

# **COURSES OF STUDY**

*Ph.D.; M.S. (Pharm.); M.Pharm.; M.Tech. (Pharm.);  
M.B.A. (Pharm.)*

## **JULY 2016**

*(All amendments till 30th June 2014 incorporated)*



**S.A.S. Nagar**

**National Institute of  
Pharmaceutical Education and Research,  
S.A.S. Nagar, Mohali**

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## Academic Administration

**Prof. K.K. Bhutani**

Director (Off.)

**Prof. A.K. Chakraborti**

Dean

## Head/ Incharge of the Departments

**Prof. A.K. Chakraborti**

Medicinal Chemistry

**Prof. K.K. Bhutani**

Natural Products

**Prof. Saranjit Singh**

Pharmaceutical Analysis

**Prof. Kulbushan Tikoo\***

Pharmacology & Toxicology

**Prof. A.K. Bansal**

Pharmaceutics

**Prof. U.C. Banerjee\***

Biotechnology

**Prof. U.C. Banerjee**

Pharmaceutical Technology

**Prof. P. Tiwari**

Pharmacy Practice

**Prof. P.V. Bharatam\***

Pharmacoinformatics

**Prof. Anand Sharma\***

Pharmaceutical Management

*\* Incharge of the Department*

## NIPER – A Brief Profile

The National Institute of Pharmaceutical Education and Research (NIPER) has been created as a centre of excellence for higher education, research and development in pharmaceutical sciences and is the first Institute of its own kind in the country. The Institute has been declared as an Institute of National Importance by Government of India through an Act of Parliament. The Institute admits students for the M.S. (Pharm.), M.Pharm., M.Tech. (Pharm.), M.B.A. (Pharm.) and Ph.D. programmes in various disciplines of pharmaceutical sciences and management.

On 29th January 2007, Central Government, in exercise of the powers conferred by sub-section (2A) of section 4 of the National Institute of Pharmaceutical Education and Research Act, 1998 (13 of 1998), notified and established four additional NIPERs at Ahmedabad (Gujarat), Hajipur (Bihar), Hyderabad (Andhra Pradesh), Kolkata (West Bengal) each as a separate body corporate, from the academic year 2007-08. This was followed by establishment of two additional NIPERs, in Rae Bareilly (Uttar Pradesh) and Guwahati (Assam).

### Educational Goals

The main goals of the Institute are:

1. To tone up the level of pharmaceutical education, research and management.
2. To produce leaders in the field and provide opportunities for training of future teachers, research scientists and managers for the industry and the profession. To provide leadership in pharmaceutical sciences, technology and management in India as well as in countries of South East Asia, West Asia and Africa.
3. To be a center for innovation in pharmaceutical sciences and technology not only to the industry but also for making in-depth studies on drug surveillance, functioning of community and institutional pharmacies and pharmaceutical management.
4. To encourage research and studies in new and emerging areas like discovery of pharmacologically active molecules, cellular and molecular biology, immunology and immunodiagnosics, recombinant DNA technology and monoclonal antibody technology, controlled drug delivery systems, chemical and biochemical process technology etc.
5. To provide scientific footing to traditional medicines and bring out scientific and the sociological aspects of drug use and abuse, family planning, rural pharmacy etc.
6. To provide facilities for curriculum and media development by revision of curricula from time to time and preparing a variety of instructional resources.
7. To provide facilities for continuing education for upgrading and updating the knowledge and skills of teachers from other pharmacy institutions and thus become a center for Quality Improvement Programme for teachers.

### Academic Programmes and Admission Procedure

The institute conducts various educational programmes at postgraduate and doctoral level and is currently offering following programmes:

1. *M.S. (Pharm.)* in Medicinal Chemistry, Natural Products, Traditional Medicine, Pharmaceutical Analysis, Pharmacology & Toxicology, Regulatory Toxicology, Pharmaceutics, Biotechnology, and Pharmacoinformatics.
2. *M.Pharm.* in Pharmaceutical Technology (Formulations), Pharmacy Practice and Clinical Research.
3. *M. Tech. (Pharm.)* in Pharmaceutical Technology (Process Chemistry) and Pharmaceutical

Technology (Biotechnology).

4. *M.B.A. (Pharm.)*.
5. *Ph.D.*

### **Summary of Ordinance & Regulations for Master' and Doctoral Programmes**

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

A (Outstanding)	= 10,
A(-) (Excellent)	= 9,
B (Very Good)	= 8,
B(-) (Good)	= 7,
C (Average)	= 6,
C(-) (Below Average)	= 5,
D (Marginal)	= 4,
E (Poor)	= 2,
F (Very poor)	= 0

2. Where student does not get E or F grade in any theory course but scores a CGPA of less than 6.00, he or she shall be allowed to repeat examination in maximum of two courses to improve the grade.
3. Due to lack of fulfilment 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 second time in a course(s).
4. The minimum credit requirement for masters degree will be 50 valid credits including a minimum of 30 credits of course work and balance credits of project work. For Pharmacoinformatics, course work will be of 36 credits and balance project work. The credit requirement for M.B.A.(Pharm.) degree will be a minimum of 100 valid credits including a minimum of 86 credits course work and balance credits of project work.
5. The minimum CGPA required for the award of the masters degree will be 6.00.
6. The maximum period for completion of the Masters Programme will be 3 years from the date of joining the Programme.
7. The Masters degree holders of the Institute getting into the Ph.D. programme will have to complete doctoral courses of minimum 12 credits and all other students will have to complete minimum of 28 credits (not less than 16 credits from the specialisation).
8. The minimum CGPA requirement for Ph.D will be 6.50. If CGPA is above 6.00 but below 6.50, student will be asked to take more courses in order to make up the required CGPA. If CGPA is below 6.00 at the end of any semester he/she will have to discontinue the Ph.D. programme.
9. Where the Ph.D has course work, he or she shall be required to submit a research proposal to the student research committee. The student shall have to prove his or her capabilities in broad field of research, academic preparation and and potential to carry out proposed research plan. For this purpose student shall be required to appear before the SRC to take comprehensive oral examination. The SRC shall evaluate the student in the context of research proposal submitted by him. A maximum of two attempts will be allowed to a student to clear the comprehensive examination. The student will be required to be registered for a period of not less than 3 years and submit the thesis within 5 years from the date of registration. The registration period of 5 years can be further extended to 7 years with the approval of Board of Studies and Research.

10. Students (of all Programmes) are required to attend every lecture and practical class during the semester. However, to be eligible to take end-semester examination, the student shall be required to attend 75% of actually held lectures and practical classes of each course.
11. For Masters programme: A student is entitled to a maximum of 45 days' leave in addition to general holidays during the four semester of their stay at the Institute. 10 days' of medical leave every year besides 45 days' leave can be granted. Students availing fellowship shall not be entitled to any vacation leave. For Ph.D. degree programme: A student is entitled to 30 days' leave in each year in addition to the general holidays.

Women student will be entitled to 3 months' maternity leave besides the 30 days' leave, once during their tenure. Leave with scholarship may be granted to students for attending academic meetings/conferences/symposia.

*Note:*

*This is the summarized form of Ordinance (Modified) 2014 for Masters and Doctoral Programmes. For details, approved document of the rules shall be referred to.*

### **Summarised rules governing conduct and maintenance of discipline for students/ research scholars 2006**

#### **Conduct:**

Every student shall at all times maintain absolute integrity and devotion to studies and research and conduct himself 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 Dean 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 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 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 in force.

Wilful insubordination or disobedience (whether or not in combination with others) of any lawful and reasonable instructions of his faculty, wilful negligence, commission of any act, subversive to discipline or good behaviour.

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 property of the Institute or of the property entrusted to the Institute or to another student.

Unauthorized custody and/or use of the Institute's 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 wrong or incomplete information or suppressing any information including dismissal removal or rustication by previous Institution/University or any punishment by any court of Law.

Conviction by Court of Law for any criminal offence involving moral turpitude or conviction by Court of Law for a serious criminal offence.

Wilful slowing down in performance of research and studies or abetment or instigation thereof.

