, applications in controlling the selectivity of alkylation.

4. **Reaction of ylides:**

   a) Phosphorous 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 of these reactions and E/Z selectivity, Petersons olefination, Application of Wittig-class of 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- lpc2BH lpcBI-12 etc.

READING MATERIAL

1. The Logic of Chemical Synthesis
   E. J. Corey and Xue-Min Cheng
2. Organic Synthesis: The Disconnection Approach
   Stuart Warren

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 reversed phase, bonded phase chromatography, stationary phases, activity of stationary phases, elutropic series, and separation mechanisms.
3. **Column chromatography and 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 Pressure Liquid Chromatography (HPLC):** 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. **Planer 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. **Gas chromatography:** Introduction to GC-MS and LC-MS techniques and their application in natural products.

READING MATERIAL

1. Introduction to Modern Liquid Chromatography, Third Edition
   Lloyd R. Snyder, Joseph J. Kirkland and John W. Dolan
2. Practical HPLC Method Development, Second Edition
   Lloyd R. Snyder, Joseph L. Glajch and Joseph J. Kirkland

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 anti-amoebic drugs
8. Biology of filarial infections
9. Mechanism of action of anti-filaria drugs
10. Targets of anti-filarial drug development
11. Biology of viral 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

READING MATERIAL

1. Foye's Principles of Medicinal Chemistry
   (Lemke, Foye's Principles of Medicinal Chemistry)
   Lippincott Williams & Wilkins
2. Burger's Medicinal Chemistry, Drug Discovery and Development, 8 Volume Set
   (Burger's Medicinal Chemistry and Drug Discovery)
   Donald J. Abraham and David P. Rotella

PT-510

INDUSTRIAL PROCESS AND SCALE UP TECHNIQUES

(1 CREDIT)

1. **Status of pharmaceutical industry: status of** bulk drugs, natural products and formulations in India vis-a-vis industrialized nations
2. **Scale-up techniques:** scale up techniques for process optimization, maximization of productivity, in process control techniques.
3. **Chemical technology of selected drugs**: Case studies with emphasis on rationale for selection of routes, raw materials, process control methods, pollution control procedures etc.
4. **Chemical technology of selected drugs:** Data collection during pilot plant trails, preparations of flow diagrams, material balance sheets and technical data sheets
5. Process technologies for some selected natural products of commercial interest, e.g. 4-hydroxyisoleucine.
6. Scale-up techniques for industrial pharmacy, typical standard operating procedures for different dosage forms; In- process control procedures
7. **Pharmaceutical manufacturing equipment: Equipment used to manufacture** bulk drugs.

8. **Pharmaceutical manufacturing equipment:** Equipment used in formulations.

READING MATERIAL

1. Burger's Medicinal Chemistry, Drug Discovery and Development, 8 Volume Set
   (Burger's Medicinal Chemistry and Drug Discovery)

Donald J. Abraham and David P. Rotella

GE-510

BIOSTATISTICS (2 CREDITS)

1. **Statistics:** Introduction and its role and uses, Collection, Organization, Graphics and pictorial 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 andregression:** Graphical presentation of two continuous variables, Pearson's product moment correlation coefficient, its statistical significance, Multiple and partial correlations, Linearregression, 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

READING MATERIAL

1. Mathematics and Biostatistics, Second Edition, 2007-2008
   G. K. Jani
   Atul Prakashan
2. Pharmaceutical Statistics: Practical and Clinical Applications, Fourth Edition, 2004
   SanfordBolton
3. Biometry, Third Edition, 1995
   Robert R. Sokal and F. James Rohlf
4. Introduction to the Practice of Statistics, Fifth Edition, 2004
   David S. Moore and George P. McCabe

5. Experimental Design in Biotechnology, 1989
Perry D. Haaland

6. Probability Statistics and Queueing Theory, 2005
P. Kandasamy, K. Thilagavathi and K. Gunavathi

GE-511

SEMINAR (1 CREDIT)

1. Introduction, information retrieval systems.
2. Writing term papers and reports.
3. Organization of scientific material, thesis, dissertation and references.
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 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 synthetic involving hitting reaction, glycidic ester condensation etc., Purification by chromatographic technique and identification by IR, NMR, and MS

MEDICINAL CHEMISTRY –SEMESTER II

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 the 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 non-linearity; Descriptor calculation, The importance of biological data in the correct form; 2D-QSAR; 3D-QSAR-examples 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 molecular dynamics in performing conformational search, 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, etc. 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:** Brief introduction to bioinformatics, cheminformatics, their relation to drug design as per the topics discussed in items 1-9 above.

READING MATERIAL

1. An Introduction to Medicinal Chemistry, Fourth Edition
   Graham L. Patrick
   Oxford Press
2. Burger's Medicinal Chemistry, Drug Discovery and Development, 8 Volume Set (Burger's Medicinal Chemistry and Drug Discovery)
   Donald J. Abraham and David P. Rotella

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 stereo-selectivity, Reduction of alkynes, Complex metal hydrides and selectrides.
2. **Reaction of electron-deficient intermediates**: Carbene, nitrene and free radical-their stability and modes of generation; Addition and insertion reactions of carbenoids and nitrenoids- regio- and stereo-selectivity, role of the metal catalysts in the transition metal-catalyzed reactions, other types of reaction 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-mimicing processes
4. **Umpolung and umpoled sythons**: Concept, acyl and glycine cation/anion, homoenolate anion, vicinyl dicarbonian, 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 diastereo-selection, 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; Electrocyclic reactions-conrotatory and disrotatory motions, [4n], [4n+2] and allyl systems, secondary orbiati interaction; Cycloaddition- antarafacial and the suprafacial additions, [4n] and [4n+2] systems with stereo chemical effects, 1,3 - dipolar cycloadditions, chelotropic reactions; Sigmatropic rearrangements- 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 efficiency; Photochemistry of carbonyl compounds, Norish type-1 and type-11 cleavages, Paterno-Buchi reaction, photo-reduction, photochemistry of enones and para-benzoquinones.

7. **Synthesis of complex molecules**: Various approaches for the synthesis of Taxol, Forskolin, FK-506, Gibberellines, Prostaglandins, Spatol, Aphidicolin etc. on the basis of disconnection and direct associative approaches.

READING MATERIAL

1. The Logic of Chemical Synthesis
   E. J. CoreyandXue-Min Cheng
2. Organic Synthesis: The Disconnection Approach
   Stuart Warren
3. Organic Chemistry
   Jonathan Clayden, Nick Greeves,Stuart Warren andPeter Wothers
   OxfordUniversityPress

MC-630

STRUCTURE AND FUNCTION OF BIOMOLECULES (2 CREDITS)

1. **Methods for the determination of structure of bio-molecules**: Biological crystallography-crystallization 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 Theormogravimetric 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; Aptechniques 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**: Relationship 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 therapeutic 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**: Crystallization data collection, refinement, identification of active site, phase determination heavy atom derivatives, electron density maps, Differences in the small molecules and biomolecule crystallography.
9. **Spectrofluorimetry and Optical methods**: Basic principles of fluorescence, intensity, fluorescent group, sensitivity of fluorescence to environment, biological applications, Optical activity measurements, ORD/CD application to Nucleic acids and proteins.
10. **Thermodynamical methods**: Different Scanning Calorimetry (DSC) and Thermo-gravimetric analysis (TA) of biomolecules, Isothermal Titration Calorimetry (ITC). Various thermodynamics based instrumental methods for estimation of structural features of bio-molecules, enthalpy vs entropy contribution to free energy.

READING MATERIAL

1. Foye's Principles of Medicinal Chemistry
   (Lemke, Foye's Principles of Medicinal Chemistry)
   Lippincott Williams & Wilkins

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 co-ordinates, 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, gauch effect, generalized anomeric effect.

5. **Assignment of configuration**: Various projectional formulae, molecule with chiral centre, 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; Enantio-selectivity in drug absorption, metabolism, distribution and elimination.

READING MATERIAL

1. The Organic Chemistry of Drug Design and Drug Action, Second Edition
   Richard B. Silverman
2. Organic Reactions Stereochemistry and Mechanism
   P.S. Kalsi

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, idiosyncrasy.
10. Acute poisoning and its treatment

READING MATERIAL

1. Medicinal Chemistry: A Molecular and Biochemical Approach
   Thomas Nogrady and Donald F. Weaver
2. Burger's Medicinal Chemistry, Drug Discovery and Development, 8 Volume Set (Burger's Medicinal Chemistry and Drug Discovery)
   Donald J. Abraham and David P. Rotella

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, Diabetes, 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

READING MATERIAL

1. Drug discovery and evaluation pharmacological assays
   Hans Gerhard Vogel
   Springer.
2. CPCSEA Guidelines

GE-611

SEMINAR (1 CREDIT)

Students are required to submit written record and present details of the project to be pursued in semester-Ill & 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)

Synthesis of a complex drug includes 4 to 5 steps; isolatation 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 the theoretical organic chemistry using computation methods for the same reaction and learn the techniques of molecular modeling.

MEDICAL DEVICES

M. S. (Pharm.)

Course no.	Course Name	Credits
Semester I		
MD-510	Medical Imaging	1
MD-520	Nanomaterials and Bionanotechnology	2
MD-550	Regulatory Perspectives of Medical Devices	1
BT-520	Cell Biology and Biochemistry	2
PC-511	Pathophysiology	1
GE-510	Biostatistics	2
GE-520	Fundamentals of Intellectual Property (IP) and Technology Management	1
GE-511	Seminar	1
LG-510	General Laboratory Experience	3
	Total Credits	**14**
Semester II		
MD-650	Bioelectricity & Biomedical Fluid Dynamics	1
MD-620	Biomedical Fluid Dynamics	1
MD-630	Medical Sensors and Diagnostics	1
MD-640	Medical Devices- Product Development	1
MD-530	Advance topics in biomaterials	3
PE-650	Biomaterials	2
PC-611	Pharmacological screening and assays	1
PE-620	Drug Delivery Systems	2
GE-611	Seminar	1
LS-610	General Lab Experience in the Area of Specialization	3
	Total Credits	**16**
Semester III Project (22 weeks)		
TH- 598	Synopsis	5
TH- 599	Presentation	3
	Total Credits	**8**
Semester IV		
TH-698	Thesis	9
TH-699	Defence of Thesis	3
	Total Credits	**12**
TOTAL CREDITS (I TO IV SEMESTERS)		**50**

MEDICAL DEVICES - SEMESTER I

MD-510
MEDICAL IMAGING (1 CREDIT)

1. **Physical Principles of Imaging:** Fundamentals of Physics and Radiation; Concepts of Radiation science; Radiographic definition and Mathematics review; Electromagnetic Radiation: Photons, Electromagnetic Spectrum, Wave Particle Duality; Interactions between Radiation and matters; Fundamentals of acoustic propagation; Interaction between sonic beams and matter; concepts of ultrasonic diagnostics.
2. **Imaging with X-Rays:** X-ray tube: The generation: Electron-Target Interactions, X-ray emission spectrum: Characteristic x-ray spectrum, Bremsstrahlung x-ray spectrum, Factors affecting X-ray Emission Spectrum: Effect of mA, kVp, added filtration; X-ray unit: generators, filters and grids; Image intensifiers; X-ray detectors: Screen film detector, Image Intensifier; Radiographic techniques, quality and exposure.
3. **X-ray Diagnostic Methods:** Fluoroscopy: Fluoroscopy and Visual Physiology, Image intensifier tube and Multifield intensification; Angiography: Arterial access, Catheters, Contrast media; Mammography: Soft tissue radiography, Equipments: Target composition, Filtration grids, Photo timers, Image receptors; Xeroradiography; Digital radiography; 3-D construction of images.
4. **Computed Tomography:** Operational modes: First generation scanners, Second, Third, Fourth, Fifth generation scanners; System components: Gantry, Collimation; High Voltage generators; Image characteristics: Image matrix, CT numbers; Image reconstruction; Image Quality: Spatial resolution, Contrast resolution, System noise, Linearity, Spatial Uniformity.
5. **Imaging with Ultrasonography:** Piezoelectric effect; Ultrasonic transducers: Mechanical and Electrical matching, The characteristics of transducer beam: Huygens principle, Beam profiles, Pulsed ultrasonic filed, Visualization and mapping of the Ultrasonic field; Doppler effect-Doppler methods; Pulse echo systems [Amplitude mode, Brightness mode, Motion mode &Constant depth mode]; Tissue characterization: velocity, Attenuation or absorption, Scattering.
6. **Developments in Ultrasound technique**: Color Doppler flow imaging: CW Doppler imaging device, Pulsed Doppler imaging system, clinical applications; Intracavity imaging: Design of the Phased array probe, Trans oesophageal, Tannsvaginal or Transrectal scanning; Ultrasound contrast media: Utilization of micro air bubbles, galactosemicroparticles and albumin encapsulated microairbubbles; 3-D image reconstruction; 2-D echo cardiography
7. **Biological effects of Radiation and Ultrasound and its protection:** Modes of Biological effects: Composition of the body and Human response to Ionizing radiation; Physical and Biological factors affecting Radiosensitivity, Radiation Dose-response relationships; Time variance of radiation exposure; Thermal / Nonthermal effects due to cavitation in ultrasound fields; Designing of radiation protections and its procedures.

8. **Advances in Imaging:** Introduction to Magnetic Resonance Imaging, Radionuclide Imaging, Longitudinal section Tomography, Single Photon Emission Computed Tomography, Positron Emission Tomography.

READING MATERIAL

1. Principles of Medical Imaging
   K. Kirk Shung, Michael B. Smith, Benjamin Tsui
   Academic Press
2. Radiologic Science for Technologists
   Stewart C. Bushong
   Mosby: A Harcourt Health Sciences Company
3. Quality Management: In the Imaging Sciences
   Jeffery Papp
   Mosby: A Harcourt Health Sciences Company

MD-520

NANOMATERIALS AND BIONANOTECHNOLOGY (2 CREDITS)

1. Introduction to Bio-Nanotechnology, Cellular nanostructures, self-assembly of colloidal nanostructures of biological relevance, bioactive nanoparticles (respiratory surfactants, magnetic nanoparticles), Nanoparticles for drug delivery (including solid lipid nanoparticles, synthetic and biopolymeric nanoparticles), carbon nanotubes, polymeric nanofibers, Implications in neuroscience, tissue engineering and cancer therapy
2. **Environmental and safety aspects of bio-nanotechnology:** Introduction to Nanotechnology, Multilayer Thin Film: Polyelectrolyte multilayers, coated colloids, smart capsules, LbL self-assembly, Colloids and Colloid Assemblies for Bio-nanotechnology, Nanoengineered biosensors, Fiber Optic Nano-sensors in medical care,
3. **Semiconductor and Metal Nanoparticles:** Synthesis and Applications, Nanotechnology in Tissue Engineering, Microemulsions and Drug Delivery in Nanotechnology.

READING MATERIAL

1. Multilayer Thin Films, 2003
   GeroDecher, Joseph B. Schlenoff
   Wiley-VCH Verlag GmbH & Co. KGaA
2. Bionanotechnology: Lessons from Nature, 2004
   David S. Goodsell
   Wiley-Liss

3. Nanoscale Materials in Chemistry, 2001
   Kenneth J. Klabunde
   John Wiley & Sons, Inc.

MD-550

REGULATORY PERSPECTIVES OF MEDICAL DEVICES (1 CREDIT)

1. Medical device safety: Medical device safety and risk management, Effectiveness/performance of medical devices, Phases in the life span of a medical device, Classification of medical devices, Participants in ensuring the safety of medical devices, The role of each participant/stakeholder, Shared responsibility for medical device safety and performance, Quality Systems Regulation, .
2. Basics of Forensic Pharmacy & Drugs and Cosmetics Act. Basics of the different systems for the Medical Device regulations - US FDA, GHTF & European regulations. Basics of the Quality Management System for medical devices (ISO, ISO 13485, FDA requirements)
3. Governmental regulation of medical devices: Critical elements for regulatory attention, Stages of regulatory control, common framework for medical device regulations, Regulatory tools and general requirements, Product control, Vendor establishment control, Post-market surveillance/vigilance, Quality system requirements.
4. Standards: need for standards, voluntary and mandatory standards, Standards development process, National and international standard system for medical devices, scenario in India.