Smoking or consumption of intoxicating drinks within the Institute. Sleeping while at work within laboratory or class-room.

Making representations to persons or bodies outside the Institute whether official or otherwise on matter connected with the affairs of Institute or personal grievances against the management of the Institute.

Making direct representation or sending grievance petitions to the members of the Board of Governors except through proper channel.

Non-payment of Institute and other dues including Mess & Cafeteria charges.

An act which interferes with personal liberty of another or subjects another to 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 students' body and the public or use of any outside agency for redressal of grievances.

Damaging 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 living in the Institute Campus.

An act which brings the Institute (and its teachers, officers or authorities) into disrepute.

Refusal to give evidence or establish or reveal identity when 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 departure or irregular attendance.

Indulging 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 specified activities.

An order directing a student to pay fine exceeding Rs.1000/- (Rupees one thousand only).

*Category-2:*

An order suspending a student for a period not exceeding 15 days whether from all activities of the Institute, department or hostel or from specified activities.

An order directing a student to pay a fine up to but not exceeding Rs.1000/- (Rupees one thousand only).

An order 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.

*Note:*

- 1) *This is the summarized form of Student discipline rules for Masters and Doctoral Programmes. For details, approved document of the rules shall be referred to.*
- 2) *Students will be required to vacate hostels for a period of one month, every year after end-semester examination for maintenance. The period of one month will be treated equivalent to only 20 days of regular leave, to be sanctioned by HoD. Before commencement of ensuing semester, fresh rooms and room partners will be re-allotted to students.*

# **Courses of Study 2016 Semester-I**

# Medicinal Chemistry

## 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 prodrugs.
8. **Nucleic acids:** NA as targets for drug action. NA-interactive agents. Classes of drugs that interact with nucleic acids. Intercalation, NA-alkylation, NA-strand breaking and their importance in drug action.
9. **Drug likeness:** Drug like molecules and theories associated with the recognition of drug like properties. Physical organic chemistry of Drug metabolism, drug deactivation and elimination.
10. **Drug action after Metabolism:** Phase I and Phase II transformations. Concept of hard and soft drugs. Chemistry of ADME and Toxicity properties of drugs.

#### **Recommended Books:**

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

7. Principles of Molecular recognition by A.D. Buckingham
8. Quantitative molecular pharmacology and Informatics by M. Lutz
9. Physical Biochemistry by K.E.V. Holde
10. Free energy calculations in rational drug design by M. Rami Reddy

## MC-511

### Spectral Analysis

(2 credits)

1. **Ultra Violet (UV) and visible spectroscopy:**
  - a) Energy levels and selection rules: Definitions, molecular orbital approach for energy absorption, various modes of transitions.
  - b) Correlation of structural variation with UV absorption: Factors influencing the position and intensity of absorptions, Inductive and resonance effects, effect of ring size, influence of stereochemical factors.
  - c) Predicting UV absorption: Woodward- Fieser, Fieser-Kuhn and Nelson rules;
  - d) Other factors: Non-conjugative effect, solvent effect, S-Cis band.
2. **Infrared (IR)spectroscopy:**
  - a) Characteristic regions of the spectrum: Various modes of vibrations, Energy levels
  - b) Correlation of structure with IR spectra: Influence of substituents, ring size, hydrogen bonding, vibrational coupling and field effect on frequency.
  - c) Applications: Determination of stereochemistry. Spectral interpretation with examples.
3. **Nuclear Magnetic Resonance (NMR)spectroscopy:**
  - a) Fundamentals: Physical basis, magnetic nuclei, resonance, relaxation processes, signal-sensitivity.
  - b) Instrumentation: Continuous-Wave (CW) instrument, Pulsed Fourier Transform (FT) instrument, Functions, Relation with sensitivity, Sampling.
  - c) <sup>1</sup>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 <sup>19</sup>F and <sup>31</sup>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) <sup>13</sup>C NMR, correlation of structure with spectra: Chemical environment, shielding and carbon-13 chemical shift, calculation, proton-coupled <sup>13</sup>C Spectra, Proton-decoupled <sup>13</sup>C spectra, Nuclear Overhauser Enhancement (NOE), Problem with integration, Distortionless Enhancement by Polarization Transfer (DEPT), Heteronuclear coupling for carbon to deuterium, carbon to <sup>19</sup>F, carbon to <sup>31</sup>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.

**Recommended Books:**

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

**MC-520**

**Logic in Organic Synthesis-I**

(3 credits)

1. **Organic reaction mechanism:**
  - a) Methods of determining reaction mechanisms: kinetic and non-kinetic methods; Energy profile diagrams, reaction intermediates, crossover experiments and isotopic labelling; order of reactions; Reversible, consecutive and parallel reactions; Solvent, ionic strength and salt effects; Acid-base catalysis.
  - b) Nucleophilic substitution reactions: Uni- and bimolecular reactions; Attacking and leaving groups; Steric and electronic effects; Neighboring group participation; Formation and hydrolysis of esters, amides and acyl halides different mechanisms.
  - c) Electrophilic substitution reactions: Aromatic electrophilic substitutions including Friedel-Crafts reactions.
  - d) Addition and elimination reactions: Addition to C=C and C=O; Mechanism; Dehydrohalogenation, dehydration, etc; E1, E2 and Syn-elimination mechanism.
2. Principles of synthetic planning: Logic-centered molecular synthesis; Dislocation, synthetic tree, synthons, logical imposition of boundary conditions, direct associated approach; Structure-functionality relationships, functionality and unsaturation levels; Polar reactivity analysis; Control elements, consonant and dissonant circuits; Protocol for synthetic design.
3. **Alkylation:**
  - a) Enolates: Regio- and stereo-selective enolate generation, "O" versus "C"- alkylation, effects of solvent, counter cation and electrophiles; Symbiotic effect; Thermodynamically and kinetically controlled enolate formations; Various transition-state models for stereoselective enolate formation.
  - b) Enamines and metalloenamines: Regioselectivity in generation, applications in controlling the selectivity of alkylation.
4. **Reaction of ylides:**
  - a) 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-  $\text{Ipc}_2\text{BH}$   $\text{IpcBH}_2$  etc.

**Recommended Books:**

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

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

## LG-510

**General Laboratory Experience - 15 hours / week**

(3 credits)

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

# Natural Products

## NP-510

### Separation Techniques

(1 credit)

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

### *Recommended Books:*

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

## NP-520

### Natural Products-I

(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).
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 alongwith 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.

**Recommended Books:**

1. Trease and Evans Pharmacognosy by William Charles Evans; Fifteenth Edition; W.B. Saunders Publisher; 2002.
2. Pharmacognosy & Phytochemistry of Medicinal Plants by Jean Bruneton; Second Edition; Lavoisier Publishing, NJ USA; 1999.
3. Organic Chemistry Vol2: Stereochemistry and The Chemistry of Natural Products by I. L. Finar; Fifth Edition; Pearson Education; 2006.
4. Organic Chemistry by Robert Thornton Morrison, Robert Neilson Boyd; Sixth Edition; Prentice-Hall of India Pvt. Ltd., New Delhi; 2006.
5. Medicinal Natural Products: A Biosynthetic Approach by Paul M. Dewick, 2nd Edition, John Wiley & Sons, Ltd., 2002.

## 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, 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 soft-ware systems. Use of computers in information retrieval systems.