READING MATERIAL

1. FOOD AND DRUG ADMINISTRATION USA.
   http://www.fda.gov/medicaldevices/deviceregulationandguidance/default.htm
2. Medical Device Regulations: Global overview and guiding principles.
   World Health Organisation.

BT-520

Cell Biology (2 Credits)

11. **Cell structure and organization:** Cells as a unit of life, prokaryotic and eukaryotic cells, biomembranes, structure and basic functions of various cell organelles i.e. nucleus, ribosomes, ER, golgi, lysosomes, peroxisomes, exosomes, cytoskeleton
12. **Tools and Techniques of Cell Biology:** Histology, staining, fluorescence, confocal microscopy, TEM and SEM, Fluorescent dyes and GFP tagged proteins in visualization, FACS, cell fractionation, cell culture.

13. **Organization of tissues:** Cell-cell and cell-matrix interactions, cell adhesion molecules, components of the extracellular matrix, cellular junctions and role.
14. **Cell cycle:** G1, G2, S and M Phase of the cell cycle. Cell cycle analysis and its applications, programmed cell death apoptosis versus necrosis. Role of telomeres in the cell cycle.
15. **Cell signaling:** Receptor concept, receptor signaling and expression, orphan receptors, extracellular signals and cell functions, hormones, second messengers and hormone actions, growth factors.
16. **Transport across membranes:** Osmosis, active and passive transport. Protein transporters ion channels, antiporters, symporters. Applications in the field of medicine.
17. **Cellular movement and Molecular motors:**. Types of movement, extravasation, role of cytoskeletal proteins in movement, molecular motors, the movement of cilia and flagella, muscle contraction, myosin and kinesins in the movement of vesicles.
18. **Protein Synthesis and Targeting:** Ribosome and endoplasmic reticulum, Secretory pathway, targeting and sorting of proteins, nuclear localization signal, organelle specific signal sequence, ATP driven translocation, glycosylation, transport of protein, endocytosis, exocytosis, macropinocytosis.
19. **Relevance of Cell Biology:** Stem cells, Tissue engineering, infectious disease.
20. **Cancer:** Tumor cells, cell lines and models, proto-oncogenes and oncognese, oncogenic mutations, loss of cell cycle control, carcinogens.

READING MATERIAL

1. Molecular Cell Biology by Harvey Lodish
2. Molecular Biology of the Cell by Bruce Alberts
3. Principles of Biochemistry: Lehgninger
4. Biochemistry by L Stryer
5. Lehninger Principles of Biochemistry, Fourth Edition, 2007
   D. L. Nelson and M. M. Cox
   W. H. Freeman and Company
6. Biochemistry, Third Edition, 2004
   D. Voet and J. G. Voet
   John Willey and Sons
7. Kuby – Immunology, Sixth Edition, 2007
   T. J. Kindt et.al.
   W. H. Freeman and Company
8. Immunology, Seventh Edition, 2006
   David Male et.al.
   ASM Press

PC-511

PATHOPHYSIOLOGY (1 CREDIT)

1. Factors influencing the disease conditions such as sex, age, nutritional status, genetic makeup etc.
2. Pathogenesis, symptoms and signs, laboratory findings and complications of respiratory, urinary tract, venereal and meningeal infections, congestive heart failure, hypertension, cardiac arrhythmias, ulcer, pancreatitis, hepatitis and cholecystitis, bronchial asthma, depression, schizophrenia, epilepsy, parkinsonism and alzheimer disease; hypo and hyper thyroidism, diabetes mellitus and other endocrine diseases; rheumatoid arthritis, gout and anemia.

READING MATERIAL

1. Essentials of Pathophysiology: Concepts of Altered Health States
   Author: Carol M. Porth, Glenn Matfin
   Publisher: Lippincott Williams & Wilkins
2. Handbook of Pathophysiology
   Author: Elizabeth J. Corwin
   Publisher: Lippincott Williams & Wilkins
3. Pathophysiology: The Biologic Basis for Disease in Adults and Children
   Author: Sue E, RN Huether, Kathryn L.,RNMcCance, Valentina L. Brashers
   Publisher: Mosby Inc

GE-510

BIOSTATISTICS (2 CREDITS)

1. **Statistics:** Introduction and its role and uses, Collection, Organization, Graphics and pictorial 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 andregression:** Graphical presentation of two continuous variables, Pearson's product moment correlation coefficient, its statistical significance, Multiple and partial correlations, Linearregression, 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

READING MATERIAL

1. Mathematics and Biostatistcs, Second Edition, 2007-2008
   G. K. Jani
   Atul Prakashan
2. Pharmaceutical Statistics: Practical and Clinical Applications, Fourth Edition, 2004.
   SanfordBolton
3. Biometry, Third Edition, 1995
   Robert R. Sokal and F. James Rohlf
4. Introduction to the Practice of Statistics, Fifth Edition, 2004
   David S. Moore and George P. McCabe
5. Experimental Design in Biotechnology, 1989
   Perry D. Haaland

GE-520

FUNDAMENTALS OF INTELLECTUAL PROPERTY (IP) AND TECHNOLOGY MANAGEMENT (1CREDIT)

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; Penalties 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 Organization), WIPO (World Intellectual Property Organization) GATT (General Agreement on Tariff and Trade), TRIP^{S} (Trade Related Intellectual Property Rights), TRIMS (Trade Related Investment Measures) and GATS (General Agreement on Trade in Services); Protection of plant and animal genetic 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-disclosure 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-provision 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 attorneys technical aspects, criteria trisection, addresses, fee, rights and responsibilities of a patentee; Practical aspects regarding maintaining of a PATENT FILE. Patent infringement- meaning, scope, litigation, case studies and examples; Patenting by research students, lecturers and scientists -University / organizational rules 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, multimedia works; Trademarks 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 infringements.

4. **Technology development / transfer/commercialization 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-commercialization and commercialization-practical aspects and problems; Significance of transfer of technology (TOT), bottlenecks; Managing technology transfer-guidelines for research students, scientists and related personal; TOT agencies in India-APCTD, NRDC,TIFAC, BCIL, TBSE/SIDBI; TOT related documentation-confidentiality agreements, licensing, MOUs, legal issues; Compulsory licensing excess to medicine issues; DOHA declaration, POST WTO product patent regime from 2005; Challenges for Indian pharmaceutical industry in the context of globalization 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, and NIPER. Documentation and related aspects.
6. **Ethics and values in IP:** IP and ethics-positive and negative aspects of IPR; Societal responsibility; Avoiding unethical practices; Echo responsibility-economic, social and environmental benefits of modern biotechnology; Voluntary adoption of pollution control strategies.

READING MATERIAL

1. Intellectual Property Rights in the WTO and Developing Countries

Jayshree Watal
OxfordUniversity Press

2. Intellectual Property Rights: Unleashing the Knowledge Economy
   Prabuddha Ganguly: Tata McGraw Hill
3. Intellectual Property, Fifth Edition
   David Bainbrige
   Pearson Education

GE- 511

SEMINARS (1 CREDIT)

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

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

LG-510 (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 nt, 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, acute toxicity testing of drugs, analgesic activity of a compound, estimation of protein and haematological parameters
4. **Specialization (50 hours):** Behavior of monolayers at air-liquid/liquid-liquid interface- Langmuir-Blodgett apparatus; Characterization of Colloids-Dynamic light scattering and Zeta potential; Material characterization-UTM, film stretching, contact angle, tensile strength.

MEDICAL DEVICES- SEMESTER II

MD-650
BIOELECTRICITY (1 CREDIT)

1. Action potential of excitable cells: Quantitative description, Hodgkin-Huxley model, significance of parameters in Hodgkin-Huxley equations; Voltage-clamp experiments: design, and analysis of results; Factors determining the initiation, amplitudes, and kinetic properties of action potentials.
2. Passive membrane electrical properties: Cellular resistance, capacitance, time constant and space constant, methods of measurement; Importance in cellular excitation and signaling: Impulse propagation.
3. Electrophysiology of synaptic transmission: Prejunctional and postjunctional electrical events; time courses of transmitter-activated membrane currents and potentials in skeletal and smooth muscle; Electrical models of the skeletal and smooth muscle membranes.
4. Review of biopotentials, Electrodes as bioelectric transducers: The electrode-electrolyte interface; Specification and selection criteria for electrodes; Surface, needle, implanted electrodes; Polarizable and non-polarizable electrodes; Practical considerations.
5. Instrumentation for biopotential recording: Practical considerations for optimum performance; Reduction of interference, grounding, safety.
6. **Electrical Stimulation:** Use in generating evoked potentials, and for therapeutic correction (ECT, pacemakers, defibrillation); Stimulation parameters; Safety limits and precautions.
7. **Safety:** Hazards associated with the use of electrical / electronic instruments; Provisions for safety; Clinical safety norms.
8. Commonly measured biopotentials and their clinical interpretation ENG, ECG, EMG, etc.; Sensory evoked potentials (visual, auditory, somatosensory).

READING MATERIAL

1. B. Katz: Nerve, Muscle, and Synapse, Mc-Graw Hill, New York, 1966.
2. J.G. Nicholls, A.R. Martin & B. Wallace: From Neuron to Brain, 3rd ed., Sinauer, Sunderland, 1992.
3. J.J.B. Jack, D. Noble & R.W. Tsien: Electric Current Flow in Excitable Cells, Oxford University Press, 1983.
4. R.D. Barr & R.L. Plonsey: Bioelectricity: A Quantitative Approach, Academic Press, N.Y., 1988.
5. E.R. Kandel& J. Shwartz (ed.): Principles of Neural Science, 3rd ed., 1991.
6. M.J. Aminoff: Electrodiagnosis in Clinical Neurology, 3rd edition, Churchill Livingstone, USA, 1992.

7. J.A. Delisa, H.J. Lee, E.M. Baran, K.S. Lai & N. Spielholz : Manual of Nerve Conduction and Clinical Electrophysiology, 3rd Edition, Academic Press, New York, 1993.

8. J. Kimura (Ed.): Peripheral Neuropathy vol. 1, W.B. Saunders & Co., Philadelphia, 1984.

MD-620

BIOMEDICAL FLUID DYNAMICS (1 CREDIT)

1. Introduction to fluid mechanics; Fluid properties, basic laws governing conservation of mass momentum and energy; Laminar flow, Couette flow and Hagen-Poiseuille equation, turbulent flow.

2. Flow dynamical study of circulatory system, heart and blood vessels, anatomy and physiological considerations; Components and functions of arterial and venous systems; Lymphatic system; Body fluids and their motions; Flow of Newtonian and non-Newtonian fluids in rigid tubes, flexible tubes and collapsible tubes; Blood flow through arteries and veins; Holt and Conrads experimental investigations.

3. Kinetic energy, flow, pressure-flow relations in vascular beds; Cardiac cycle; Cardiac valve dysfunctions; Blood pressure, regulation and controlling factors; Coronary circulation, heart failure.

READING MATERIAL

1. J.F. Green: Fundamental Cardiovascular and Pulmonary Physiology, Lea &Febiger, Philadelphia, 1982.

2. C.A. Keele, E. Neil & N. Joels: Samson Wright's applied physiology, 13th ed., Oxford University Press, Delhi, 1982.

3. A. Noordergraft: Circulatory System dynamics, Academic Press, New York, 1978.

4. R.R. Puniyani: Clinical Haemorheology, New Age Int. Publishers, New Delhi, 1996.

MD-630

MEDICAL SENSORS AND DIAGNOSTICS (1 CREDIT)

1. **Sensor architecture and Classification**; Medically significant measurands, functional specifications of medical sensors; Sensor characteristics: linearity, repeatability, hysteresis, drift; Sensor models in the time & frequency domains.

2. **Sensors for physical measurands:** strain, force, pressure, acceleration, flow, volume, temperature and biopotentials.

3. **Sensors for measurement of chemicals:** potentiometric sensors, ion selective electrodes, ISFETS; Amperometric sensors, Clark Electrode; Biosensors, Catalytic biosensors, immunosensors

READING MATERIAL

1. John G. Webster (ed.): Medical Instrumentation - Application and Design; Houghton Mifflin Co., Boston, 1992.
2. Richard Aston: Principles of Biomedical Instrumentation and Measurement, Merril Publishing Co., Columbus, 1990.
3. Richard S.C. Cobbold: Transducers for Biomedical Measurements: Principles and Applications, John Wiley & Sons, 1974
4. Ernest O. Doeblin: Measurement Systems, Application and Design, McGraw-Hill, 1985
5. A.P.F. Turner, I. Karube & G.S. Wilson : Biosensors : Fundamentals & Applications, Oxford University Press, Oxford, 1987

MD-640

MEDICAL DEVICES - PRODUCT DEVELOPMENT (1 CREDIT)

1. **cGMP Quality Principles for Medical Devices:** Introduction, The Food Drug and Cosmetic Act (FD&C), Differences between Medical Device and Drug development, Documentation Management, What is Good Documentation Practice (GDP), What is the purpose of documentation?, The types of GMP documents, Document and record retention
2. **Material selection and properties:** Mechanical strength testing, performance testing of medical devices
3. Incorporation of fluid dynamics and bioelectricity
4. Storage considerations for medical devices; implications on material content
5. **Sterilization Procedures:** Technology, Equipment and Validation
6. **Package development:** Packaging materials, Package development and design, Testing of packages and labeling
7. Clinical Trial Design for Medical Devices

MD-530

ADVANCE TOPICS IN BIOMATERIALS (3 CREDITS)

1. Structure and property relationships in materials, ceramics and polymers; Interactions of materials with the human body; Influence of microstructure and environment on fatigue and fracture of materials. Composite materials concepts and applications; Whiskers and fibres medical applications such as structures, orthopedic implants, artificial organs, dental materials, etc.
2. **Implementation problems-** inflammation, rejection, corrosion, structural failure. Consists of biomaterial applications and tissue engineering for artificial organs, Types of biomaterials and their applications for the human body, Issues of

biocompatibility and its evaluation, Surface characterization of biomaterials, biomaterial-blood (bio-fluid) interface, Surface modifications for improved compatibility.

3. **Biomaterials in cardiovascular system:** Collagen, hyaluronic acid and other biopolymer applications, Cardiovascular implant biomaterials: artificial heart valves, Mechanical and bio-prosthetic valves, materials used, criteria required for fulfillment of physiological functions, Vessel grafts, Endothelial cell seeding as a surface modification of biomaterials.
4. **Orthopaedic implant materials:** temporary external fixators, Materials for reconstruction of cartilage. Ligaments and tendons, Bone replacement and bone cement, artificial joint replacement.
5. **Ophthalmology:** Artificial cornea, contact lenses, intra-ocular lenses, artificial aqueous and artificial vitreous humour, artificial tears, artificial tympanic membrane.
6. Tissue engineering and artificial organs, Properties of skin, Wound dressings, artificial skin, facial implants, dental restorative materials, implanted dental interfaces, denture resins and cements, artificial red blood cells, artificial lung surfactants, artificial saliva, artificial synovial fluid, dialysis membranes, artificial liver, artificial pancreas, biodegradable block copolymers & their applications for drug delivery, materials used for neuronal reconstruction and regeneration.

READING MATERIAL

1. Biomaterials: An Introduction, 1992
   Joon B. Park & Roderic S. Lakes
   Plenum Press, New York
2. Encyclopedic Handbook of Biomaterials and Bioengineering (4 vols.), 1995
   Donald L. Wise et al. ed.
   Marcel Dekker, New York.
3. Biomaterials, Medical Devices & Tissue Engineering: An Integrated Approach, 1994
   Fredrick H. Silver
   Chapman & Hall, 1994.
4. Biomaterials, An Interfacial Approach, 1982
   L.L. Hench, E. C. Ethridge
   Academic Press, New York
5. Biomaterial Science and Biocompatibility, 1999
   S. Frederick, H. Chrstiansen, L. David
   Springer-Verlag, New York

PE-650

BIOMATERIALS (2 CREDITS)

1. **Introduction to biomaterials:** Fundamentals of polymer science and polymer classification.
2. **Synthesis and modification methods of biomaterials:** Polymerization methods, polymer fabrication.
3. **Physical and chemical characterization techniques:** Thermal, spectroscopic, microscopic and laser based techniques.
4. **Manipulating biomaterials in various forms depending upon end use specification:** Hydrogels, micro and nano particles, films, fibres.
5. **Host reaction to biomaterials and their evaluation:** Inflammation, wound healing, foreign body response, systematic toxicity
6. **Biocompatibility testing of biomaterials:** In vitro assessment of tissue compatibility, invivo assessment of tissue compatibility, testing blood materials interactions.
7. **Degradation of biomaterials in biological environment**: Chemical and biochemical degradation of polymers; Degradative effects of biological environment.
8. **Use of polymers in controlled release of active agents:** Diffusion controlled devices, Solvent-controlled devices and chemically controlled devices.
9. **Regulatory considerations:** Assessment of safety and long term toxicity evaluation, toxicity considerations on repetitive accumulation of polymeric materials.
10. **Pharmaceutical and biomedical applications:** Drug delivery, tissue engineering.

READING MATERIAL

1. Biomaterials Science: An Introduction to Materials in Medicine, 1996
   Buddy D. Ratner and Allan S. Hoffman
   Academic Press

PC-611

PHARMACOLOGICAL SCREENING AND ASSAYS (1 CREDIT)

4. General principles of screening, correlations between various animal models and human situations, animal ethics
5. Pharmacological screening models for therapeutic areas such as Hypertension, Cerebral Ischaemia, Pain, Epilepsy, Depression, Parkinson's disease, Alzheimer's disease, Diabetes, Leishmaniasis etc.
6. 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

READING MATERIAL

1. Drug discovery and evaluation pharmacological assays
   Hans Gerhard Vogel
   Springer.
2. CPCSEA Guidelines

PE-620

DRUG DELIVERY SYSTEMS (2 CREDITS)

1. **Influence of drug properties and routes of drug administration on the design of sustained and controlled release systems:** Rationale for controlled drug delivery, physicochemical properties and biological factors influencing the design and performance of sustained/controlled release products.
2. **Biopharmaceutic and pharmacokinetic aspects of PO CRDDS**. Stratergies and design, factor affecting controlled release drug delivery systems, computation of desired release rate and dose for CRDDS. Pharmacokinetic design for DDS; in-vitro/in-vivo considerations. Intermittent zero order and first order release.
3. **Peroral controlled-release delivery*:*** Design and fabrication of oral systems, dissolution controlled release, diffusion controlled release, diffusion and dissolution controlled release, ion exchange resins, PH-independent formulations, osmotically controlled release, altered density formulations, case studies.
4. **Parenteral drug delivery**: Major routes of parenteral administration; Selection, design and development, biopharmaceutics of sustained /controlled release parenteral products, polymer microspheres, and dispersed DDS.
5. **Transdermal/skin drug delivery systems:** Principles of skin permeation, factors affecting percutaneous absorption drugs, sorption promoters, absorption enhancement by energy input – iontophoresis, sonophoresis and electroporation pharmacokinetics of skin permeation, development and evaluation of transdermal devices, case studies.
6. **Implantable Therapeutic systems:** Introduction, historical development, approaches to development of implantable therapeutic systems, benefits of controlled drug administration via implantation, medical aspects of implantation.
7. **Drug targeting:** Different levels of drug targeting-first order, second order and third order targeting, active and passive targeting, EPR effect, receptor mediated endocytosis, prodrug based drug targeting, brain targeting, tumor targeting.
8. **Overview of different carrier systems for drug delivery:** Microparticles, liposomes, niosomes, polymeric nanoparticles, solid lipid nanoparticles, carbon nanotubes etc.
9. **Protein/peptide drug delivery systems**, enzyme, epithelial/endothelial barriers, pharmacokinetics, different routes of delivery, practical considerations.
10. **Regulatory assessment of controlled release products:** Potential pharmacodynamics and bioavailability problems of oral controlled release products,

dissolution rate assessment, biopharmaceutic consideration in the regulatory assessment.

READING MATERIAL

1. Controlled Drug Delivery: Fundamentals and Application, Second Edition, Vol. 29, 1987
   Joseph R. Robinson and Vincent H. L. Lee
   Marcel Dekker
2. Modern Pharmaceutics, Fourth Edition, 2008
   Gilbert S. Banker and Christophex T. Rhodes
   Marcel Dekker
3. Novel Drug Delivery Systems, Second Edition, 1992
   Yie W Chien: Marcel Dekker
4. Controlled Drug Delivery: Concepts and Advances, 2008
   S. P. Vyas and Roop K. Khar
   Vallabh Prakashan

GE-611

SEMINAR (1CREDIT)

Students are required to submit written record and present details of the project to be pursued insemester-III and 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 IN THE AREA OF SPECIALIZATION-10 HOURS/WEEK (3 CREDITS)

Experiments on Spirometry and lung physiology; Energy expenditure and Energy Balance; Microscopy and tissue visualization. Advanced laboratory techniques and quantitative methods for parameter estimation in biomedical systems (e.g. nerve muscle physiology, cardiovascular physiology, dental devices, medical microsystems, biomaterials, bio-interfaces etc)

Review of Basic Electric Circuits: Kirchhoff's laws, Thevenin's and Norton's Theorems; Complex impedance and phasors; Electronic Devices: PN junction diodes, diode circuits; Transistors: bipolar and field-effect transistors; Integrated circuit fabrication; Operational Amplifiers, amplifier circuits, non-linear circuits; Transfer functions, Bode plots, Filters. Boolean algebra; Logic circuits: Simple logic circuits, combinational logic, sequential logic, multivibrators, counters.

Fluid mechanics-Microscopy and Image Analysis; Emulsion liquid membranes-spectrophotometry; Heat effects associated with phase transformation-Differential

Scanning Calorimeter / Thermogravimetry; Reactive Distillation-GC/HPLC analysis, Adsorptive separations-High Performance Thin Layer Chromatography; Kinetics of electrochemical reactions- Cyclic voltammetry; Heat of complexation-Microcalorimetry; Catalyst characterization-BET, mercury porosimetry; Rheology of Non-Newtonian Fluids-Rheometry;

NATURAL PRODUCTS

M. S. (Pharm.)

Course no.	Course Name	Credits
Semester I		
NP-510	Separation Techniques	1
NP-520	Natural Products-I	2
MC-510	Basis of Drug Action	2
MC-511	Spectral Analysis	2
PC-540	Chemotherapy of Parasitic and Microbial Infections	1
BT-510	Biotechnology in Pharmaceutical Sciences	1
GE-510	Biostatistics	2
GE-511	Seminar	1
LG-510	General Laboratory Experience	3
	Total Credits	**15**
Semester II		
NP-610	Natural Product and Bio-organic Chemistry	2
NP-620	Natural Products – II	2
NP-630	Standardization of Natural Product Drugs/ Formulations	2
NP-640	Structure Elucidation	2
NP-650	Medicinal Plant Biotechnology and Cultivations Propagation	1
MC-650	Stereochemistry and Drug Action	2
PC-611	Pharmacological Screening and Assays	1
GE-611	Seminar	1
LS-610	General Lab Experience in the Area of Specialization	2
	Total Credits	**15**
Semester III Project (22 weeks)		
TH- 598	Synopsis	5
TH- 599	Presentation	3
	Total Credits	**8**
Semester IV		
TH-698	Thesis	9
TH-699	Defence of Thesis	3
	Total Credits	**12**
TOTAL CREDITS (I TO IV SEMESTERS)		**50**

NATURAL PRODUCTS - SEMESTER I

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 reversed phase, bonded phase chromatography, stationary phases, activity of stationary phases, elutropic series, and separation mechanisms.
3. **Column chromatography and 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 Pressure Liquid Chromatography (HPLC):** 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. **Planer 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. **Gas chromatography:** Introduction to GC-MS and LC-MS techniques and their application in natural products.

READING MATERIAL

1. Applied Thin Layer Chromatography, Second Edition
   Elke Hahn Deinstrop
   Wiley-VCH
2. HPLC Made to Measure: A Practical Handbook for Optimization
   Stavros Kromidas
   Wiley-VCH

3. Thin Layer Chromatography: A Modern Practical Approach Practical HPLC method development.

   Lloyd R. Snyder, Joseph J. Kirkland and Joseph L. Glajch
   John Wiley and Sons

4. Handbook on Ion Chromatography
   J. Weiss
   Wiley-Interscience

5. Counter Current Chromatography
   Jean-Michel Menet

NP-520

NATURAL PRODUCTS - 1 (2 CREDITS)

1. Approaches available for drug development, role of natural products in new drug development.
2. Plant-derived drugs, novel drug templates, chemical diversity, and structure-based drug design.
3. Bioactive compounds from microorganisms**:** Antibiotics, non-antibiotic drugs from fungal and other microbial sources, microbial phytotoxins.
4. Some typical structure elucidation insights for natural products by combination of classical, spectroscopic, synthetic and degradative methods depicting examples.
5. Natural products as a guide (leads) to the future design of new drugs with case histories (e.g. many toxins like venom proteins have opened up new area of synthetic protein drugs), statin drugs with anti-hyperlipidemic activity to be included.
6. Methods for extraction, isolation, molecular separation and purification of biomolecules from natural sources.
7. Bioassay-directed fractionation of natural products depicting examples.
8. Disease pattern where use of natural products is preferred, recent developments on adaptogens, immunomodulators, memory enhancers, anti-inflammatory agents, anti-parasitics along with screening methods for isolation guidance.
9. Genetically engineered natural products, naturally occurring proteins, biotechnology-derived products.
10. Elucidation of some biosynthetic pathways and impact of molecular biology to control these pathways and bypass the metabolism of the living cell.

READING MATERIAL

1. Laboratory Handbook for the Fractionation of Natural Extracts, Second Edition, 1998
   Houghton PJ, Amala Raman
   Chapman & Hall, London
2. Elements of Biotechnology, First Edition, 2000

P. K. Gupta
Rastogi Publications, Meerut

3. Biochemistry and Molecular Biology of Plants
Buchanan, Gruissem and Jones
I. K. International Pvt. Ltd., New Delhi

4. Genetic Engineering: Principles and Practice, 2007
Sandhya Mitra
Macmillan India Ltd., New Delhi

5. Biologically Active Natural Products: Pharmaceuticals
S. J. Cutler and H. G. Cutler

MC-510

BASIS 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 der Waals 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 and prodrugs.

8. **Nucleic acids**: 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 de-activation 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.

READING MATERIAL

1. The organic chemistry of drug design and drug action.
   Richard B. Silverman
   Academic Press
2. The Pharmacological Basis of Drug Action
   Goodman and Gilman
3. Advanced organic chemistry, Fourth Edition
   Jerry March
   Wiley-VCH

MC-511

SPECTRAL ANALYSIS (2CREDITS)

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-conjugated interactions, 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) ^{1}H 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 ^{19}F and ^{31}P, 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)^{13}C NMR, correlation of structure with spectra: Chemical environment, shielding and carbon-13 chemical shift, calculation, proton-coupled ^{13}C spectra, Proton-decoupled ^{13}C spectra, Nuclear Overhauser Enhancement (NOE), Problem with integration, Distortionless Enhancement by Polarisation Transfer (DEFT), Heteronuclear coupling for carbon to deuterium, carbon to ^{19}F, carbon to ^{31}P, Explanation of spectra of some compounds and drugs.

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

READING MATERIAL

1. Introduction to Spectroscopy: A Guide for Students of Organic Chemistry
   Donald L. Pavia, Gary M. Lamlman and George S. Kriz
   Thomson
2. Spectroscopy of Organic Compounds, Sixth Edition
   P S Kalsi
   New Age International United Publication
3. Instrumental Methods of Analysis, Seventh Edition
   Hobart H. Willard, Lynne L. Merrit, John A. Dean and Frank A. Settle
   CBS Publishers
4. Spectrometric Identification of Organic Compounds, Sixth Edition
   Robert M. Silverstein and Webster Fransis
   Wiley-VCH

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.

READING MATERIAL

1. Berger's Medicinal Chemistry and Drug Discovery, Vol. 5, Sixth Edition, 2007
   Wiley & Sons Inc
2. Hamson's Principles of Internal Medicine, Seventeenth Edition, 2007
   McGraw Hill
3. The Leishmaniases in Biology and Medicine, Vol. I & II
   Peters W and Killick-Kendrick R
   Academic Press, London
4. Lymphatic Filariasis
   T.B. Nutman
   ImperialCollege Press, London
5. Handbook of Drugs for Tropical Parasitic Infection, Second Edition, 1996
   Abdi Y.A., Gustafsson L.L., Ericsson Ö. and Hellgren U.
   Taylor& Francis, Basingstoke

BT- 510

BIOTECHNOLOGY IN PHARMACEUTICAL SCIENCES (1 CREDIT)

BT – 510 (Not offered to M.S. (Pharm.) Biotechnology)

Biotechnology in Pharmaceutical Sciences (1 Credit)

1. **Biotechnology in pharmaceutical 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 (e.g. BLAST), gene expression comparison methods (microarray). Comparative genomics and expression genomics for target discovery of communicable diseases 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 industry:** Major areas for biotechnology in the pharmaceutical industry such as antibiotics, vaccines, diagnostics, antibodies, biopharmaceuticals (insulin, interferon, GSF, CSF & 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.

READING MATERIAL

1. Molecular Biology of The Cell, Fourth Edition, 2002
   Bruce Alberts et.al.
   Taylor and Francis Group
2. Principles of Gene Manipulation, Sixth Edition, 2004
   S. B. Primrose et. al.
   Blackwell Science
3. Gene Cloning and DNA Analysis, Fourth Edition
   T. A. Brown
   Blackwell Science
4. Biotechnology - The Science and the Business, Second Edition, 1999
   Ed: D. G. Springham
   Harwood Academic Publisher
5. Pharmaceutical Biotechnology, Second Edition, 2002
   Ed: D. J. A. Cromelin and R. D. Sindelar
   Taylor and Francis Group
6. Basic Biotechnology, Second Edition, 2001
   Ed: C. Ratledge and B. Kristiansen
   CambridgeUniversity Press
7. Related review Articles

GE-510

BIOSTATISTICS (2 CREDITS)

1. **Statistics:** Introduction and its role and uses, Collection, Organization, Graphics and pictorial 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

READING MATERIAL

1. Mathematics and Biostatistics, Second Edition, 2007-2008
   G. K. Jani
   Atul Prakashan
2. Pharmaceutical Statistics: Practical and Clinical Applications, Fourth Edition, 2004
   SanfordBolton
3. Biometry, Third Edition, 1995
   Robert R. Sokal and F. James Rohlf
4. Introduction to the Practice of Statistics, Fifth Edition, 2004
   David S. Moore and George P. McCabe
5. Experimental Design in Biotechnology, 1989
   Perry D. Haaland
6. Probability Statistics and Queueing Theory, 2005
   P. Kandasamy, K. Thilagavathi and K. Gunavathi

GE-511

SEMINAR (1 CREDIT)

1. Introduction, Information retrieval systems.
2. Writing term papers and reports.
3. Organization of scientific material, thesis, dissertation and references.
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 units and functions, H/W and S/W, operating systems, word processing, spread sheet, graphic programs, dDbase, 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, acute toxicity, analgesis activity of a compound, estimation of protein and haematological parameters.

4. **Biotechnology for pharmaceutical sciences (20 hours)**

   Preparation for plasmid miniprep, Plasmid miniprep and restriction digestion, Gel electrophoresis and molecular weight calculation. Discussion of result and viva.

5. **Specialization (50 hours)**

   List of practical for separation techniques course (NP-510)

a) Extraction and isolation of curcumin from *Curcuma longa* rhizomes by CC and flash chromatography

b) Extraction and isolation of a triterpene compound from *Emblica officinalis* bark by flash chromatography

c) Extraction and isolation of piperine from *Piper longum* fruits by VLC.

d) Extraction and isolation of sterols from soya seeds.