3. **Pharmacology (25 hours):** Animal handling, route of administration of drugs, dose response relationship, acute toxicity, analgesic activity of a compound, estimation of protein and haematological parameters.
4. **Biotechnology in pharmaceutical sciences (20 hours):**  
Day -1: Preparation for plasmid miniprep.  
Day-2: Plasmid miniprep and restriction digestion.  
Day-3: Gel electrophoresis and molecular weight calculation.  
Day-4: Discussion of result and viva.
5. **Specialization (50 hours):**  
List of practicals 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 *Embllica 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 Products-I (NP-520)
  - a) Characterization of given glycoside (rutin) or saponin (glycyrrhizin) by identification of its hydrolytic products using TLC. (15 hours)
  - b) Isolation of eugenol from clove oil (5 hours)
  - c) Preparation of sequential extracts by Soxhlet apparatus and TLC finger printing (25 hours)
  - d) Extraction of  $\beta$ -Sitosterol and stigmasterol from soya seeds OR Extraction of lupeol from *Embllica officinalis* bark. This practical will include extraction, separation, identification and isolation of the desired component (20 hours).
  - e) Preparative TLC.
  - f) Acetylation and oxidation reactions of pentacyclic triterpene (30 hours).
  - g) Extraction of essential oil and study of its composition by GC (10 hours).
  - h) Extraction, identification and isolation of an alkaloid from given plant material. (25 hours)

## Traditional Medicine

### TM-510

#### Introduction to Traditional Systems of Medicine

(1 credit)

1. Introduction and principles of traditional medicine systems in India.
2. **Ashtang Ayurveda and departments at present in Ayurveda:** Humours Saptadhatu, Principles of treatment, Prakriti, Panchkarma and Ksharsutra.
3. **Pathogenesis and ancient's pathological test:** Movement of pulse and finding of different dosha; importance of geriatrics, aphrodisiac and Ayurvedic ethics in present scenario.
4. Importance of Ayurvedic system and its practice in India.
5. Sidhha and Unani medicine systems and their practice in India.
6. Introduction and importance of different traditional (alternative) systems of medicine such as herbal medicine, Homeopathic medicine, Chinese traditional medicine.
7. **Introduction and importance of aroma therapy:** African traditional medicine and various other alternative therapies e.g. acupuncture, acupressure.
8. **Herbal medicine:** Growth, market and need for development.
9. Nutraceuticals and dietary supplements.
10. Home remedies.

#### **Recommended Books:**

1. Carak Samhita (Second Revised Edition), translated by A. Chandra Kaviratna & P. Sharma
2. One Hundred Useful Drugs by Dr. A. Lakshimipathi
3. Ayurvedic Home Remedies by Dr Prakash Paranjpe
4. Acupuncture, Marma and Other Asian Therapeutic Techniques by Dr. D.G. Thatte

### TM-520

#### Ayurvedic Pharmacy

(1 credit)

1. **Ayurveda:** Definition, therapeutic classification, aims, contents and types of Ayurveda.
2. Ten points for examination that is Karana, karana Kara, Kariyayoni, Karya phala, Anubandha, Desa, kala, Prakrthi and Ypaya and their utility and application in pharmacy.
3. **Concept of Bhesaja examination:** Pharmacology and pharmaceutical knowledge according to Ayurveda.
4. Concept of health- Svasthya definition.
5. **Dosha, Dhatu, Mala Mulam Hi Shariram:** Main components of body.

6. **Definition of Dosha and their types, Vayu and Pitta:** Importance, definition, type and functions.
7. **Study of different Ayurvedic formulations and preparations belonging to three broad classes:** Solids, semi-solids and liquids such as tablets/pills, capsules, churna, taila, ghrita, Avaleha, Asava/Arishta, bhasma etc.
8. **Study of various pharmaceutical processes used in Ayurveda:** This includes extraction of drugs and fermentation of vegetable drugs.
9. Guidelines for Good Manufacturing Practices (GMP) of Ayurvedic and herbal drug materials.
10. Good Laboratory practice (GLP) for Ayurvedic and herbal drug materials.

**Recommended books:**

1. Carak Samhita (Second Revised Edition), translated by A. Chandra Kaviratna & P. Sharma
2. Sarngadhara Samhita, translated by Prof. K.R. Srikantha Murthy Bangalore
3. Bhaishajya Ratnavali translated by Dr. Kanjiv Lochan
4. Ayurvedic Pharmacy (Bhaishajya Kalpana) by Dr. Anil K. Mehta and Dr. Raghunandan Sharma
5. Ayurvedic Pharmacopoeia of India (API) Govt. of India, Part I volume I to VII, Part II volume I & II
6. Ayurvedic Formulary of India (AFI), Govt. of India , Part I & II;

## LG-510

### General Laboratory Experience-15 hours/week

(3 credits)

1. **Analytical techniques:** 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, analgesic activity of a compound, estimation of protein and haematological parameters.
4. **Specialization (115 hours):**
  - (I) Complete scientific pharmacognostical evaluation and preparation of permanent slides of 5 medicinal plants under the guidelines of "The Ayurvedic Pharmacopoeia of India". (65 hours)

List of practicals for the evaluation and identification of crude drugs:

- a) Macroscopical study of root, leaf, stem, fruit, seed, wood, bark of drugs for size, shape.

- b) Microscopical study of leaf by (T.S. through mid rib) to evaluate the nature of epidermis, trichomes, stomata and arrangements of tissue like palisade cells, vascular bundles and nature of cell contents.
  - c) Study of the bark, root, rhizome and wood by T.S. and L.S.
  - d) Study of the powder drug by testing of lignified elements, starch, tannin, Anthraquinone, inulin, fixed oils. Pre-prepared permanent slides shall be used.
- (ii) Qualitative testing of aflatoxin (WHO method) (15 hours)
- (iii) List of practicals to study the physio-chemical parameters of Ayurvedic formulations (35 hours)
- a) Measurement of sieve size to study the particle size in powder/ churna.
  - b) Estimation of the specific gravity in taila/ghrita.
  - c) Absence of MeOH test in asava/arista.
  - d) Quantification of EtOH in asava/arista.
  - e) Quantification of sugars (reducing and non-reducing) in asava/arista.
  - f) Identification of metals in bhasma.
  - g) Quantification of metals in bhasma.
  - h) Estimation of total solid in asava/arista.

# Pharmaceutical Analysis

## PA-510

### Topics in Pharmaceutical Analysis

(2 credits)

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

#### **Recommended books:**

1. Chemical Analysis: Modern Instrumentation Methods and Techniques' by Francis Rouessac and Annick Rouessac
2. Principles of Analytical Chemistry by Miguel Valcarcer
3. Analytical Method Development and Validation by Michael E. Swartz, Ira S. Krull
4. Good Laboratory Practices by Jurg P. Seiler
5. Principles of Instrumental Analysis by Douglas A. Skoog, F. James Holler, Timothy A. Nieman
6. Handbook of Modern Pharmaceutical Analysis by Satinder Ahuja, Stephen Scypinski
7. Principles and Practice of Bioanalysis by Richard F. Venn

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

*Day -1:* Preparation for plasmid minirep.

*Day-2:* Plasmid minirep and restriction digestion.

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

*Day-4:* Discussion of result and viva.
5. **Specialization (50 hours)**
  - a) To calibrate thermometer
  - b) To calibrate the common glassware (volumetric flask, burette and pipette) found in an analytical laboratory
  - c) Calibration of 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
  - l) Determination of pKa of given sample by spectrophotometric method.

# Pharmacology and Toxicology

## PC-511

### Pathophysiology

(1 credit)

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

#### **Recommended books:**

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

## PC-520

### General Pharmacology

(2 credits)

1. Drug receptor interaction theories, occupation theory, rate theory.
2. Receptor occupation and response relationship, spare receptors, silent receptors, orphan receptors, presynaptic and postsynaptic receptors.
3. Receptor characterization methods: Pharmacological characterization, radioligand methods, monoclonal anti-bodies, receptor subtypes, IUPHAR nomenclature, clinical significance of receptor subclassification.
4. Receptor down regulation and upregulation.
5. Structure activity relationships, pharmacodynamic and pharmacokinetic aspects of chiral drugs, allosteric binding, thermodynamics of drug interactions with the receptors.
6. Transmembrane signal mechanisms, second messengers, viz., cAMP, cGMP, calcium.

7. Dose response relationship and different types of antagonisms.
8. Desensitization and tachyphylaxis.
9. Drug dependence and withdrawal responses.
10. Non therapeutic uses of drugs.

**Recommended Books:**

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

## 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; Anaesthesia used in laboratory animals, common agents, dose calculations, cannulation methodology, ventilation rate, recording of arterial blood pressure, intestinal motility etc.
4. Conscious animal experimentation precautions to be taken in behavioural experiments.
5. **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.