   List of practical for Natural Product – I (NP-520)

e) Chracterizationof given glycoside (rutin) or saponin (glycyrrhizin) by identification of its hydrolytic products using TLC. (15 hours)

f) Isolation of eugenol from clove oil

g) Preparation of sequential extracts by soxlet apparatus and TLC finger printing (25 hours)

h) Extraction of b-Sitosterol and stigmasterol from soya seeds OR Extraction of lupeol from *Emblica officinalis* bark. This practical will include extraction, separation, identification and isolation of the desired component (20 hours).

i) Preparation of TLC.

j) Acetylation and oxidation reactions of pentacyclic triterpene (30 hours).

k) Extraction and oxidation reactions of pentacyclic triterpene (10 hours).

l) Extraction, identification and isolation of an alkaloid from given plant material. (25 hours)

NATURAL PRODUCT - SEMESTER II

NP-610

NATURAL PRODUCT AND BIO-ORGANIC CHEMISTRY (2 CREDITS)

1. **Importance of marine natural products chemistry in drug development**: Chemistry and biology of marine natural products, marine chemical ecology, marine biomedicinals and marine toxins from bacteria, microalgae, rhodophyta, chlorophyta, porifera, ascidians, corals, nudibranchs, biosynthesis of marine natural products.
2. Recent developments in natural product chemistry of plant and microbial sources.
3. **Carbohydrates:** Mono, di, oligo- and polysaccharides, separation and isolation, purification, structure determination, linkage stereochemistry, biological activity.
4. **Glycoproteins, lipoproteins and glycopeptidolipids**: Structure and biological activity, isolation, purification, degradation, structure determination
5. **Glycosides and saponins:** Classification, separation and isolation, linkage stereochemistry, structure determination, biological activity, study of examples.
6. **Alkaloids:** Classification, methods of isolation, stereochemistry, biological activity, general theory of biogenesis.
7. **Steroids and triterpenoids:** Classification, methods of isolation, stereochemistry, biological activity, general theory of biogenesis.
8. **Flavonoids:** Classification, isolation, stereochemistry, biological activity, biosynthesis.
9. **Coumarins and lignans:** Classification, isolation, stereochemistry, biological activity, biosynthesis.
10. **Lipids and autocoids:** Classification, identification, biological activity, study of examples.

READING MATERIAL

1. Pharmacognosy, Phytochemistry, Medicinal Plants, Second Edition, 1999
   Jean Bruneton
   Intercept Ltd. New York
2. Pharmacognosy, Fourth Edition, 2005
   C. K. Kokate
   Nirali Prakashan, Pune
3. Pharmacognosy, Fifteenth Edition, 2002
   Trease and Evans
   W. B. Saunders Edinburgh, UK
4. Bioactive Marine Natural Products
   D.S. Bhakuni and D.S. Rawat : Anamaya Publishers, New Delhi

5. Natural Product Isolation, Second Edition, In: Methods in Biotechnology, Vol 20, 2005
   Eds: Satyajit Sarker, Zahid Latif and Alexander Gray
   Humana Pres Inc., Totowa, NJ
6. Chemistry of Natural Products, First Edition, 2008
   S. V. Bhat, B. A. Nagasampagi and M. Sivakumar
   Narosa Publishing House, New Delhi

NP-620

NATURAL PRODUCTS - II (2 CREDITS)

1. **Chemotaxonom**y: Significance in classification of medicinal plants, distribution of chemotaxonomical groups of constituents in plants.
2. **Comparative phytochemistry**: Phytochemical classification of plants, relationship between phytochemistry and taxonomy, variations, novel and unpredicted compounds.
3. **Phytopharmaceuticals for the following therapeutic classes:** anticancer, (b) anti-diabetic, (c) anti-haemmorids, (d) anti-viral (e) bronchial asthma (f) cardiovascular, (g) hepatoprotective, (h) sedative / tranquilizer, (i) urinary stone (j) laxative etc.
4. Terrestrial and marine based bioactive leads, synthesis of some bio-active natural products and their analogues.
5. Plantibodies (immunoglobins) from plants.
6. Edible dyes, plant sweeteners, perfumery and cosmetic agents.
7. **Bioactivity:** Activity versus toxicity, rapid screening methods, correlation between enzyme inhibition and pharmacological activity, general screening of enzyme, inhibitors,
8. Radio ligand receptor binding assays (adrenoreceptors, opiate, benzodiazepine, ion channels, 5 HT, dopamine, adenosine, muscarinic, histamine, ATPase, GABA), cytotoxicity tests; Bioassay-guided fractionations
9. Dietary anti-oxidants in disease prevention.
10. **Dereplication for natural products**: Concept of dereplication, importance of dereplication, development of dereplication protocols with examples.

READING MATERIAL

1. Taxonomy of Angiosperms
   A.V. S. S. Sambamurt
   K. International Pvt. Ltd., New Delhi
2. Textbook of Industrial Pharmacognosy, First Edition, 2007
   A. N. Kalia
   C. B. S. Publisher, New Delhi

3. Advanced Plant Taxonomy
A. K. Mondal
New Central Book Agency (P) Ltd.

4. Bioactive Natural Products-Detection, Isolation and Structure Determination, First and Second Edition
R. J. Molyneux and S. M. Coligate

5. Handbook of Plant Biotechnology
Paul Chiristou and Harry Klee
Wiley and Sons Ltd.

6. Natural Products Isolation, First Edition, In: Methods in Biotechnology, Vol. 4, 1998
Ed. Cannell RJP
Humana Pres Inc., Totowa, NJ

7. Free Radicals in Biology and Medicine, Third Edition, 1996
Halliwell and Gutteridge
OxfordUniversity Press, London

8. Goodman and Gilmans Pharmacological Basis of Therapeutics, Nineteenth Edition, 1995
Hardman, J.G
McGraw Hill

9. Drug Discoveryand Evaluation: Pharmacological Assays, Second Edition, 2002
H. Gerhard Vogel
Springer-Verlag Berlin Heidelberg

10. Medicinal Chemistry of Bioactive Natural Products
X-T Liang and W-S Fang
Wiley Interscience

NP-630

STANDARDIZATION OF NATURAL PRODUCT DRUGS/ FORMULATIONS (2 CREDITS)

1. **Standardization requirements of herbal medicines:** Traditional and folk-loric remedies / preparations and their quality, safety and efficacy assessment and intended use for acceptance by FDA.
2. **Factors affecting quality of plant drugs**: Safe and economical methods for documentation and preservation of herbs and herbal products detection of common adulterants, microbial contamination, toxic trace metals, pesticides and insect infestation in whole and powdered drugs.
3. **General methods of estimation**: analysis for alkaloids, steroids, terpenoids and flavonoids.
4. **Quantitative assays for extraction efficiency:** Active component analysis of carbohydrates, peptides and proteins, glycosides and lipids. Purity determination

using UV, GLC, HPLC and electrophoretic methods. Quality control of various types of official formulations including Ayurvedic preparations.

5. HPTLC & HPLC fingerprint identification of crude drugs/raw material or congeners or their single or multi-component preparations, recognition and evaluation of fingerprints.
6. Combinatorial library for constituents obtained from natural resources, extracts used for developing new drugs.
7. Potency assays for adaptogens and memory enhancers, single and multi-component formulations, pharmacological tests, cell line - derived assays, in-vitro biochemical tests (corticoids estimation).
8. **Stability testing of natural products:** Procedures, predictable chemical and galenical changes, technical limitations, testing methods and combination products.
9. Bioavailability and pharmacokinetics aspects for herbal drugs with examples of well known documented clinically used herbal drugs. Phytoequivalence, pharmaceutical equivalence.
10. Importance of monographs of standards of medicinal plants and their parts, comparative study of BHP, API, Chinese, Japanese Herbal Pharmacopoeia, European pharmacopoeia, US formulary, WHO, EMEA and ESCOP guidelines for herbal medicinal products. Preparation of Drug Master File (DMF) for herbal medicines.

READING MATERIAL

1. Quality Control Herbal Drugs – An Approach to Evaluation of Botanicals, First Edition 2002
   Pulok K. Mukherjee
   Business Horizons, New Delhi
2. Laboratory Handbook for the Fractionation of Natural Extracts, First Edition, 1998
   Houghton PJ and Amala Raman
   Chapman & Hall, London
3. Combinatorial Synthesis of Natural Product-Based Libraries, First Edition, 2006
   Armen M. Boldi
   CRC Press, Taylor & Francis Group
4. Phytochemical Methods: Guide to Modern Techniques of Plant Analysis, Second Edition, 1984, J. B. Harbone
   Chapman & Hall, London

NP-640

STRUCTURE OF 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 elucidations.

3. **Chemical methods**: general methods of structure elucidation of steroids, terpenoids, alkaloids with few examples.
4. **Ultraviolet spectroscopy**: basic principles, tools to calculate max, applications in structure elucidation with examples.
5. **Infrared spectroscopy**: basic principles, various factors affecting frequency, functional group identification, applications in structure elucidation with examples.
6. **Mass spectroscopy:** basic principles, various ionization modes, EI, CI, FAB, etc. fragmentation patterns, HRMS, applications in structure elucidation with examples.
7. **H^1 NMR and C^{13} NMR spectroscopy:** basic principles, chemical shift, factors affecting chemical shift, predictions of chemical shift, coupling constant, curve plus curve, advanced 1D NMR experiments such as NOE, DEPT.
8. **2D NMR:** 1H-1H COSY, HSQC, HMBC, NOESY experiments, their use in structure elucidation.
9. **Structure elucidation:** examples from Alkaloids, Flavonoids, sterols.
10. Structure elucidation- examples Coumarins, Triterpenes, Xanthones.

READING MATERIAL

1. Spectrometric Identification of Organic compounds, Seventeenth Edition 2005
   Silverstein Robert M, Francis X. Webster and David J. Kiemle
   John Wiley & Sons Inc
2. Stereochemistry, Conformation and Mechanism, Seventeenth Edition, 2008
   P. S. Kalsi
   New Age Publishers, New Delhi
3. Thin Layer Chromatography: A Modern Practical Approach
   Peter E. Wall
   The Royal Society of Chemistry
4. Organic Chemistry, Vol I: The Fundamental Principles, Sixth Edition, 2006
   I. L. Finar
   Darling Kindersley (India) Pvt. Ltd.

NP-650

MEDICINAL PLANT BIOTECHNOLOGY AND CULTIVATIONS (1 CREDIT)

1. **Medicinal plant Based industry:** export and import of plants, threatened/endangered medicinal plants.
2. **Plant drug collection and cultivation with plant growth regulators**: transgenic plants, and approaches for production of transgenic plants.
3. **Plant genome and genomic organization**: gene families, genetic regulations in transcription and translation in plants.

4. **Mutations and mutagenesis:** transposable elements, genetic manipulations and plant genetic engineering
5. Cultivation technology for commercial production of some selected medicinal and aromatic plants.
6. **Tissue culture techniques:** micropropagation of medicinal and aromatic plants, secondary metabolism in tissue culture, germplasm storage, methods of cell immobilization.
7. Biotechnology of propagation and production of antibiotic and non-antibiotic drugs from lower plants.
8. **Use of herbicides:** weedicides and insecticides, microbial phytotoxins as herbicides.
9. Indian soils, soil analysis and soil fertilizers.
10. Ecology, biodiversity, plant, variety from one area vs another area, genotypes.

READING MATERIAL

1. Text book of Industrial Pharmacognosy, First Edition, 2007
   A. N. Kalia
   C. B. S. Publisher, New Delhi
2. Principles of Gene Manipulation, Sixth Edition, 2004
   S. B. Primrose, R. M. Twyman and R. W. Old
   Blackwell Science
3. Genes IX, Nineteenth Edition, 2008
   Benjamin Lewin: Jones & Bartlett, Inc. U.S.A.
4. Commercial Cultivation of Medicinal and Aromatic Plants
   Dhananjay J. Deshpande
   Himalaya Publishing House
5. Elements of Biotechnology, First Edition, 2000
   P. K. Gupta
   Rastogi Publications, Meerut
6. Genetic Engineering: Principles and Practice
   Sandhya Mitra
   Macmillan India Ltd., New Delhi

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 co-ordinates, 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, gauch effect, generalized anomeric effect.

5. **Assignment of configuration**: Various projectional formulae, molecule with chiral centre, 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; Enantio-selectivity in drug absorption, metabolism, distribution and elimination.

READING MATERIAL

1. Stereochemistry, Conformation and Mechanism, Seventh Edition, 2008
   P. S. Kalsi
   New Age Publishers, New Delhi
2. Stereochemistry of Organic Compounds: Principles and Applications, 2nd edition, 2008
   D. Nasipuri
   New Age Publishers, New Delhi
3. Stereochemistry of Carbon Compounds
   Ernest L. Eliel: McGraw-Hill Book Company Inc., New York
4. Advanced Organic: Chemistry Reactions, Mechanisms and Structure, Fourth Edition
   Jerry March: Wiley, India

PC-611

PHARMACOLOGICAL SCREENING AND ASSAYS (1 CREDIT)

7. General principles of screening, correlations between various animal models and human situations, animal ethics

8. Pharmacological screening models for therapeutic areas such as Hypertension, Cerebral Ischaemia, Pain, Epilepsy, Depression, Parkinson's disease, Alzheimer's disease, Diabetes, Leishmaniasis etc.

9. 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

READING MATERIAL

1. Drug discovery and evaluation pharmacological assays
   Hans Gerhard Vogel
   Springer.
2. CPCSEA Guidelines

GE-611

SEMINAR (1 CREDIT)

Students are required to submit written record and present details of the project to be pursued in semester-III and 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 LAB EXPERIENCE - 10 HOURS / WEEK (2 CREDITS)

1. Structure elucidation using spectroscopic techniques (UV, IR & NMR) and shift reagents.
2. Analytical methods for identification of sterols and triterpenses and rearrangement studies of sterols.
3. Separation of polar compounds using ion exchange and gel filtration chromatography.
4. Preparation of 16-DPA from Solasidine
5. Synthesis of coumarin
6. Synthesis of chalcones and their conversion to flavones.

PHARMACEUTICS

M. S. (Pharm.)

Course no.	Course Name	Credits
Semester I		
PE-510	Dosage Form Design Parameters	1
PE-520	Biopharmaceutics and Pharmacokinetics	2
MC-510	Basis of Drug Action	2
MC-511	Spectral Analysis	2
NP-510	Separation Techniques	1
BT-510	Biotechnology in Pharmaceutical Sciences	1
GE-510	Biostatistics	2
GE-520	Fundamentals of Intellectual Property (IP) and Technology Management	1
GE-511	Seminar	1
LG-510	General Laboratory Experience	3
	Total Credits	**16**
Semester II		
PE-620	Drug Delivery Systems	2
PE-630	Pharmaceutical Product Development – I	2
PE-640	Pharmaceutical Product Development – II	2
PE-650	Biomaterials	2
PC-610	Drug Metabolism	1
PC-611	Pharmacological Screening and Assays	1
PE-660	Solid State Pharmaceutics	1
GE-611	Seminar	1
LS-610	General Lab Experience in the Area of Specialization	2
	Total Credits	**14**
Semester III Project (22 weeks)		
TH- 598	Synopsis	5
TH- 599	Presentation	3
	Total Credits	**8**
Semester IV		
TH-698	Thesis	9
TH-699	Defense of Thesis	3
	Total Credits	**12**
TOTAL CREDITS (I TO IV SEMESTERS)		**50**

PHARMACEUTICS – SEMESTER I

PE-510

DOSAGE FORM DESIGN PARAMETERS (1 CREDIT)

1. **Physicochemical aspects:**
   a) pKa, b) Partition Coefficient, c) Solubility, d) Reaction kinetics and mechanisms.
2. **Biological aspects:**
   a) Role of physicochemical parameters on drug absorption and their Implications.
   b) Routes of administrations and implication on bioavailability.
   c) Physicochemical aspects of drugs and first pass metabolism.
3. **Dissolution:**
   a) Theories of dissolution, release rates and constants.
   b) Mechanisms of conventional release and controlled release.
   c) Dissolution data handling and correction factors.
   d) Dissolution equipments.
   e) IVIVC

READING MATERIAL

1. Controlled Drug Delivery:Fundamentals and Application, Second Edition, Vol. 29 Marcel Dekker, Joseph R Robinson and Vincent H L Lee.
2. Modern Pharmaceutics, Fourth Edition
   Marcel Dekker,Gilbert S Banker and Christophex T Rhodes.
3. Novel Drug Delivery Systems, Second Edition
   Marcel Dekker and Yie W Chien
4. Controlled Drug Delivery: Concepts and Advances
   S. P. Vyas and Roop K. Khar
   Vallabh Prakashan

PE-520

BIOPHARMACEUTICS AND PHARMACOKINETICS (2 CREDITS)

1. **Introduction:** Definitions, ADME, concentration time profile, plotting the data, different fluid compartments and blood flow rates compartment models, biological half life, elimination rate constant, biopharmaceutics and pharmacokinetics in drug research.
2. **GIT absorption of drugs:** Mechanism, physiochemical, biological and pharmaceutical factors affecting drug absorption through GIT. Techniques for the GIT absorption assessment.
3. **Drug disposition:** Total body clearance**,** renal clearance, mechanism of clearance, clearance ratio, factors affecting renal clearance, hepatic clearance, volumes of distribution and its significance.
4. **Protein and tissue binding:** factors effecting protein binding, kinetics of protein

binding, determination of rate constants and different plots (direct, scat chard and reciprocal), implication of protein binding on pharmacokinetic parameters.

5. **Bioavailability and bioequivalence:** Definitions, federal requirement, methods of determination of bioavailability using blood and urinary excretion data. Protocol design for bioavailability assessment. Methods for bioequivalence determination
6. **Pharmacokinetic characterization of drugs:** Pharmacokinetics of drugs following one/two compartment open model with first order elimination kinetics as applied to rapid I.V. injection, I.V. transfusion and oral administration. Determination of absorption rate constants using Wagner Nelson, Loo Reigelman methods. Flip-flop models, method of residual. Urinary excretion data and its application in pharmacokinetic characterization of drugs. Pharmacokinetics of multiple dosing.
7. **Dosage regimen**: Dosage regimen adjustment in patients with renal and hepatic diseases. Drug dosage in elderly, children and obese patients.
8. **Nonlinear pharmacokinetics**: Various causes of non-linearity, Michaelis- Menten kinetics, In-vivo estimation of K_m and V_{max}. Case Studies.
9. **Physiologic pharmacokinetics models:** Mean Residence time, Statistical moment theory, Application and limitations of physiologic pharmacokinetic models.
10. **Miscellaneous Topics:** Chronopharmacokinetics, drug toxicity and forensic pharmacokinetics, kinetics of maternal-fetal drug transfer, pharmacokinetics v/s pharmacological/clinical response, metabolic kinetics.

READING MATERIAL

1. Pharmaceutical Dissolution Testing
   Umesh V. Banakar andMarcel Dekker
2. Physicochemical Principles of Pharmacy, Fourth Edition
   Alexander T. Florence and David Attwood
   Pharmaceutical press
3. Biopharmaceutics and Pharmacokinetics
   Brahmankar and D. M. Jaiswal
   Vallabh Prakashan
4. Pharmaceutical Dissolution Testing
   Jennifer Dressman and Johannes Kramer
   Taylor and Francis

MC-510

BASIS 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 der Waals 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 and prodrugs.
8. **Nucleic acids**: 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 de-activation 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.

READING MATERIAL

1. The Organic Chemistry of Drug Design and Drug Action
   Richard B. Silverman
   Academic press
2. The Pharmacological Basis of Drug Action
   Goodman and Gilman
3. Advanced Organic Chemistry, Fourth Edition
   Jerry March
   Wiley-VCH

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-conjugated interactions, 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) ^{1}H 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 ^{19}F and ^{31}P, 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) ^{13}C NMR, correlation of structure with spectra: Chemical environment, shielding and carbon-13 chemical shift, calculation, proton-coupled ^{13}C spectra, Proton-decoupled ^{13}C spectra, Nuclear Overhauser Enhancement (NOE), Problem with integration, Distortionless Enhancement by Polarisation Transfer (DEFT), Heteronuclear coupling for carbon to deuterium, carbon to ^{19}F, carbon to ^{31}P, 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.

READING MATERIAL

1. Introduction to Spectroscopy: A Guide for Students of Organic Chemistry
   Donald L. Pavia, Gary M. Lamlman and George S. Kriz
   Thomson
2. Spectroscopy of Organic Compounds, Sixth Edition
   P S Kalsi
   New Age International United Publication
3. Instrumental Methods of Analysis, Seventh Edition
   Hobart H. Willard, Lynne L. Merrit, John A. Dean and Frank A. Settle
   CBS Publishers
4. Spectrometric identification of organic compounds,6^{th} edition,
   Robert M. Silverstein ans Webster Fransis
   Wiley-VCH

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 reversed phase, bonded phase chromatography, stationary phases, activity of stationary phases, elutropic series, and separation mechanisms.
3. **Column chromatography and 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 Pressure Liquid Chromatography (HPLC):** 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. **Planer 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. **Gas chromatography:** Introduction to GC-MS and LC-MS techniques and their application in natural products.

READING MATERIAL

1. Applied Thin Layer Chromatography, Second Edition
   Elke Hahn Deinstrop
   Wiley-VCH
2. HPLC Made to Measure: A Practical Handbook for Optimization
   Stavros Kromidas Wiley-VCH
3. Thin Layer Chromatography: A Modern Practical Approach
   Practical HPLC Method Development
   Lloyd R. Snyder,Joseph J. Kirkland and Joseph L. Glajch
   John Wiley and Sons

BT- 510

BIOTECHNOLOGY IN PHARMACEUTICAL SCIENCES (1 CREDIT)

BT – 510 (Not offered to M.S.(Pharm.) Biotechnology)

Biotechnology in Pharmaceutical Sciences (1 Credit)

11. **Biotechnology in pharmaceutical 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
12. **Genomics in target discovery:** Concept of genome, genes and gene expression, genome sequencing and sequence comparison methods (e.g. BLAST), gene expression comparison methods (microarray). Comparative genomics and expression genomics for target discovery of communicable diseases and lifestyle disease.
13. **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.
14. **Protein expression systems:** Gene expression in bacteria, yeast, insect and mammalian cells.
15. **Enzyme purification and assay:** Various protein purification methods, enzyme based assay for small molecule screening.

16. **Bioprocess technology:** Upstream process: Introduction to microbial growth, media formulation, sterilization, inoculum preparation.
17. **Bioprocess technology:** Fermentation: Fermentation process design, operation and characteristics of fermentation processes; batch, fed-batch and continuous culture systems, instrumentation and bioprocess control.
18. **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.
19. **Biotechnology in pharmaceutical industry:** Major areas for biotechnology in the pharmaceutical industry such as antibiotics, vaccines, diagnostics, antibodies, biopharmaceuticals (insulin, interferon, GSF, CSF & therapeutic proteins etc.); Commercial aspects, priorities for future biotechnological research.
20. **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.

READING MATERIAL

1. Molecular Biology of the Cell, Fourth Edition, 2002
   Bruce Alberts et.al.
   Taylor and Francis Group
2. Principles of Gene Manipulation, Sixth Edition, 2004
   S. B. Primrose *et. al.*
   Blackwell Science
3. Gene Cloning and DNA Analysis, Fourth Edition
   T. A. Brown
   Blackwell Science
4. Biotechnology - The Science and the Business, Second Edition, 1999
   Ed: D. G. Springham
   Harwood Academic Publisher
5. Pharmaceutical Biotechnology, Second Edition, 2002
   Ed. D. J. A. Cromelin and R. D. Sindelar
   Taylor and Francis group.
6. Basic Biotechnology, Second Edition, 2001
   Ed: C. Ratledge and B. Kristiansen
   Cambridge University Press.
7. Related Review Articles

GE-510

BIOSTATISTICS (2 CREDITS)

1. **Statistics:** Introduction and its role and uses, Collection, Organization, Graphics and pictorial 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

READING MATERIAL

6. Mathematics and Biostatistcs, Second Edition, 2007-2008
   G. K. Jani
   Atul Prakashan
7. Pharmaceutical Statistics: Practical and Clinical Applications, Fourth Edition, 2004.
   SanfordBolton
8. Biometry, Third Edition, 1995
   Robert R. Sokal and F. James Rohlf
9. Introduction to the Practice of Statistics, Fifth Edition, 2004
   David S. Moore and George P. McCabe
10. Experimental Design in Biotechnology, 1989
    Perry D. Haaland

GE-520

FUNDAMENTALS OF INTELLECTUAL PROPERTY (IP) AND TECHNOLOGY MANAGEMENT (1CREDIT)

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; Penalties 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 Organization), WIPO (World Intellectual Property Organization) GATT (General Agreement on Tariff and Trade), TRIPs (Trade Related Intellectual Property Rights), TRIMs (Trade Related Investment Measures) and GATS (General Agreement on Trade in Services); Protection of plant and animal genetic 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-disclosure 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-provision 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 attorneys technical aspects, criteria trisection, addresses, fee, rights and responsibilities of a patentee; Practical aspects regarding maintaining of a ATENT FILE. Patent infringement- meaning, scope, litigation, case studies and examples; Patenting by research students, lecturers and scientists -University / organizational rules India and abroad; Thesis research paper publication, credit sharing by workers, financial incentives; Useful information sources for patents related information internet sites, broucher, periodicals, CD roms; Significance of copyright protection for researchers; Indian Copyright Laws and digital technologies-Beme convention, WIPO copyright treaty(WCT), WIPO performance and phonogram treaty PPT); Protection for computer data bases, multimedia works; Trademarks 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 infringements.

4. **Technology development / transfer/commercialization related aspects: Technology development-meaning; Drug related technology development; Toxicological studies, bioequivale**nce (BU), clinical trials phase-I, phase-II and phase-III; Approved bodies and agencies; Scale-up, semi-commercialization and

commercialization-practical aspects and problems; Significance of transfer of technology (TOT), bottlenecks; Managing technology transfer-guidelines for research students, scientists and related personal; TOT agencies in India-APCTD, NRDC,TIFAC, BCIL, TBSE/SIDBI; TOT related documentation-confidentiality agreements, licensing, MOUs, legal issues; Compulsory licensing excess to medicine issues; DOHA declaration, POST WTO product patent regime from 2005; Challenges for Indian pharmaceutical industry | in the context of globalization 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, and NIPER. Documentation and related aspects.
6. **Ethics and values in IP:** IP and ethics-positive and negative aspects of IPP; if Societal responsibility; Avoiding unethical practices; Echo responsibility-economic, social and environmental benefits of modern biotechnology; Voluntary adoption of pollution control strategies.

READING MATERIAL

1. Intellectual Property Rights in the WTO and Developing Countries
   Jayshree Watal
   OxfordUniversity Press

2. Intellectual Property Rights: Unleashing the Knowledge Economy
   Prabuddha Ganguly: Tata McGraw Hill
3. Intellectual Property, Fifth Edition
   David Bainbrige
   Pearson Education

GE-511

SEMINAR (1 CREDIT)

1. Introduction, Information retrieval systems.
2. Writing term papers and reports.
3. Organization of scientific material, thesis, dissertation and references.
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 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, acute toxicity testing of drugs, analgesic activity of a compound, estimation of protein and hematological parameters.
4. **Biotechnology for pharmaceutical sciences (20 hours)**

   Preparation for plasmid miniprep, Plasmid miniprep and restriction digestion, Gel electrophoresis and molecular weight calculation. Discussion of result and viva.
5. **Specialization (50 hours):**
   a) To prepare granules by dry granulation using roller compactor.
   b) To optimize wet granulation process and perform scale up using rapid mixer Granulator (RMG).
   c) Study the dissolution behavior/drug release pattern of various conventional, sustained release, enteric coated and nanoparticulate dosage form and establishment of dissolution kinetics. Study of various factors affecting dissolution/ drug release.
   d) Study of drug protein binding and effect of competitive agent on binding kinetics.
   e) Plotting and Interpretation of pharmacokinetics data and calculation of various pharmacokinetic parameter.

PHARMACEUTICS - SEMESTER II

PE-620

DRUG DELIVERY SYSTEMS (2 CREDITS)

1. **Influence of drug properties and routes of drug administration on the design of sustained and controlled release systems:** Rationale for controlled drug delivery, physicochemical properties and biological factors influencing the design and performance of sustained/controlled release products.
2. **Biopharmaceutic and pharmacokinetic aspects of PO CRDDS**. Strategies and design, factor affecting controlled release drug delivery systems, computation of desired release rate and dose for CRDDS. Pharmacokinetic design for DDS; in-vitro/in-vivo considerations. Intermittent zero order and first order release.
3. **Peroral controlled-release delivery*:*** Design and fabrication of oral systems, dissolution controlled release, diffusion controlled release, diffusion and dissolution controlled release, ion exchange resins, PH-independent formulations, osmotically controlled release, altered density formulations, case studies.
4. **Parenteral drug delivery**: Major routes of parenteral administration; Selection, design and development, biopharmaceutics of sustained /controlled release parenteral products, polymer microspheres, and dispersed DDS.
5. **Transdermal/skin drug delivery systems:** Principles of skin permeation, factors affecting percutaneous absorption drugs, sorption promoters, absorption enhancement by energy input – iontophoresis, sonophoresis and electroporation pharmacokinetics of skin permeation, development and evaluation of transdermal devices, case studies.
6. **Implantable Therapeutic systems:** Introduction, historical development, approaches to development of implantable therapeutic systems, benefits of controlled drug administration via implantation, medical aspects of implantation.
7. **Drug targeting:** Different levels of drug targeting-first order, second order and third order targeting, active and passive targeting, EPR effect, receptor mediated endocytosis, prodrug based drug targeting, brain targeting, tumor targeting.
8. **Overview of different carrier systems for drug delivery:** Microparticles, liposomes, niosomes, polymeric nanoparticles, solid lipid nanoparticles, carbon nanotubes etc.
9. **Protein/peptide drug delivery systems**, enzyme, epithelial/endothelial barriers, pharmacokinetics, different routes of delivery, practical considerations.
10. **Regulatory assessment of controlled release products:** Potential pharmacodynamics and bioavailability problems of oral controlled release products, dissolution rate assessment, biopharmaceutic consideration in the regulatory assessment.

READING MATERIAL

1. Controlled Drug Delivery: Fundamentals and Application, Second Edition, Vol. 29, 1987
   Joseph R. Robinson and Vincent H. L. Lee
   Marcel Dekker
2. Modern Pharmaceutics, Fourth Edition, 2008
   Gilbert S. Banker and Christophex T. Rhodes
   Marcel Dekker
3. Novel Drug Delivery Systems, Second Edition, 1992
   Yie W Chien: Marcel Dekker
4. Controlled Drug Delivery: Concepts and Advances, 2008
   S. P. Vyas and Roop K. Khar
   Vallabh Prakashan-

PE-630

PHARMACEUTICAL PRODUCT DEVELOPMENT-I (2 CREDITS)

1. **Preformulation studies:** Preformulation studies of drug substances, proteins and peptides. Fundamental and derived properties in preformulation profiling, preformulation worksheet.
2. **Role of pre-formulation in drug discovery:** Material properties in lead selection, high throughput preformulation studies, 'drugability' of new chemical entities, tools to assist in lead selection.
3. **Role of preformulation in drug development:** Preformulation as a support for formulation development, identification of challenges during formulation development, dosage form specific studies.
4. **Complexation:** Metal and organic molecular complexes, inclusion compounds with reference to cyclodextrins, chemical characteristics of inclusion complexes, applications in sloubilization/taste masking/enhancement of permeability/enhancement of oral bioavailability, methods of preparation of cyclodextrin complexes.
5. **Solubilization:** Solubility and solubilization of nonelectrolyte, drug solubilization in surfactant systems, use of co solvents, solid-state manipulations and drug derivitization.
6. **Rheology:** Thixotropy, methods for evaluation of viscosity, implications of viscosity on performance of liquid dosage forms like suspensions and emulsions.
7. **Micromeritics:** Particle size distribution, evaluation methods including advanced techniques like atomic force microscopy, significance of particle size in different dosage forms including aerosols, parenterals and solid dosage forms.
8. Development of dosage forms, four stage development, biological basis and opportunities, dosage form and its implications; Manipulation of physiological processes.