**Recommended books:**

1. Pharmacology by Lippincott
2. Drug Discovery and Evaluation: Pharmacological Assays by Vogel

## PC-540

### Chemotherapy of Parasitic and Microbial Infections

(1 credit)

1. Introduction to parasitic and infectious diseases.
2. Biology of tuberculosis.
3. Mechanism of action of anti-tuberculosis drugs.
4. Targets for anti-tuberculosis drug development.
5. Mechanism of drug-resistance in tuberculosis.
6. Biology of human amoebiasis.
7. Mechanism of action of anti-amoebic drugs.
8. Biology of filarial infections.
9. Mechanism of action of anti-filarial drugs.
10. Targets of anti-filarial drug development.
11. Biology of HIV infection.
12. Mechanism of action of anti-HIV drugs.
13. Targets for anti-HIV drug development.
14. Biology of malaria.
15. Mechanism of action of anti-malarial drugs.
16. Targets for anti-malarial drug development.
17. Mechanism of drug-resistance in malaria.
18. Biology of leishmaniasis.
19. Mechanism of action of anti-leishmanial drugs.
20. Targets for anti-leishmanial drug development.
21. Drug-resistance in leishmaniasis.

#### **Recommended books:**

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

## 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 haematological parameters.
4. **Biotechnology in pharmaceutical sciences (20 hours):**  
*Day -1:* Preparation for plasmid minirep.  
*Day-2:* Plasmid minirep and restriction digestion.  
*Day-3:* Gel electrophoresis and molecular weight calculation.  
*Day-4:* Discussion of result and viva.
5. **Specialization (95 hours):** Introduction to lab. experience and animal experimentation, blood glucose estimation, IC50 determination, demonstration of motor coordination, microscopic techniques, to study effect of drug on food and water intake, histopathological study, SDS PAGE demonstration, cell culture demonstration, cell viability assay.

# Regulatory Toxicology

## RT-540

### Principles and Methods in Toxicology

(1 credit)

1. Introduction to general toxicology.
2. History of toxicology.
3. Classification and ramification in toxicology.
4. **Toxicants:** Exposure, exposure characterization.
5. **Routes of exposure:** Organism environment interaction.
6. Animal and plant toxins.
7. Absorption and distribution of toxicants.
8. Human health risk assessment.
9. **Hazard identification:** Risk assessment.
10. Risk prediction and management.

#### *Recommended books:*

1. Casarett & Doull's Essentials of Toxicology by Curtis D. Klaassen, John B. Watkins
2. Principles of Toxicology by Karen Stine, Thomas M. Brown
3. Text Book of Pathology by Harsh Mohan

## RT-550

### Introduction to Regulatory Toxicology

(2 credits)

1. **Drug discovery and development:** Drug Laws, FDA, OECD, ICH.
2. **Schedule Y:** Design non-clinical toxicity studies and clinical development.
3. Clinical risk/benefit analysis.
4. **Drug discovery and registration:** Regulatory affairs, WTO, patent regime, accreditation and harmonization process.
5. **Models and bioassay:** Methods in toxicity testing, dose-response characterization.
6. **Threshold limitations:** Hormesis, lower dose extrapolation.
7. **Animal to human extrapolation:** Flow chart, "Case by Case" basis in non-clinical development and its influences in safety assessment, usefulness and limitations.
8. **Regulations of human pharmaceuticals:** Preclinical development.
9. **Environmental impact:** Regulation for biological products.
10. **Influence of new technologies:** Discovery development gap, future of drug safety.

**Recommended books:**

1. Regulatory Toxicology by Shayne C. Gad Taylor & Francis
2. Principles and Methods of Toxicology by A. Wallace Hayes

**LG-510**

**General Laboratory Experience-15 hours/week**

(3 credits)

1. **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.
2. **Pharmacology (25 hours):** Animal handling, route of administration of drugs, dose response relationship, analgesic activity of a compound, estimation of protein and haematological parameters.
3. **Specialization (145 hours):** Experiment protocol, quarantine procedures; Animal health check ups, acclimatization, grouping, animal marking; Cage cards, dose calculation for mice and rats; Common solvents, uses, storage conditions, dosing procedures (oral, intraperitoneal); Common toxic symptoms- definitions and observation, feed intake measurements, water intake measurements, urine output, anesthesia and gross necropsy; Blood removal from mice and rats and anticoagulants. Separation and isolation of plasma, case of hemolysis sample. Body weight, organ weight, body to organ ratio calculation, different target organs isolation, fixative, preservations, autolysis, raw data collection, computation, statistics and report preparation.

# Pharmaceutics

## 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.

#### **Recommended books:**

1. Martin's Physical Pharmacy and Pharmaceutical Sciences by P.J. Sinko
2. Pharmaceutical Dosage Forms and Drug Delivery, by Mahato R.I. and Narang A.S

## PE-520

### Biopharmaceutics and Pharmacokinetics

(2 credits)

- 1. Introduction:** Definitions, ADME, concentration time profile, plotting the data, different fluid compartments and blood flow rate compartment models, biological half life, elimination rate constant. Biopharmaceutics and pharmacokinetics in drug research.
- 2. GIT Absorption of drugs:** Mechanism, physico-chemical, 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, volume of distribution and its significance.
- 4. Protein and tissue binding:** Factors affecting protein binding, kinetics of protein binding, determination of rate constant and different plots (direct, scatchard and reciprocal), Implication of protein binding on pharmacokinetic parameters.
- 5. Bioavailability and bioequivalence:** Definitions, federal requirements, 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 models with first order elimination kinetics as applied to rapid intravenous injection, Intravenous transfusion and oral administration. Determination of absorption rate constant using Wagner-Nelson, Loo Riegelman 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. **Non Linear Pharmacokinetics:** Various causes of non-linearity, Michaelis-Menten kinetics, In-vivo estimation of  $K_m$  and  $V_m$ . 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.

**Recommended books:**

1. Applied Biopharmaceutics & Pharmacokinetics, by Shargel, L., S. Wu-Pong
2. Biopharmaceutics and Pharmacokinetics: An Introduction by Notari, R. E.
3. Introduction to Biopharmaceutics, by Gibaldi, M.
4. Biopharmaceutics and Relevant Pharmacokinetics, by Wagner, J. G.
5. Textbook of Biopharmaceutics and Clinical Pharmacokinetics by Niazi, S.K.
6. Handbook of Bioequivalence Testing, by Niazi, S. K.
7. Modeling in Biopharmaceutics, Pharmacokinetics, and Pharmacodynamics: Homogeneous and Heterogeneous Approaches, by Macheras, P. and A. Iliadis
8. Comparative Pharmacokinetics: Principles, Techniques and Applications, by Riviere, J. E
9. Foundations of Pharmacokinetics, by Rescigno, A.
10. Clinical Pharmacokinetics and Pharmacodynamics: Concepts and Applications, by Rowland, M. and T. N. Tozer

## LG-510

### General Laboratory Experience

(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 haematological parameters.
4. **Biotechnology in pharmaceutical sciences (20 hours):**  
Day -1: Preparation for plasmid miniprep.  
Day-2: Plasmid miniprep and restriction digestion.  
Day-3: Gel electrophoresis and molecular weight calculation.  
Day-4: 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 behaviour/ 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.

# Biotechnology

**BT-510** {Not offered to M.S. (Pharm.) Biotechnology}

## Biotechnology in Pharmaceutical Sciences

(1 credit)

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

### **Recommended books:**

1. Analysis of Genes and Genomes by Richard J Reece. John Wiley & Sons
2. Molecular Biotechnology by Principles and Applications of Recombinant DNA by Bernard R. Glick, Jack J. Pasternak and Cheryl L. Patten, ASM Press
3. Principles of Fermentation Technology by P F Stanbury, A. Whitaker, S. J. Hall. Butterworth-Heinemann

4. Bioprocess Engineering Principles by Pauline M. Doran, Academic Press
5. Pharmaceutical Biotechnology by Concepts and Applications by Gary Walsh, John Wiley & Sons

## 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 Signalling:** Receptor concept, receptor signalling 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 & 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 oncogenes, oncogenic mutations, loss of cell cycle control, carcinogens.