9. Case studies will be discussed after each topic with current literature, case study dealing with use of preformulation data for lead selection and dosage form decision.

READING MATERIAL

1. Physicochemical Principles of Pharmacy, 2006
   Alexander T. Florence and David Attwood
   Pharmaceutical Press
2. Martin's Physical Pharmacy and Pharmaceutical Science, 2006
   Pratrick J. Sinko
   B.I. Publication Pvt. Ltd.
3. Pharmaceutics: The Science of Dosage Form Design, Second Edition, 2006
   M. E. Aulton
   Chrchill livingstone
4. Pharmaceutical Preformulation: The Physicochemical Properties of Drug Substances
   James I. Wells
   Ellis Horwood Limited

PE-640

PHARMACEUTICAL PRODUCT DEVELOPMENT-II (2 CREDITS)

1. **Formulation additives:** Study of different types of additives e.g. antioxidants and preservatives, coloring and flavoring agents, emulsifying and suspending agents, basic materials for ointment bases, diluents and pharmaceutical solvents, regulatory perspectives: GRAS, IIG; new developments in excipient science, functional and co-processed excipients, international patented excipients. Implication of quantitative selection of each excipient in product development.
2. **Drug-excipient interaction:** Drug-excipient interaction and incompatibilities, physical, chemical, pharmaceutical and therapeutic, analytical techniques to characterize drug excipient incompatibility.
3. **Solid dosage forms:** Tablets, benefits, improved tablet production, advances in materials, material handling and granulation;process automation. Processing problems in tablet and troubleshooting. Specialized tablets: formulation and evaluation of effervescent, orodispersible and chewable tablets.
4. **Tablet Coating:** Coating pans, sugar coating, film coating, advanced coating technologies, aqueous based film coating, solvent free coating, coating defects.
5. **Liquids and poly-disperse systems:** Suspensions: theoretical considerations, flocculated and deflocculated suspensions, adjuvants utilized, evaluation of suspension stability. Emulsions: descriptive theory of emulsification, formulation aspects, stability evaluation, advances in emulsion technology-multiple, micro and nano emulsions.
6. **Sterile products and admixtures:** Formulation development, vehicles and other additives, containers and closures, evaluation of stability and sterility, requirements of facilities for production, recent advances and developments.

7. **Aerosols:** Components of aerosol package, containers, nebulizers, pressured metered dose inhalers, dry powder inhalers, formulation aspects, types of propellants used, stability testing of pharmaceutical aerosols, Quality control and testing evaluation of pharmaceutical aerosols.
8. **Package development:** Package types for different dosage forms, packaging materials like glass and plastic, selection of proper material, labelling, preformulation screening of package components, regulatory perspectives.
9. **Design of materials and product specifications:** Factory design, laying down and optimization of material and product specifications, process and in-process controls.
10. **Documentation:** Protocols, forms and maintenance of records in product development department including clinical batches.

READING MATERIAL

1. Pharmaceutical Dosage Forms: Tablets, Vol. 1-3, 2008
   Herbert A. Lieberman,Leon Lachman andJoseph B.Schwartz
   Marcel Dekker
2. Pharmaceutical Dosage Forms: Disperse System, Vol. 1-3, 1996
   Herbert A. Lieberman, Gilbert S. Banker and Martin M. Rieger
   Marcel Dekker
3. Pharmaceutical dosage forms:Parenteral medication,Vol. 1-3, 2005
   Herbert A. Lieberman,Leon Lachman andKenneth E. Avis
   Marcel Dekker
4. The Theory and Practice of Industrial Pharmacy, 1991
   Herbert A. Lieberman,Leon Lachman andJoseph L. Kanig
   Varghese Publication House
5. Pharmaceutics: The Science of Dosage Form Design, Second Edition, 2006
   M.E.Aulton, Chrchill Livingstone

PE-650

BIOMATERIALS (2 CREDITS)

1. **Introduction to biomaterials:** Fundamentals of polymer science and polymer classification.
2. **Synthesis and modification methods of biomaterials:** Polymerization methods, polymer fabrication.
3. **Physical and chemical characterization techniques:** Thermal, spectroscopic, microscopic and laser based techniques.
4. **Manipulating biomaterials in various forms depending upon end use specification:** Hydrogels, micro and nano particles, films, fibres.
5. **Host reaction to biomaterials and their evaluation:** Inflammation, wound healing, foreign body response, systematic toxicity

6. **Biocompatibility testing of biomaterials:** In vitro assessment of tissue compatibility, invivo assessment of tissue compatibility, testing blood materials interactions.
7. **Degradation of biomaterials in biological environment**: Chemical and biochemical degradation of polymers; Degradative effects of biological environment.
8. **Use of polymers in controlled release of active agents:** Diffusion controlled devices, Solvent-controlled devices and chemically controlled devices.
9. **Regulatory considerations:** Assessment of safety and long term toxicity evaluation, toxicity considerations on repetitive accumulation of polymeric materials.
10. **Pharmaceutical and biomedical applications:** Drug delivery, tissue engineering.

READING MATERIAL

1. Biomaterials Science: An Introduction to Materials in Medicine, 1996
   Buddy D. Ratner and Allan S. Hoffman
   Academic Press

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, idiosyncrasy.
10. Acute poisoning and its treatment

READING MATERIAL

1. Biopharmaceutics and Pharmacokinetics – A Treatise, 1995
   D. M. Brahmankar and Sunil B. Jaiswal
   Vallabh Prakashan
2. Drug Interactions, 1989
   Philip D. Hansten
   Lea and Febiger, Philadelphia

PC-611

PHARMACOLOGICAL SCREENING AND ASSAYS (1 CREDIT)

10. General principles of screening, correlations between various animal models and human situations, animal ethics
11. Pharmacological screening models for therapeutic areas such as Hypertension, Cerebral Ischaemia, Pain, Epilepsy, Depression, Parkinson's disease, Alzheimer's disease, Diabetes, Leishmaniasis etc.
12. 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

READING MATERIAL

1. Drug discovery and evaluation pharmacological assays
   Hans Gerhard Vogel
   Springer.
2. CPCSEA Guidelines

PE-660

SOLID STATE PHARMACEUTICS (1 CREDIT)

1. **Levels of solid state properties:** Molecular/ Particle/ bulk level properties, interdependence of various levels on each other, role of different levels during pharmaceutical development and process development.
2. **Molecular level:** Crystalline form, definition, concept of long range order, supramolecular arrangements, building blocks of crystals, unit cell, basic types of unit cells, demonstration of unit cells using crystal visualization softwares.
3. **Polymorphism:** Definition, Significance of polymorphism in drug product performance, packaging/conformational polymorphism, thermodynamics of polymorphs, enatiotropy/ monotropy, concept of transition temperature, Burger and Ramberger rule.
4. **Crystallization process:** molecular aggregation events in crystallization, energetic of crystallization, enthalpy entropy balance, types of nucleation, Ostwald’s step rule.experimental protocols for polymorph screening.
5. **Implications of polymorphism in pharmaceutical development:** Regulatory concerns related to polymorphism, introduction to latest regulatory position on polymorphism.
6. **Amorphous state:** Definition, long range order versus short range order, disorder in the amorphous state, concept of glass transition temperature (Tg), thermodynamic necessity for Tg, entropy crisis.

7. **Role of amorphous state in drug delivery:** solubility advantage, spring parachute effect during solubility studies, physical instability of the amorphous form, techniques for the stabilization of amorphous form, amorphous solid dispersions.
8. **Particle level properties:** Crystal habit, generation of different crystal habits, implications of crystal habit on product performance and processing.
9. **Bulk level:** Bulk density, compressibility, flow properties, Cohesivity, electrostatics, aggregation, agglomeration, role in formulation development and processing.

READING MATERIAL

1. Martin's Physical Pharmacy and Pharmaceutical Sciences
   Patrick J. Sinko
   Lippincott Williams & Wilkins
2. Pharmaceutics: The Science of Dosage Form Design
   Michael E. Aulton
   Churchill Livingstone

GE-611

SEMINAR (1 CREDIT)

Students are required to submit written record and present details of the project to be pursued in semester-III and 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)

Preparation and evaluation of biomaterials for different DDS, development and evaluation of drug delivery systems, formulation development and evaluation.

PHARMACEUTICAL ANALYSIS
M. S. (Pharm.)

Course no.	Course Name	Credits
Semester I		
PA-510	Topics in Pharmaceutical Analysis	2
MC-511	Spectral Analysis	2
NP-510	Separation Techniques	1
PE-510	Dosage Form Design Parameters	1
BT-510	Biotechnology in Pharmaceutical Sciences	1
GE-510	Biostatistics	2
GE-520	Fundamentals of Intellectual Property (IP) and Technology Management	1
GE-511	Seminar	1
LG-510	General Laboratory Experience	3
	Total Credits	**14**
Semester II		
PA-610	Pharmacopoeia: Methods of Analysis	2
PA-620	Instrumental Techniques for Evaluation of APIs and Drug Products	2
PA-630	Stability Testing	1
PA-640	Quality Control and Quality Assurance	2
NP-640	Structure Elucidation	2
PC-611	Pharmacological Screening and Assays	1
PE-630	Pharmaceutical Product Development-I	2
PE-660	Solid State Pharmaceutics	1
GE-611	Seminar	1
LS-610	General Lab Experience in the Area of Specialization	2
	Total Credits	**16**
Semester III Project (22 weeks)		
TH- 598	Synopsis	5
TH- 599	Presentation	3
	Total Credits	**8**
Semester IV		
TH-698	Thesis	9
TH-699	Defense of Thesis	3
	Total Credits	**12**
TOTAL CREDITS (I TO IV SEMESTERS)		**50**

PHARMACEUTICAL ANALYSIS - SEMESTER I

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 specification:** 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 of 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 audits and inspections.

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-conjugated interactions, 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) ^{1}H 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 ^{19}F and ^{31}P, 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)^{13}C NMR, correlation of structure with spectra: Chemical environment, shielding and carbon-13 chemical shift, calculation, proton-coupled ^{13}C spectra, Proton-decoupled ^{13}C spectra, Nuclear Overhauser Enhancement (NOE), Problem with integration, Distortionless Enhancement by Polarisation Transfer (DEFT), Heteronuclear coupling for carbon to deuterium, carbon to ^{19}F, carbon to ^{31}P, Explanation of spectra of some compounds and drugs.

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

READING MATERIAL

1. Introduction to Spectroscopy: A Guide for Students of Organic Chemistry
   Donald L. Pavia,Gary M. Lamlman and George S. Kriz
   Thomson
5. Spectroscopy of Organic Compounds, Sixth Edition
   P. S. Kalsi
   New Age International United Publication
6. Instrumental Methods of Analysis, Seventh Edition
   Hobart H. Willard, Lynne L.Merrit, John A. Dean and Frank A. Settle
   CBS Publishers
4. Spectrometric Identification of Organic Compounds, Sixth Edition
   Robert M. Silverstein and Webster Fransis
   Wiley-VCH

NP-510

SEPARATION TECHNIQUES (1CREDIT)

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 reversed phase, bonded phase chromatography, stationary phases, activity of stationary phases, elutropic series, and separation mechanisms.
3. **Column chromatography and 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 Pressure Liquid Chromatography (HPLC):** 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. **Planer 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. **Gas chromatography:** Introduction to GC-MS and LC-MS techniques and their application in natural products.

READING MATERIAL

1. Applied Thin Layer Chromatography, Second Edition
   Elke Hahn Deinstrop
   Wiley-VCH
2. HPLC Made to Measure: A Practical Handbook for Optimization
   Stavros Kromidas
   Wiley-VCH
3. Thin Layer Chromatography: A Modern Practical Approach
   Practical HPLC Method Development.
   Lloyd R. Snyder, Joseph J. Kirkland and Joseph L. Glajch
   John Wiley and Sons
4. Handbook on Ion Chromatography
   J. Weiss
   WileyInterscience
5. Counter Current Chromatography
   Jean-Michel Menet

PE-510

DOSAGE FORM DESIGN PARAMETERS (1 CREDIT)

1. **Physicochemical aspects:**
   a. pKa
   b. Partition Coefficient
   c. Solubility
   d. Reaction kinetics and mechanisms.
2. **Biological aspects:**
   a. Role of physicochemical parameters on drug absorption and their Implications.
   b. Routes of administrations and implication on bioavailability.
   c. Physicochemical aspects of drugs and first pass metabolism.
3. **Dissolution:**
   a. Theories of dissolution, release rates and constants.
   b. Mechanisms of conventional release and controlled release.
   c. Dissolution data handling and correction factors.
   d. Dissolution equipments.
   e. IVIVC

READING MATERIAL

1. Controlled Drug Delivery: Fundamentals and Applications, Vol. 29
   J. R. Robinson, V. H. L. Lee and Marcel Dekker
2. Modern Pharmaceutics
   G S Banker, C T Rhodes and Marcel Dekker
3. Novel Drug Delivery Systems
   Y. W. Chien and Marcel Dekker
4. Controlled Drug Delivery: Concepts And Advances,
   S. P. Vyas and R. K. Khar
   Vallab Prakashan
5. Basic Pharmacokinetics
   Mohsen and Hadaya
   CRC
6. Pharmaceutical Dissolution Testing
   J. Dressman and J. Krama
   Taylor and Francis
7. Biopharmaceutics Application in Drug Development
   R. Krishna and L. Yu, Springer

BT- 510

BIOTECHNOLOGY IN PHARMACEUTICAL SCIENCES (1 CREDIT)

BT – 510 (Not offered to M.S. (Pharm.) Biotechnology)

Biotechnology in Pharmaceutical Sciences (1 Credit)

1. **Biotechnology in pharmaceutical 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 (e.g. BLAST), gene expression comparison methods (microarray). Comparative genomics and expression genomics for target discovery of communicable diseases 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 industry:** Major areas for biotechnology in the pharmaceutical industry such as antibiotics, vaccines, diagnostics, antibodies, biopharmaceuticals (insulin, interferon, GSF, CSF & 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.

READING MATERIAL

1. Molecular Biology of the Cell, Fourth Edition, 2002
   Bruce Alberts et.al.
   Taylor and Francis Group
2. Principles of Gene Manipulation, Sixth Edition, 2004
   S. B. Primrose *et.al.*
   Blackwell Science
3. Gene Cloning and DNA Analysis, Fourth Edition
   T. A. Brown, Blackwell Science
4. Biotechnology - The Science and the Business, Second Edition, 1999
   Ed: D. G. Springham
   Harwood Academic Publisher
5. Pharmaceutical Biotechnology, Second Edition, 2002
   Ed. D. J. A. Cromelin and R. D. Sindelar
   Taylor and Francis group.
6. Basic Biotechnology, Second Edition, 2001
   Ed: C. Ratledge and B. Kristiansen
   CambridgeUniversity Press.
7. Related Review Articles

GE-510

BIOSTATISTICS (2 CREDITS)

1. **Statistics:** Introduction, its role and uses. Collection; Organization; Graphics and pictorial 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-1 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.

READING MATERIAL

1. Mathematics and Biostatistcs, Second Edition, 2007-2008
   G. K. Jani, Atul Prakashan
2. Pharmaceutical Statistics: Practical and Clinical Applications, Fourth Edition, 2004.
   SanfordBolton
3. Biometry, Third Edition, 1995
   Robert R. Sokal and F. James Rohlf
4. Introduction to the Practice of Statistics, Fifth Edition, 2004
   David S. Moore and George P. McCabe
5. Experimental Design in Biotechnology, 1989
   Perry D. Haaland
6. Probability Statistics and Queuing Theory, 2005
   P. Kandasamy, K. Thilagavathi and K. Gunavathi

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) and GATS (General Agreement on Trade in Services); Protection of plant and animal genetic 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 attorneys technical aspects, criteria for selection, addresses, fee, rights and responsibilities of a patentee; Practical aspects regarding maintaining of a PATENT FILE; Patent infringement- 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; Trademarks 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 infringements.

4. Technology development / transfer / commercialisation related aspects: Technology development-meaning; Drug related technology development; Toxicological studies, bioequivalence (BU), clinical trials-phase-1, phase-11 and phase-Ill; 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 personnel; TOT agencies in India-APCTD, NRDC, TIFAC, BCIL, TBSE/SIDBI; TOT related documentation-confidentiality agreements, licensing, MOUs, legal issues; Compulsory 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 11T, 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 benefits of modern biotechnology; Voluntary adoption of pollution control strategies.

READING MATERIAL

1. Intellectual Property Rights in the WTO and Developing Countries
   Jayshree Watal
   Oxford University Press
2. Intellectual Property Rights: Unleashing the Knowledge Economy
   Prabuddha Ganguly
   Tata McGraw Hill
3. Intellectual Property, Fifth Edition
   David Bainbrige, Pearson Education

GE- 511

SEMINARS (1 CREDIT)

1. Introduction, information and retrieval systems
2. Writing term papers and reports
3. Organization of scientific material, thesis, dissertation and references
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 NT, computer languages with emphasis on 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, acute toxicity testing of drugs, analgesic activity of a compound, estimation of protein and haematological parameters.

4. **Biotechnology in pharmaceutical sciences (20 hours):**

   Preparation for plasmid miniprep, Plasmid miniprep and restriction digestion, Gel electrophoresis and molecular weight calculation. Discussion of result and viva.

5. **Specialization:**

   a. To calibrate thermometer
   b. To calibrate the common glassware (volumetric flask, burette and pipette) found in an analytical laboratory.
   c. Calibration of pH meter
   d. To determine water content in the given sample by Karl Fischer 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.
   h. Determination of pK_a of given sample by spectrophotometric method.

PHARMACEUTICAL ANALYSIS - SEMESTER II

PA-610

PHARMACOPOEIAL METHODS OF ANALYSIS (2 CREDITS)

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:** Anti-microbial 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:** Tests for epianhydrotetracycline and epitetracycline (USP).

READING MATERIAL

1. Indian Pharmacopoeia,Vol. I and II
   The Controller of Publications, Govt. of India, New Delhi
2. The International Pharmacopoeia, Vol. 1,2,3,4, Third Edition
   General Methods of Analysis and Quality Specification for Pharmaceutical Substances, Excipients and Dosage Forms
3. Pharmaceutical Analysis – Modern Methods, Part A and B
   James W. Munson

PA-620

MODERN INSTRUMENTAL TECHNIQUES FOREVALUATION 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, source of errors) and their influence, advantages and disadvantages, pharmaceutical applications.

   b. **DTA:** Principle, instrumentation, advantage and disadvantage, pharmaceutical applications, derivative differential thermal analysis (DDTA).

   c. **TGA:** Principle, instrumentation, factors affecting results, advantages and disadvantages, pharmaceutical applications.

3. **Particle sizing:** Laser diffraction equipment, photo correlation spectroscopy:
   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 principles (zeta potential), instrumentation, different modes of CE, advantages and disadvantages, pharmaceutical applications.

5. **Chromatographic techniques:**

   a. HPLC: principle, instrumentation and pharmaceutical applications.
   b. UPLC: principle and applications.
   c. LC-MS and LC-NMR: nature of interfaces and applications.

READING MATERIAL

1. Chromatographic Analysis of Pharmaceuticals
   John A. Adamovics
2. Practical HPLC Method Development
   Lloyd R. Snyder, Joseph J. Kirkland and Joseph I. Glajch
   John Wiley and Sons
3. Instrumental Methods of Analysis
   Hobert H. Willard
4. Text Book of Pharmaceutical Analysis
   K. A. Connors, Wiley Interscience, NewYork
5. Introduction to Thermal Analysis Techniques and Applications
   M. E. Brown
   Kluwer Academic Publishers

PA-630

STABILITY TESTING (1 CREDIT)

1. **Drug development cycle and stability-testing:** Role and types of stability studies during different stages of drug and product development.

2. **Stress testing of drug substances:** Role, regulatory aspects, protocols / approaches, practical considerations.
3. **Stability-indicating assays:** Definition, regulatory requirement, steps in development, practical considerationss.
4. **Role of kinetic 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 requency, specifications, storage conditions, recording of results, concept of stability commitment, etc.
6. **Retest period/shelf-life determination:** Evaluation of stability data.
7. **Photo stability testing:** 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 guidelines.
9. **Stability testing of phytopharmaceuticals:** Regulatory requirements, protocols, HPTLC / HPLC fingerprinting, 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.

READING MATERIAL

1. ICH Guideline for Impurity Determination and Stability Studies
2. Identification and Determination of Impurities in Drugs
   S. Gorog
   Elsevier
3. Analysis of Drug Impurities
   R. J. Smith and M. L. Webb
4. Handbook of Isolation and Characterization of Impurities in Pharmaceuticals
   S. Ahuja, K. M. Alsante and A. Press

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 testing and release, control of packaging materials and 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

READING MATERIAL

1. Quality Assurance Guide by Organisation of Pharmaceutical Products of India
2. Good Laboratory Practice Regulations, Vol. 69
   Sandy Weinberg
   Decker Series
3. Quality Assurance of Pharmaceuticals – A Compendium of Guidelines and Related Materials, Vol. I
   WHO Publications
4. A Guide to Total Quality Management
   Kaushik Maitra and Sedhan K.Ghosh.
5. How to Practice GMPs
   P. P. Sharma
6. Pharmaceutical Quality Assurance
   M A Potdar
   Nirali/ Pragati
7. Quality Assurance and Good Laboratory Practices
   Y Anjaneyulu
8. Quality Control and Applications
   B L Hanser
9. Quality Assurance in Analytical Chemistry
   Werner Funk

NP-640
STRUCTURE OF 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 elucidations.
3. **Chemical methods**: general methods of structure elucidation of steroids, terpenoids, alkaloids with few examples.
4. **Ultraviolet spectroscopy**: basic principles, tools to calculate max, applications in structure elucidation with examples.
5. **Infrared spectroscopy**: basic principles, various factors affecting frequency, functional group identification, applications in structure elucidation with examples.
6. **Mass spectroscopy:** basic principles, various ionization modes, EI, CI, FAB, etc. fragmentation patterns, HRMS, applications in structure elucidation with examples.
7. **H^1 NMR and C^{13} NMR spectroscopy:** basic principles, chemical shift, factors affecting chemical shift, predictions of chemical shift, coupling constant, curve plus curve, advanced 1D NMR experiments such as NOE, DEPT.
8. **2D NMR:** 1H-1H COSY, HSQC, HMBC, NOESY experiments, their use in structure elucidation.
9. **Structure elucidation:** examples from Alkaloids, Flavonoids, sterols.
10. Structure elucidation- examples Coumarins, Triterpenes, Xanthones.

READING MATERIAL

1. Spectrometric Identification of Organic compounds, Seventeenth Edition 2005
   Silverstein Robert M, Francis X. Webster and David J. Kiemle
   John Wiley & Sons Inc
2. Stereochemistry, Conformation and Mechanism, Seventeenth Edition, 2008
   P. S. Kalsi
   New Age Publishers, New Delhi
3. Thin Layer Chromatography: A Modern Practical Approach
   Peter E. Wall
   The Royal Society of Chemistry
4. Organic Chemistry, Vol I: The Fundamental Principles, Sixth Edition, 2006
   I. L. Finar
   Darling Kindersley (India) Pvt. Ltd.

PC-611

PHARMACOLOGICAL SCREENING AND ASSAYS (1 CREDIT)

13. General principles of screening, correlations between various animal models and human situations, animal ethics
14. Pharmacological screening models for therapeutic areas such as Hypertension, Cerebral Ischaemia, Pain, Epilepsy, Depression, Parkinson's disease, Alzheimer's disease, Diabetes, Leishmaniasis etc.
15. 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

READING MATERIAL

1. Drug discovery and evaluation pharmacological assays
   Hans Gerhard Vogel
   Springer.
2. CPCSEA Guidelines

PE-630

PHARMACEUTICAL PRODUCT DEVELOPMENT-I (2 CREDITS)

1. **Preformulation studies:** Preformulation studies of drug substances, proteins and peptides. Fundamental and derived properties in preformulation profiling, preformulation worksheet.
2. **Role of pre-formulation in drug discovery:** Material properties in lead selection, high throughput preformulation studies, 'drugability' of new chemical entities, tools to assist in lead selection.
3. **Role of preformulation in drug development:** Preformulation as a support for formulation development, identification of challenges during formulation development, dosage form specific studies.
4. **Complexation:** Metal and organic molecular complexes, inclusion compounds with reference to cyclodextrins, chemical characteristics of inclusion complexes, applications in sloubilization/taste masking/enhancement of permeability/enhancement of oral bioavailability, methods of preparation of cyclodextrin complexes.
5. **Solubilization:** Solubility and sloubilization of nonelectrolyte, drug sloubilization in surfactant systems, use of co solvents, solid-state manipulations and drug derivitization.
6. **Rehology:** Thixotropy, methods for evaluation of viscosity, implications of viscosity on performance of liquid dosage forms like suspensions and emulsions.

7. **Micromeritics:** Particle size distribution, evaluation methods including advanced techniques like atomic force microscopy, significance of particle size in different dosage forms including aerosols, parenterals and solid dosage forms.
8. Development of dosage forms, four stage development, biological basis and opportunities, dosage form and its implications; Manipulation of physiological processes.
9. Case studies will be discussed after each topic with current literature, case study dealing with use of preformulation data for lead selection and dosage form decision.

READING MATERIAL

1. Physicochemical Principles of Pharmacy, 2006
   Alexander T. Florence and David Attwood
   Pharmaceutical Press
2. Martin's Physical Pharmacy and Pharmaceutical Science, 2006
   Pratrick J. Sinko
   B. I. Publication Pvt. Ltd.
3. Pharmaceutics: The Science of Dosage Form Design, Second Edition, 2006
   M. E. Aulton
   Chrchill livingstone
4. Pharmaceutical Preformulation: The Physicochemical Properties of Drug Substances
   James I. Wells
   Ellis Horwood Limited

PE-660

SOLID STATE PHARMACEUTICS (1 CREDIT)

1. **Levels of solid state properties:** Molecular/ Particle/ bulk level properties, interdependence of various levels on each other, role of different levels during pharmaceutical development and process development.
2. **Molecular level:** Crystalline form, definition, concept of long range order, supramolecular arrangements, building blocks of crystals, unit cell, basic types of unit cells, demonstration of unit cells using crystal visualization softwares.
3. **Polymorphism:** Definition, Significance of polymorphism in drug product performance, packaging/conformational polymorphism, thermodynamics of polymorphs, enatiotropy/ monotropy, concept of transition temperature, Burger and Ramberger rule.
4. **Crystallization process:** molecular aggregation events in crystallization, energetic of crystallization, enthalpy entropy balance, types of nucleation, Ostwald's step rule.experimental protocols for polymorph screening.
5. **Implications of polymorphism in pharmaceutical development:** Regulatory concerns related to polymorphism, introduction to latest regulatory position on polymorphism.

6. **Amorphous state:** Definition, long range order versus short range order, disorder in the amorphous state, concept of glass transition temperature (Tg), thermodynamic necessity for Tg, entropy crisis.
7. **Role of amorphous state in drug delivery:** solubility advantage, spring parachute effect during solubility studies, physical instability of the amorphous form, techniques for the stabilization od amorphous form, amorphous solid dispersions.
8. **Particle level properties:** Crystal habit, generation of different crystal habits, implications of crystal habit on product performance and processing.
9. **Bulk level:** Bulk density, compressibility, flow properties, Cohesivity, electrostatics, aggregation, agglomeration, role in formulation development and processing.

READING MATERIAL

1. Martin's Physical Pharmacy and Pharmaceutical Sciences
   Patrick J. Sinko
   Lippincott Williams & Wilkins
2. Pharmaceutics: The Science of Dosage Form Design
   Michael E. Aulton
   Churchill Livingstone

GE-611

SEMINAR (I CREDIT)

Students are required to submit written record and present details of the project to be pursued in semester-Ill and 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)

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 establishment 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 analyzer.
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 AND TOXICOLOGY

M. S. (Pharm.)

Course no.	Course Name	Credits
Semester I		
PC-511	Pathophysiology	1
PC-520	General Pharmacology	2
PC-530	Experimental Pharmacology	1
PC-540	Chemotherapy of Parasitic and Microbial Infections	1
NP-510	Separation Techniques	1
PE-520	Biopharmaceutics and Pharmacokinetics	2
BT-510	Biotechnology in Pharmaceutical Sciences	1
GE-510	Biostatistics	2
GE-520	Fundamentals of Intellectual Property (IP) and Technology Management	1
GE-511	Seminar	1
LG-510	General Laboratory Experience	3
	Total Credits	**16**
Semester II		
PC-610	Drug Metabolism	1
PC-611	Pharmacological Screening and Assays	1
PC-620	CNS and Respiratory Pharmacology	2
PC-630	Autonomic, CVS, Blood, Renal and Gl Pharmacology	2
PC-640	Autocoid and Endocrine Pharmacology	1
PC-650	Clinical Pharmacology and Regulatory Toxicology	2
PC-660	Chemotherapy and Immunopharmacology	2
GE-611	Seminar	1
LS-610	General Lab Experience in the Area of Specialization	2
	Total Credits	**14**
Semester III Project (22 weeks)		
TH- 598	Synopsis	5
TH- 599	Presentation	3
	Total Credits	**8**
Semester IV		
TH-698	Thesis	9
TH-699	Defense of Thesis	3
	Total Credits	**12**
TOTAL CREDITS (I TO IV SEMESTERS)		**50**

PHARMACOLOGY AND TOXICOLOGY - SEMESTER I

PC-511

PATHOPHYSIOLOGY (1 CREDIT)

1. Factors influencing the disease conditions such as sex, age, nutritional status, genetic makeup etc.
2. Pathogenesis, symptoms and signs, laboratory findings and complications of respiratory, urinary tract, venereal and meningeal infections, congestive heart failure, hypertension, cardiac arrhythmias, ulcer, pancreatitis, hepatitis and cholecystitis, bronchial asthma, depression, schizophrenia, epilepsy, parkinsonism and alzheimer disease; hypo and hyper thyroidism, diabetes mellitus and other endocrine diseases; rheumatoid arthritis, gout and anemia.

READING MATERIAL

1. Essentials of Pathophysiology: Concepts of Altered Health States
   Author: Carol M. Porth, Glenn Matfin
   Publisher: Lippincott Williams & Wilkins
2. Handbook of Pathophysiology
   Author: Elizabeth J. Corwin
   Publisher: Lippincott Williams & Wilkins
3. Pathophysiology: The Biologic Basis for Disease in Adults and Children
   Author: Sue E, RN Huether, Kathryn L.,RN McCance, Valentina L. Brashers
   Publisher: Mosby Inc

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 subtypes, IUPHAR nomenclature, clinical significance of receptor subclassification, receptor characterization methods (pharmacological characterization, radioligand methods and monoclonal antibodies).
4. Receptor down regulation and upregulation.
5. Structure activity relationships, pharmacodynamic and pharmacokinetic aspects of chiral drugs, allosteric binding and 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.

READING MATERIAL

1. Essentials of Medical Pharmacology-Background for Drug Design
   Author: Andrejus Korolkovas
   Wiley-Interscience

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. ***In vitro*** **experimentation:** 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. ***In vivo*** **experimentation:** Advantages and disadvantages; anesthesia 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 behavioral experiments.
5. **Animal cell-culture techniques:** Aseptic handling, cell counting and cell viability assays.
6. **Protein and DNA gel electrophoresis:** Western, northern, southern blot hybridization and PCR techniques.
7. **Ultra, differential and analytical centrifugation**: Protein purification and identification by RF-HPLC, LCMS-MS, MALDI
8. **Radiochemical methods of analysis:** Principle of radiation and radioactivity, decay of radioactivity, units, isotopes detection, scintillation detector (crystal and liquid), quenching, radioimmunoassay.
9. **Drug solution preparations:** Storage, concentration expression, common solvents, stabilizing agents, storage conditions, reference standards, methods of procurement of reference standards
10. Data collection, data reduction, data representation, cumulative and noncumulative dose response curves, transformation of data logit, probit, pA scale, pD scale.