#### *Recommended books:*

1. Molecular Cell Biology by Harvey Lodish
2. Molecular Biology of the Cell by Bruce Alberts
3. Principles of Biochemistry: Lehninger
4. Biochemistry by L.Stryer

## 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, typtophan 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. Details 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.

**Recommended books:**

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 & Bartlett
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 research and review papers.

**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<sup>+</sup>/NADP<sup>+</sup>, FAD, lipoic acid, tetrahydrofolate, B<sub>12</sub>-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,  $\alpha$ -,  $\beta$ - and  $\omega$ - 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.

**Recommended books:**

1. Principles of Biochemistry by Lehninger
2. Biochemistry by L.Stryer

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

*Day-1:* Preparation for plasmid miniprep.  
*Day-2:* Plasmid miniprep and restriction digestion.  
*Day-3:* Gel electrophoresis. and molecular weight calculation.  
*Day-4:* Discussion of result and viva.

4. **Biotechnology specialization (75 hours):**

*Cell biology (25 hours):*

*Day-1:* Sterilization by autoclaving and filtration.

*Day-2 :* Media preparation and cell counting.

*Day-3 :* Sub cellular fractionation by homogenization, solubilization, sonication and protein estimation.

*Day-4 :* Running SDS-PAGE and Viva.

*Enzyme kinetics (25 hours):*

*Day-1 :* Assay of trypsin.

*Day-2 :* Thermal stability of trypsin.

*Day-3 :* Lineweaver-Burk plot for trypsin.

*Day-4 :* Plotting of graphs and discussion of result

*Enzyme biochemistry (25 hours):*

*Day-1:* Enzyme kinetics, time course.

*Day-2:* Effect of pH and temperature.

*Day-3:* Inhibition studies and characterization.

*Day-4:* Ionic strength effect and viva.

*Bacterial Culture & Growth Kinetics:*

*Day-1:* Direct and indirect methods to measure bacterial growth, Media preparation, setting up of primary cultures.

*Day-2:* Monitoring growth kinetics, effect of different parameters on growth, plotting of growth curves.

*Day-3:* Calculation of mean generation time and growth rate constant, analysis of results, discussion of results & viva.

# Pharmacoinformatics

## PI-510

### Introduction to Pharmacoinformatics

(1 credit)

1. **Introduction of bioinformatics:** Different sub domains of bioinformatics, Applications, Amino acid and nucleic acid structure, Properties.
2. **Protein folding:** Concept, Theoretical and experimental techniques to identify the molecular structure, Principles of protein structure, Structural bioinformatics in drug discovery, Metric system.
3. **Structural genomics:** Approaches, Structural genomics effort, Protein structural initiative, structural genomics consortium, Impact of structural genomics.
4. **Introduction to chemoinformatics:** Chemoinformatics and drug discovery, Simulation methods and their importance, Representation of molecules, Visualization and generation of 2D and 3D molecular structures; Molecular modeling, Data analysis, Chemical information.
5. **Databases and its importance:** 2D and 3D databases, Structural and chemical databases, Implications.
6. **Energy of molecules:** Bioactive conformation of the molecules, Crystallography, energy minimized and bioactive conformation, Conformational search approaches, Force field, Potential energy surface, Different conformations, examples.
7. **Ligand based drug design:** Over view, Similarity methods, Superimposition methods, Pharmacophore, QSAR methods.
8. **Structure based methods:** Over view, Introduction to molecular docking methods, scoring function, synergy between ligand and structure based methods.
9. **ADME/T predictive methods:** Overview of methods, in silico approaches to ADME/T models, pharmaceutical issues; software tools in ADME/T prediction, limitations of in silico approaches.
10. **Applications:** Application of bioinformatics, chemoinformatics, ADMET in drug discovery and development.

#### **Recommended books:**

1. Molecular Modeling : Basic Principles and Applications by Holtje, Hans-Dieter Wiley-VCH
2. Molecular Modelling for Beginners by Hinchliffe, Alan John Wiley
3. Computer-Aided Drug Design by Perun, Thomas J. , B. I. Waverly
4. An Introduction to Chemoinformatics by Leach, Andrew R, Kluwer Academic
5. Modern Methods of Drug Discovery by Hillisch, Alexander, Birkhauser Verlag
6. Drug Discovery Strategies and Methods by Makriyannis, Alexandros, Wiley-VCH
7. Evaluation of Drug Candidates for Preclinical Development: Pharmacokinetics, Metabolism, Pharmaceutics, and Toxicology by Han, Chao, John Wiley

## PI-520

### Pharmacoinformatics - Programming

(2 credits)

1. Introduction to high level languages, Problem Solving, C++ development environment, program structure and main function.
2. Input and output statements, comments, data types, variables, constants, statements, block of codes.
3. **Iteration:** While loops, do-while loops, for loops, nesting of loops.

4. **Selection:** Switch statement, if-then-else statement, terminating a program.
  5. **Functions:** Definition, declaration, prototypes, return type, arguments, inline functions, recursive functions.
  6. **Arrays:** Dimension, initialization, arrays as arguments to functions, strings- arrays of characters, string manipulation.
  7. **Files:** File stream objects, open and close files, input and output filestreams, stream' states.
  8. **Pointers:** Defining pointer variables, pointers and arrays, pointers as arguments to functions.
  9. **Class:** Objects, object oriented design, data abstraction, operator overloading, inheritance, polymorphism and virtual functions, exception handling.
  10. The application areas like data structures, sorting algorithms if required.
- All the programming exercises will be related to problem solving the pharmaco informatics

**Recommended books:**

1. Thinking in C++ by Bruce Eckel
2. A Beginners C++ by Neil Gray

## PI-530

### Physicochemical Parameters in Drug Design

(2 credits)

1. **Drug like properties of molecules:** Structural, physicochemical and biological properties of molecules. Relevance of these properties to ADMET, drug stability.
2. **Pka:** Ionizability of a compound, pKa in preformulation, lipophilicity and pKa, solubility and pKa.
3. **Solubility:** Definition, factors affecting solubility, drug solubility trends, impact of poor solubility, approaches to deal with insolubility.
4. **Permeability:** Permeation mechanisms, strategies for improving permeability by structural modification.
5. **Transporters:** Variability in drug response, location of variability, membrane transporters, structural modification strategies to reduce P-gp efflux.
6. **Protein binding of drugs:** Factors affecting protein binding, assessment of protein binding, effects of protein binding, clinical relevance of protein binding and applications of protein binding.
7. **Drug transporters in efficacy and toxicity:** Efflux transporters as effective barriers to drug exposure, excipients as efflux transporter inhibitors.
8. **Drug metabolism:** Definition, absorption Vs metabolism, consequences of drug metabolism, pro-drug approach, design strategies for modification of drug properties.
1. **Polymers for drug delivery:** types of polymer, pharmaceutical polymers, physicochemical properties of polymers and relationship with structure, properties, kinetics, mechanisms

and applications, delivery systems for macromolecules, polymers in modifying oral and parenteral drug delivery, interaction of polymers with drug transporters and metabolising enzymes.

10. **Toxicophores in drug molecules:** Mutagenicity, hepatotoxicity, and cardiotoxicity.