READING MATERIAL

1. Handbook of Experimental Pharmacology
   Editor-in-chief: Hofmann, Franz B. Series Editors: Ganten, D., Page, C. P., Rosenthal, W., Michel, M. C., Beavo, J. A., Busch, A., Karlsson, J. A.
   Publisher: Springer
2. Practical Pharmacology and Clinical Pharmacy
   Author: S K Kulkarni
   Publisher: Vallabh Prakashan
3. Current Protocols in Molecular Biology
   Author: Frederick M. Ausubel, Roger Brent, Robert E. Kingston, David D. Moore, J. G. Seidman, John A. Smith, Kevin Struhl
   Publisher: John Wiley & Sons, Inc.
4. Practical Biochemistry: Principles and Techniques, Fifth Edition - 2005
   A. K. Wilson and J. Walker
5. Experimental Biochemistry, Third Edition - 1999
   R. L. Switzer and L. F. Garrity, W. H. Freeman and Company.

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 antituberculosis drugs.
4. Targets for anti-tuberculosis drug development.
5. Mechanism of drug-resistance in tuberculosis.
6. Biology of human amoebiasis.
7. Mechanism of action 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 viral 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.

READING MATERIAL

1. Burger's Medicinal Chemistry and Drug, Six Edition- 2007
   Discovery, Vol. 5
   Wiley & Sons Inc
2. Hamson's Principles of internal medicine, Seventeenth Editation-2007
   McGraw Hill
3. The leishmaniasis in biology and medicine
   (Vol. I & II)
   Peters W, Killick-Kendrick R
   Academic Press, London
4. Lymphatic filariasis
   T. B. Nutman
   London: Imperial College Press
5. Handbook of drugs for tropical parasitic infection, Second Editation 1996
   Taylor& Francis, Basingstoke
   Abdi Y. A., Gustafsson L.L.,
   Ericsson Ö., HellgrenU.

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 reversed phase, bonded phase chromatography, stationary phases, activity of stationary phases, elutropic series, and separation mechanisms.
3. **Column chromatography and 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 Pressure Liquid Chromatography (HPLC):** 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. **Planer 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. **Gas chromatography:** Introduction to GC-MS and LC-MS techniques and their application in natural products.

READING MATERIAL

1. Applied thin layer chromatography, 2nd edition.
   Wiley-VCH.
   Elke Hahn Deinstrop.
2. HPLC made to measure: A practical Handbook for optimization
   Wiley-VCH.
   Stavros kromidas.
3. Thin layer chromatography: A modern practical approach
   Practical HPLC method development.
   John wiley and sons.

PE-520

BIOPHARMACEUTICS AND PHARMACOKINETICS (2 CREDITS)

1. **Introduction:** Definitions, ADME, concentration time profile, plotting the data, different fluid compartments and blood flow rates compartment models, biological half life, elimination rate constant, biopharmaceutics and pharmacokinetics in drug research.
2. **GIT absorption of drugs:** Mechanism, physiochemical, biological and pharmaceutical factors affecting drug absorption through GIT. Techniques for the GIT absorption assessment.
3. **Drug disposition:** Total body clearance**,** renal clearance, mechanism of clearance, clearance ratio, factors affecting renal clearance, hepatic clearance, volumes of distribution and its significance.

4. **Protein and tissue binding:** factors effecting protein binding, kinetics of protein binding, determination of rate constants and different plots (direct, scat chard and reciprocal), implication of protein binding on pharmacokinetic parameters.
5. **Bioavailability and bioequivalence:** Definitions, federal requirement, methods of determination of bioavailability using blood and urinary excretion data. Protocol design for bioavailability assessment. Methods for bioequivalence determination
6. **Pharmacokinetic characterization of drugs:** Pharmacokinetics of drugs following one/two compartment open model with first order elimination kinetics as applied to rapid I.V. injection, I.V. transfusion and oral administration. Determination of absorption rate constants using Wagner Nelson, Loo Reigelman methods. Flip-flop models, method of residual. Urinary excretion data and its application in pharmacokinetic characterization of drugs. Pharmacokinetics of multiple dosing.
7. **Dosage regimen**: Dosage regimen adjustment in patients with renal and hepatic diseases. Drug dosage in elderly, children and obese patients.
8. **Nonlinear pharmacokinetics**: Various causes of non-linearity, Michaelis- Menten kinetics, In-vivo estimation of Km and Vm. Case Studies.
9. **Physiologic pharmacokinetics models:** Mean Residence time, Statistical moment theory, Application and limitations of physiologic pharmacokinetic models.
10. **Miscellaneous Topics:** Chronopharmacokinetics, drug toxicity and forensic pharmacokinetics, kinetics of maternal-fetal drug transfer, pharmacokinetics v/s pharmacological/clinical response, metabolic kinetics.

READING MATERIAL

1. Umesh V Banakar
   Pharmaceutical dissolution testing
   Marcel Dekker
2. Alexander T Florence,
   David Attwood
   Physicochemical principles of pharmacy,4th edition
   Pharmaceutical press
3. Brahmankar, D M Jaiswal
   Biopharmaceutics and pharmacokinetics
   Vallabh Prakashan
4. Jennifer Dressman,
   Johannes Kramer
   Pharmaceutical dissolution testing
   Taylor and francis

BT-510

BIOTECHNOLOGY IN PHARMACEUTIAL SCIENCES (1 CREDIT)

BT – 510 (Not offered to M.S.(Pharm.) Biotechnology)

Biotechnology in Pharmaceutical Sciences (1 Credit)

1. **Biotechnology in pharmaceutical 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 (e.g. BLAST), gene expression comparison methods (microarray). Comparative genomics and expression genomics for target discovery of communicable diseases 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 industry:** Major areas for biotechnology in the pharmaceutical industry such as antibiotics, vaccines, diagnostics, antibodies, biopharmaceuticals (insulin, interferon, GSF, CSF & 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.

READING MATERIAL

1. Molecular Biology of the Cell, Fourth Edition - 2002

Bruce Alberts *et. al.*
Taylor and Francis Group.

2. Principles of Gene Manipulation, Sixth Edition - 2004
S. B. Primrose et. al.
Blackwell Science.

3. Gene Cloning and DNA Analysis, Fourth Edition
T. A. Brown
Blackwell Science.

4. Biotechnology - The Science and the Business, Second Edition, 1999
Ed: D. G. Springham
Harwood academic publisher.

5. Pharmaceutical Biotechnology, Second edition- 2002
Ed. D. J. A. Cromelin and R. D. Sindelar
Taylor and Francis group.

6. Basic Biotechnology, Second Edition, 2001
Ed: C. Ratledge and B. Kristiansen
CambridgeUniversity Press.

GE- 510

BIOSTATISTICS (2 CREDITS)

1. **Statistics:** Introduction, its role and uses. Collection; Organization; Graphics and pictorial 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 regressions 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

READING MATERIAL

1. Mathematics and Biostatistics
   G. K. Jani, Atul Prakashan, Second Edition, 2007-2008
2. Pharmaceutical Statistics: Practical and Clinical Applications
   Sanford Bolton; Fourth Edition, 2004.
3. Biometry
   Robert R. Sokal, F. James Rohlf; Third Edition, 1995
4. Introduction to the practice of Statistics
   David S. Moore, George P. McCabe; Fifth Edition, 2004
5. Experimental Design in Biotechnology
   Perry D. Haaland, 1989

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; Penalties 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) and GATS (General Agreement on Trade in Services); Protection of plant and animal geneticresources; 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; VVTO 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 attorneys technical aspects, criteria for selection, addresses, fee, rights and responsibilities of a patentee; Practical aspects regarding maintaining of a PATENT FILE; Patent infringement 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; Trademarks 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 infringements.

4. **Technology development / transfer / commercialization 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-commercialization and commercialization-practical aspects and problems; Significance (TOT), bottlenecks; Managing technology transfer-guidelines for research students, scientists and related personal; TOT agencies in India APCTD, NRDC, TIFAC, BCIL, TBSE/SIDBI; TOT related documentation-confidentiality agreements, licensing, MOUs, legal issues; Compulsory 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 benefits of modern biotechnology; Voluntary adoption of pollution control strategies

READING MATERIAL

1. Jayshree Watal
   Intellectual property rights in the WTO and developing countries
   Oxford university press
2. Prabuddha Ganguly
   Intellectual property rights: unleashing the knowledge economy
   Tata McGraw Hill

3. David Bainbrige
   Intellectual property, 5th edition
   Pearson education

GE-511

SEMINAR (1 CREDIT)

1. Introduction, information retrieval systems.
2. Writing term papers and reports.
3. Organization of scientific material, thesis, dissertation and references.
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 (30 hours)**
   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 hematological parameters
4. **Biotechnology in pharmaceutical sciences (20 hours)**
   Preparation for plasmid miniprep, Plasmid miniprep and restriction digestion, Gel electrophoresis and molecular weight calculation. Discussion of result and viva.
5. **Specialization (95 hours)**
   ECG recording in rat, pA2 value for atropine in G.pig ileum, strength of an unknown sample of histamine by four point assay, analgesic effect of pentazocine using hot plate method, demonstration of receptor binding studies, effects of a drug on food and water intake. Demonstration of recording of rat blood pressure, anticonvulsive activity of a drug, locomotor activity, muscle relaxant activity using rotarod apparatus; Working of physiograph, chlopromazine induced catalepsy, anti-inflammatory property of indomethacine, plasma glucose levels in streptozotocin treated rats; histology, cell culture techniques, cell viability assay, isolation of DNA from sample, SDS PAGE and DNA gel electrophoresis, genotoxic effects of drugs.

PHARMACOLOGY AND TOXICOLOGY – SEMESTER II
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, idiosyncrasy.
10. Acute poisoning and its treatment

READING MATERIAL

1. Biopharmaceutics and Pharmacokinetics – A Treatise
   D. M. Brahmankar and Sunil B. Jaiswal
   Vallabh Prakashan-1995
2. Drug Interactions
   Philip D. Hansten
   Lea and Febiger-1989, Philadelphia

PC-611

PHARMACOLOGICAL SCREENING AND ASSAYS (1 CREDIT)

16. General principles of screening, correlations between various animal models and human situations, animal ethics
17. Pharmacological screening models for therapeutic areas such as Hypertension, Cerebral Ischaemia, Pain, Epilepsy, Depression, Parkinson's disease, Alzheimer's disease, Diabetes, Leishmaniasis etc.
18. 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

READING MATERIAL

1. Drug discovery and evaluation pharmacological assays
   Hans Gerhard Vogel

Springer.

2. CPCSEA Guidelines

PC-620

CNS AND RESPIRATORY PHARMACOLOGY (2 CREDITS)

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:** Benzodaizepines and its antagonists. Barbiturates, loacal anesthetics.
4. Pharmacodynamic, 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 anti-epileptics.
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 anti-inflammatory agents used in asthma, cough suppressants.

READING MATERIAL

1. Essentials of Medical Pharmacology
   K.D. Tripathi
   Jaypee publications
2. Goodman & Gilman’s The pharmacological Basis of Therapeutics
   Publisher: Mc-Graw Hills

3. Lipincott's Illustrated reviews: Pharmacology

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 following:** Muscarinic cholinergic receptor agonists and antagonists, Ganglionic stimulants and blocking agents, neuromuscular blocking agents, drugs acting on adrenoreceptors.
3. **Cardiac glycosides and other cardiotonic agents:** Anti dysrhythmic drugs, antianginal drugs.
4. **Antihypertensives:** Calcium channel antagonists, ACE inhibitors, endothelium derived relaxing factors, lipid lowering agents.
5. **Diuretics:** drug 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 haemostatic agents.
8. **Factors necessary for erythropoiesis:** Homopoietic growth factors.
9. H_2 receptor antagonists: proton pump inhibitors, antacids, emetics, antiemetics and cancer chemotherapy, purgatives.
10. **Drugs regulate the GIT motility:** cholagogues and drugs used in cholelithiasis.

READING MATERIAL

1. Essentials of Medical Pharmacology
   K.D. Tripathi
   Jaypee publications
2. Goodman & Gilman's The pharmacological Basis of Therapeutics
   Publisher: Mc-Graw Hills
3. Lipincott's Illustrated reviews: Pharmacology
   Publisher: Lippincott Williams & Wilkins

PC-640

AUTACOIDS AND ENDOCRINE PHARMACOLOGY (1 CREDIT)

Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of the following

1. Histamine and bradykinin 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 calcification, estrogens and progesterone and their antagonists.
9. Oral contraceptive.
10. Androgens.

READING MATERIAL

1. Essentials of Medical Pharmacology
   K.D. Tripathi
   Jaypee publications
2. Goodman & Gilman's The pharmacological Basis of Therapeutics
   Publisher: Mc-Graw Hills
3. Lipincott's Illustrated reviews: Pharmacology
   Publisher: Lippincott Williams & Wilkins

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 organization of phase-I to phase-IV clinical studies.
6. **Single dose and repeat dose toxicity studies**: Factors influencing such studies such as species, sex, size, route, dose level; Data evaluation and regulatory requirements.
7. **Reproductive toxicology assessment:** 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 metabolites complicating factors in exposure interpretation, analytical method, good laboratory practices; Stereiosomerism 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.

READING MATERIAL

1. Basic & Clinical Pharmacology
   Bertram G. Katzung
   Publisher: LANGE Basic Science
2. Regulatory Toxicology
   Shayne C Gad
   Publisher: Taylor & Francis Inc
3. Regulatory Toxicology, Second Edition
   Christopher P Changelis, Shayne Cox Gad, Joseph F Holson
   Publisher: Informa Healthcare

PC-660

IMMUNOPHARMACOLOGY AND CHEMOTHERAPY (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 antimalarialagents, 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.

READING MATERIAL

1. Immunopharmacology
   Khan, Manzoor M.
   Publisher: springer
2. Immunopharmacology
   By Steven C. Gilman, Thomas J. Rogers
   Publisher: the telford press INC.
3. Essentials of Medical Pharmacology
   K.D. Tripathi
   Jaypee publications
4. Goodman & Gilman's The pharmacological Basis of Therapeutics
   Publisher: Mc-Graw

GE-611

SEMINAR (1 CREDIT)

Students are required to submit written record and present details of the project to be pursued in semester-III and 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)

Effect of drugs on rat blood pressure, estimation of blood glucose in normal and diabetic rats, OGTT test, effect of unknown drug on food and water intake, effect of unknown drug on rat ECG, effect of cyclophosphamide on neutrophil count in vitro experiments on rats prostrate, in vitro experiment on rat vas deference, effect of drug on passive

avoidance apparatus, effect of drug on TFL using analgesiometer, demonstration of ischemic model, effect of antioxidants on lipid peroxidation, genotoxic effect of unknown drug (micronucleus test and chromosomal aberration), demonstration of nerve conduction velocity in rats, effect of antidepressant on tail suspension test, identification of stages of estrus cycle in rats, antinflammtory activity of unknown compounds using carrageenan induced paw oedema in rats, finding out pA2 value of atropine, antihistaminic activity of unknown drug in g.pig cell culture techniques, effect of drug on locomotor activity, to study motor incoordination using rota rod apparatus, effect of unknown drug on PTZ seizure, effect of unknown drug on MES seizure, effect of unknown drug on gastric emptyping, effect of NSAIDs on gastric mucosa, effect of unknown drug using elevated plus maze, effect of unknown drugs on gastric acid secretion in pylorus ligated rats, demonstration of brain oedema/ BBB disruption, demonstration of blood flow, measurement of cholesterol and TGs in rats, radioligand binding demonstration, effect of unknown agent on hot plate test, demonstration of molecular biology technique, SDS PAGE, DNA GEL electrophoresis, MALDI and LCMS. Microarray techniques, effect of cyclophosphamide on neutrophil counts; Microscopic techniques, blood cell counting and histopathological studies.