**Recommended books:**

1. Drug-like Properties: Concepts, Structure, Design and Methods from ADME to Toxicity Optimization by Edward H Kerns and Li Di
2. Optimizing the "Drug-Like" Properties of Leads in Drug Discovery (Biotechnology: Pharmaceutical Aspects) by Ronald Borkardt, Edward Kerns, Michael Hasgeman, Dhiren Thakker, James Stevens
3. Models for Assessing Drug Absorption and Metabolism (Pharmaceutical Biotechnology) by Ronald T. Borchardt, Philip L. Smith, Glynn Wilson

## LS-510

### General Laboratory Experience with Computer Lab.

(3 credits)

#### I. Computer programming and modeling (170 hours)

List of programs (These are only representative examples; Many more programmes will be set on the same lines)

1. Write a program to calculate the amount of CFC left after specific time by using half life of decay reaction.
2. Write a program to construct a Fibonacci series by using first two value of series.
3. Write a program to find the factorial of a number.
4. Write a program to find out the prime number.
5. Write a program to calculate the sum of n term of given series.
6. Write a program to find the square roots of quadratic equation.
7. Write a program to design a calculator that simulate the workings of a basic four operation.
8. Write a program to find the factorial of a number by using the recursive function.
9. Write a program to assign a value to variable using \* pointer (dereferencing operator) and & (address operator).
10. Write a program to swap value of two variable using functions and pointers.
11. Write a program to appending and comparing two string.
12. Write a program to find out length of string.
13. Write a program to convert decimal number into hexadecimal or octal form.
14. Write a program for addition of matrixes.
15. Write a program for multiplication of matrixes.
16. Write a program to find square root of number by using Newton Raphason methods.

17. Write a program to generate distance matrix for molecule using coordinates of its atoms.
  18. Write a program to find the angle between three atoms using their Cartesian coordinates.
  19. Write a program to find the torsion angle using Cartesian coordinates of atoms.
  20. Write a program to find the RMSD of different structure of protein by using the information given in their PDB
  21. Write a program to calculate tanimoto coefficient from bitmap
  22. Write a program to calculate value of mathematical functions like tan, sin, cos etc.
  23. Write a program to arrange number in increasing and decreasing order.
  24. Write a program to calculate total no of residue, no of same type of residue, no of het atom, avg of beta factor by analysis of PDB file of protein.
  25. Write a program to extract coordinate of ligand from PDB of Co crystal protein-drug complex into a small file and convert it into a mol2 file.
  26. Calculate the RMSD of ligand take from PDB by using the coordinate before and after energy minimization.
  27. Write a program extracts the coordinate of final conformation ligand from Gaussian output file with energy.
  28. Write a program to calculate the molecular wt using smile notation of molecule.
  29. Write a program to find out the linear equation between two variable, also calculate the coefficient of correlation, standard deviation and F-value.
  30. Write a program to calculate the wiener index of compound by using its mol2 file.
  31. Write a program to calculate charge on protein and generate file without hydrogen by using PDB of protein.
- II. *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 lan guages with emphasis to FORTRAN language and programming, hands on experience in pharmaceutical software systems. Use of computers in information retrieval systems.

## Pharmacy Practice

### PP-510

#### Pharmacy Practice-I

(1 credit)

1. **Understanding terminologies and concepts:** Primary, secondary and tertiary care; Pharmacy practice; Institutional, hospital, ward, clinical and community pharmacy; Patient confidentiality, patient compliance, counselling, informed consent.
2. Pharmaceutical care and planning.
3. **Hospital pharmacy:** Overview of organization and structure (comparison with community pharmacy), basic hospital pharmacy services.
4. Specialized services e.g. Drug Information Centre and service provision.
5. **Role of patients in decision-making regarding therapeutic management:** Factors affecting patients' decision to take/not to take the medication.
6. **Professional responsibilities:** Profession of pharmacy and pharmacists as practitioners; Responsibilities of pharmacy practitioners as stated in developed countries; Relevance and scope of adopting these in India; Opportunities and legislation; Relationships with other health care professionals - doctors, nurses, paramedical staff, drug inspectors, excise officers and police officers; Ethics of practice.
7. **Skills:** Communication, counselling; Reading, writing, thinking; Factors affecting development of these skills.

#### **Recommended books:**

1. A Practical Guide to Contemporary Pharmacy Practice by Judith E. Thompson, Lippincott Williams & Wilkins
2. Introduction to Hospital and Health-System Pharmacy Practice by David A. Holdford and Thomas R. Brown
3. Communication Skills in Pharmacy Practice: A Practical Guide for Students and Practitioners, by Robert S. Beardsley, Carole Kimberlin and William N. Tindall
4. Hospital Pharmacy by Martin Stephens
5. Hospital Pharmacy, by William Hassan, Lea & Febiger

### PP-520

#### Clinical and Applied Therapeutics-I

(3 credits)

1. **Geriatrics:** Issues based on age related physiologic and pharmacokinetic/dynamic changes; Variations in management from other patient groups; Pharmaceutical care plan in view of compliance, ability to use devices for other diseases/disorders) including discharge and home care plan.
2. **Paediatrics:** Specific childhood diseases and management; Immunizations, national immunization programmes and scope for pharmacists' involvement in these; Special issues of paediatric management; Dosage adjustments based on age and physiological and pharmacokinetic/dynamic development stage; Availability of 'adequate' formulations,

dosage forms; Drug administration, timing; Compliance, psychology and hormonal changes in adolescents.

3. **Cardiology:** Hypertension; Congestive heart failure.
4. Cardiology: Angina; Myocardial Infarction; Arrhythmias; Lipid disorders; Guidelines for management of patient and monitoring drug therapy, TDM for digoxin.
5. **Respiratory diseases and treatment:** Asthma; COPD; TDM of Theophylline; Use and maintenance of different inhalers and devices, operation of oxygen cylinders; Monitoring therapy; Guidelines; Respiratory infections (treatment in view of resistant states, isolation, monitoring therapy and duration of treatment, side effects, drug interactions)- URTIs and LRTIs; TB, pneumonia.
6. **Nephrology:** Influence and importance of fluid and electrolyte balance and acid-base balance; Acute renal failure; Chronic renal failure; Renal dialysis (types and points of pharmacists' involvement).
7. **Infections and antimicrobial therapy:** Special emphasis on communicable diseases in India, introduction to related national health programmes; UTIs, GI, CNS, bone and joint infections, sexually transmitted diseases, mycotic and parasitic infections; Need and relevance of antibiotic policies.
8. **Diabetes:** Type 1 and 2 (incidence, prevalence, etiology, influencing factors, genetic basis); Treatment options and guidelines; Insulin types and formulations, administration, monitoring therapy, patient education; Resistant cases (causes, alternatives to treatment); Management of gestational diabetes.

*Note: Applicable to all practice based subjects/topics:*

- a) Teaching of individual drugs should not be included: Only specific practical as against theoretical issues of drugs commonly used in practice should be discussed along with the recent advances in drugs, formulations and dosage forms.
- b) Teaching should be practice and primary literature based with emphasis on issues in therapy, advances and guidelines with case studies throughout the course.
- c) In all areas, primary literature review and individual appraisal (as can be assessed in practice) of recent developments is encouraged.

**Recommended books:**

1. Koda-Kimble and Young's Applied Therapeutics: The Clinical Use of Drugs by Brian K. Alldredge, Robin L. Corelli, Michael E. Ernst, and B. Joseph Guglielmo
2. Pharmacotherapy: A Pathophysiologic Approach, by Joseph DiPiro, Robert L. Talbert, Gary Yee and Gary Matzke
3. Clinical Pharmacy and Therapeutics by Eric T. Herfindal and Joseph L. Hirschman  
Clinical Pharmacy and Therapeutics, by Roger Walker and Cate Whittlesea
4. Goodman and Gilman's Manual of Pharmacology and Therapeutics by Laurence Brunton, Donald Blumenthal, Iain Buxton and Keith Parker
5. Goodman and Gilman's The Pharmacological Basis of Therapeutics, by Laurence Brunton, Bruce Chabner and Bjorn Knollman

## PP-530

### Clinical Pharmacy

(1 credit)

1. Evolution of clinical pharmacy and current scenario (ward and clinical pharmacy services responding to symptoms).
2. **Modified release dosage forms:** Advantages and limitations of modified release dosage forms for patient treatment.
3. Update on advances in biotechnology and gene therapy.
4. **Biochemical and other laboratory data interpretation (in association with clinical information and limitations of laboratory results):** Case studies (workshops) of renal, hepatic, cardiac, respiratory, diabetic (including dose adjustment of insulin with glucose monitoring), epileptic (including DIs, TDM) and elderly osteoporotic patients; Inclusion of issues around hypo/hyperthyroid/thyrotoxicosis and anticoagulation therapy within these cases.
5. Therapeutic drug monitoring of digoxin, theophylline, phenytoin, phenobarbitone, carbamazepine and gentamicin.
6. **Understanding audit:** Audit cycle, identifying key issues, setting standards; Audit process; Results and re-audit.
7. **Clinical trials and pharmacists' involvement:** Legal and ethical requirements of trials.
8. **Research Methods:** Designing, planning and carrying out a research project; Research methodologies (quantitative, qualitative) - uses, adequacy and limitations; Choice of methods for a particular project; Process, analysis and interpretation of data; Project itself-in process, written report and defence.

#### **Recommended books:**

1. Tietz Fundamentals of Clinical Chemistry, Edited by Carl A Burtis & Edward R Ashwood
2. Oxford American Handbook of Clinical Pharmacy (Oxford American Handbooks of Medicine by Michelle McCarthy and Denise R. Kockler
3. Laboratory Tests and Diagnostic Procedures by Cynthia C Chernecky, Barbara J Berger
4. Research Methods by Patrick Mc Neill & Steve Chapman
5. Schedule Y of the Drugs and Cosmetics Act, Govt of India, current version

## LG-511

### Clinical Placement

(3 credits)

1. **Choice of patients for case studies:** Relevance to pharmacists' involvement.
2. Patient profiles (Three).
3. Case presentations (Two).
4. Group discussions for 'real' patient issues (6 per semester).
5. Ability to pick the right cases/problems/issues, which would be relevant to pharmaceutical care.

6. **Communication skills with staff, patients and care givers/relatives (level of improvement):** Gathering additional information e.g. drug history, allergies, previous medical history, self-medication, use of OTC preparations and knowledge about these and other information relevant to therapy; Counselling ability in view of patients' wish to be so counselled.

## **LG-512**

### **Computer Applications**

(2 credits)

1. **Separation Techniques (30 hours):**
2. **Computer and application in pharmaceutical sciences (100 hours):** Introduction to computer, basic unit and function, 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. **Pharmacy practice specialization practical (50 hours):** Handling of databases on medicines, medicine management and retrieval of information as required in medicine information activity; and handling EBM software are parts of the pharmacy practice specialization practical.

## Clinical Research

### CR-510

#### Drug Discovery and Development

( 2 credits)

1. **History of drug development:** Discovery and selection of compounds for human Investigation.
2. **Pharmacokinetics and pharmacodynamics:** Drug interactions, Special populations: elderly, children, renal and hepatic insufficiency.
3. The principal innovative steps in discovering, modifying, assessing and patenting new chemical and biological compounds.
4. The laboratory and animal testing of new compounds and the correlation of animal with human pharmacology.
5. The selection of compounds for exploratory human investigation and planning initial development work to permit human exposure.
6. **Bioequivalence:** Formulation and stability testing.
7. **Scheduling of toxicological tests:** linked to development plans, to regulatory needs, to human and animal pharmacology, and intended clinical use and route(s) of administration.
8. Toxicological requirements.
9. The size, cost and administration of a toxicological programme, its data management and its quality assurance, and report writing.
10. Review of toxicology data, its inclusion into clinical trial protocols and brochures, and the appropriate planning of and correlation with the clinical evaluation of potential and observed toxicity in patients.

#### **Recommended books:**

1. Principles and Practice of Pharmaceutical Medicine edited by Lionel D. Edwards, Andrew J. Fletcher, Anthony W. Fox
2. New Drugs: Discovery and Development, edited by Alan A. Rubin
3. The Drug Development Process: Increasing Efficiency and Cost Effectiveness, edited by Peter G. Welling, Louis Lasagna, and Umesh V. Banakar

These are just the indicative books. Students are advised to update themselves with recent regulatory guidelines issued by different agencies like USFDA, ICH, EMEA, CDSCO

### CR-520

#### Introduction to Clinical Research

(1 credit)

1. Fundamental principles of comparative clinical trials in investigating effectiveness, efficacy and safety of treatments.
2. Main features of clinical trials, including methodological & organizational considerations.
3. The principles of trial conduct and reporting.
4. Key decisions surrounding clinical trial design and sample size.
5. Delivery and assessment of clinical trials.
6. Primary and secondary objectives and endpoints of clinical trials.
7. The implications of design choices for implementation of a trial: Trial governance, clearances, and data collection and recruitment methods.

8. Good clinical practice.
9. International conference on harmonization, USFDA, EMEA, ICMR, Schedule Y.

**Recommended books:**

1. Clinical Drug Trials and Tribulations: Second Edition, Revised and Expanded, Edited by Allen Cato, Lynda Sutton, and Allen Cato III
2. Principles and Practice of Clinical Research by John I. Gallin

These are just the indicative books. Students are advised to update themselves with recent regulatory guidelines issued by different agencies like USFDA, ICH, EMEA, CDSCO

## CR-530

### IRBs and Ethics in Clinical Trials

(1 credit)

1. **Declaration of Helsinki:** Roles and responsibilities of ethics review board / Institutional review board.
2. Role of Independent ethics committee.
3. Approval/permission for the conduct of clinical trials.
4. **Document review:** Review progress.
5. Regulatory compliance.
6. Selection of subjects, informed consent.
7. **Therapeutic Research-Randomized controlled trials:** Control groups, randomization, blinding (masking), random allocation and concealment, drop outs, concomitant medication.
8. **Non-therapeutic research:** The use of placebos, allotment of treatment.
9. **Ongoing trials:** Stopping the study, confidentiality, fraud, continuing treatment.
10. Trial results and moral theory

**Recommended books:**

1. Design, Execution and Management of Medical Device Clinical Trial by Salah Abdel-Aleem
2. Adaptive Design Methods in Clinical Trials by S.C Chow, M. Chang  
Design and Analysis of Quality of Life Studies in Clinical Trials by Diane L. Faircloth

## LG-513

### Computer Applications

(2 credits)

1. **Computer application in pharmaceutical sciences (100 hours):** Introduction to computer, basic unit and function, 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.
2. **Lab experience in data entry, database management, & data handling (80 hrs.):**  
The 80 hrs of training would comprise experience and development of skills in using different drug databases, priming on SPSS software and use of web-based resources for clinical research. This experience will also cover techniques on Clinical Data Management to an extent.

## Pharmaceutical Technology (Formulations)

### PT-580

#### Regulatory Considerations for Formulation Development

(1 credit)

1. International regulatory trends in pharmaceutical industry.
2. Harmonizing formulation development for global filings.
3. Product development information in regulatory filings development pharmaceuticals guidelines. Chemistry manufacturing and controls (CMC).
4. Global requirements on stability studies, residual solvents and impurities.
5. Dealing with post-approval changes.

#### **Recommended books:**

1. New Drug Approval Process, Edited by Richard A. Guarino, Marcel Dekker
2. The Pharmaceutical Regulatory Process, Edited by Ira R. Berry, Marcel Dekker
3. Medical Product Regulatory Affairs, Edited by J. J. Tobin and G. Walsh, Wiley VCH

### 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, analgesic activity of a compound, estimation of protein and haematological parameters.
4. **Biotechnology in pharmaceutical sciences (20 hours):**

Day -1: Preparation for plasmid minirep.

Day-2: Plasmid minirep and restriction digestion.

Day-3: Gel electrophoresis and molecular weight calculation.

Day-4: Discussion of result and viva.
5. **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 behaviour/ drug release pattern of various conventional, sustained release, enteric coated and nano particulate 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.

## Pharmaceutical Technology (Process Chemistry)

### 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.

#### *Recommended books:*

1. Process Chemistry in Pharmaceutical Industry by Kumar Gadamasetti, Vol I & II
2. Advanced Organic Chemistry by Jerry March
3. Pharmaceutical Process Chemistry for Synthesis: Rethinking the Routes to Scale-Up by Peter J. Harrington, Wiley
4. Practical Process Research and Development by Neal G. Anderson, Academic Press
5. Strategies for Organic Drug Synthesis and Design by Daniel Lednicer

### PT-560

#### Synthetic aspects of Process Chemistry

(2 credits)

1. **Reaction progress kinetic analysis:** Streamlining reaction steps, route selection, characteristics of expedient routes, characteristics of cost-effective routes, reagent selection, families of reagents useful for scale-up, solvent selection, selecting solvents based on physical characteristics, selected solvent impurities
2. **Green chemistry:** 12 Principles of green chemistry, examples of greener route to chemical reactions, designing robust reaction conditions, reaction media for green chemistry, organic reactions in water, sustainable development of a process
3. **Transition-metal and Organo-catalysis in organic synthesis:** Metal-catalyzed reactions, asymmetric organocatalysis, phase transfer catalysis, benefits and challenges of applying phase transfer catalysis technology in pharmaceutical industry
4. **Emerging trends in process chemistry:** Use of Domino, Cascade, and Tandem reactions, multi-component reactions, development of efficient one-pot process with examples, lithium-halogen exchange reactions in process chemistry
5. **Click chemistry:** Beyond the paradigm of carbonyl chemistry, Click chemistry reaction

types, Click chemistry in water, Click reactions in “solid phase synthesis”, examples of Click Chemistry sequences-diversity with ease, its application in the synthesis of heterocycles and macromolecules

6. **Microwave reactions:** Discovery and advantages of its use, increased reaction rates, mechanism, superheating effects of microwave, effects of solvents in microwave assisted synthesis, microwave technology in process optimization, its applications in various organic reactions and heterocycles synthesis
7. **Impurity consideration:** Introduction, Steps to optimizing reactions, minimizing impurity formation by indentifying impurities first, method development for separation, synthesis and isolation of impurities and their characterization, Statistical design of experiments
8. **Troubleshooting:** Physical and chemical causes of processing problems, steps for troubleshooting a process, debottlenecking a problem, Stereoselective enzymatic synthesis of APIs

**Books recommended:**

1. Process Chemistry in the Pharmaceutical Industry by Kumar Gadamasetti, Marcel Dekker Inc.
2. Practical Process Research & Development by Neil G. Anderson, Academic Press
3. Principles of Process Research and Chemical Development in the Pharmaceutical Industry by O. Repic, John Wiley & Sons, Inc
4. Pharmaceutical Process Chemistry for Synthesis by Peter J. Harrington

## 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 on FORTRAN language and programming, hands-on experience in pharmaceutical software systems. Use of computers in information retrieval systems.
3. **Specialization (95 hours):**

*List of Experiments:*

Esterification; Etherification; Tosylation; Hydrogenation; Nitration; Grignard; Witting; Claisen- Schmidt; Friedel-Crafts alkylation and acylation; Halogenation; Cyloaddition; Sulphonation; Cannizzaro; Benzoin condensation; Aldol and cross-aldol condensation; Dehydration reaction of amides and aldoximes; Hydroxylation; Coupling and Hofmann reaction.

## Pharmaceutical Technology (Biotechnology)

### PT-520

#### Microbiology

(1 credit)

1. **Introduction, aims and scope:** Organization and function of prokaryotic and eukaryotic cells; structure and function of cell organelles-structure, special organelles, cellular reserve materials.
2. **Distinguishing feature of various groups of microorganisms:** Actinomycetes, bacteria, moulds, yeasts and algae and their broad classification.
3. **Characteristics of selected groups of microbes:** Archaeobacteria and microorganisms of extreme environment: Control of microorganisms by physical and chemical agents; pure culture concept and culture 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-doudorff and glyoxalate pathways: Anaerobic respiration: Microbial pathogenicity.
7. **Recycling of energy sources:** Bioassays, recycling of carbon, nitrogen and sulphur: Role of micro-organisms 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; Basic aspects of the immune response; Bacterial agents of disease.

#### **Recommended books:**

1. Microbiology, 5th Edition by Michael J. Pelzer, Jr. E.C.S. Chan, Noel R. Krieg
2. Biotechnology: A Textbook of Industrial Microbiology by Wulf Crueger, Anneliese Crueger,
3. Prescott's Microbiology by Joanne M. Willey, Linda Sherwood, Christopher J. Woolverton, Lansing M. Prescott
4. Brock's Biology of Microorganisms by Michael T. Madigan, John M. Martinko, Jack Parker
5. Principles of Fermentation Technology by Peter F. Stanbury, Allan Whitaker, Stephen J. Hall
6. Principles of Microbe and Cell Cultivation by S.J.Pirt
7. Instant notes in Microbiology by S. Baker, Jane Nicklin
8. Biotol series (This series has many books pertaining to all fields of Biotechnology, students have to select the books as per the topics of interest)

## PT-530

### Biochemical Engineering Fundamentals

(2 credits)

1. **Homogeneous 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; First-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 of 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-ualescence 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 the 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 coefficients; Heat transfer equipment; Steady state conduction; 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.

#### **Recommended books:**

1. Bioprocess Engineering: Basic Concepts 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. Biochemical Engineering Fundamentals by James Edwin Bailey, David F. Ollis

6. Biotol series (This series has many books pertaining to all fields of Biotechnology, students have to select the books as per the topics of interest)

## PT-540

### Animal and Plant Cell Technology

(1 credit)

1. **Animal cell metabolism:** Regulation and nutritional requirement; Animal cell growth characteristics and kinetics.
2. **Transport of nutrients:** Substrate and product transport through mammalian cell. Active and passive transport, calculation of free energy from the transport system.
3. **Growth and mass transfer:** Micro-carrier attached growth, cell culture in continuous, perfusion and hollow-fibre reactor; mass transfer in mammalian cell culture.
4. **Plant and animal cell culture:** Ovary and ovule culture, In vitro pollination and fertilization; Pollen culture; Anther culture, Embryo culture; Embryo rescue; Somatic embryogenesis; Endosperm culture and production of triploids; Organ culture; Primary explant cultures; Established cell lines; Cell fusion; Transplantation of cultured cells (Grafting); Commonly used cell lines: origin and characteristics.
5. **Scale up:** Scale up of cell culture process; Case studies: Special features and organization of plant cells; Totipotency; regeneration of plants; examples of regeneration from leaves, roots, stem etc.
6. **Plant products:** Plant products of industrial importance, biochemistry of major metabolic pathways and products; Cell suspension culture development; Metabolite productions in culture for pharmaceutical, agrochemical and food industries.
7. **Kinetics:** Characterization, kinetics of growth, product formation and examples; Large scale production of secondary metabolites from suspension cultures-nutrient optimization, cell growth regulators, Somaclonal variations, plant cell reactors, types of reactors, comparison of reactor performance; Immobilized plant cells reactors; Novel design concept.
8. **Stem cells:** Embryonic stem cells; reprogramming somatic cells into induced pluripotent stem cells; Stem cells in domestic live stock species; Adult stem cells In clinical trials.
9. **Plant genetic engineering:** Protoplasts and tissue culture for genetic manipulation of plants; Agrobacterium tumefaciens mediated gene transfer, Case studies of Agrobacterium tumefaciens mediated transgenic plants generation.
10. **Animal genetic engineering:** Transfixion methods and Transgenic animals gene transfer, Transfixion of cultured cells; Targeted gene transfer; Principles of ex vivo and in vivo gene transfer.

#### **Recommended books:**

1. Biotol series, Invitro Cultivation of Animal Cells by Butterworth Heinemann
2. Biotol series, Invitro Cultivation of Plant Cells by Butterworth Heinemann
3. Animal Biotechnology by M.M. Ranga
4. Molecular Biotechnology by Bernard R. Glick, Jack J. Pasternak
5. Animal and Plant Biotechnology by Bhojwani & Razdan
6. Molecular Cell Biology by Harvey F. Lodish
7. Introduction to Plant Tissue Culture by M. K. Razdan

## PT-550

### Enzyme and Microbial Technology

(1 credit)

1. **Improvement of industrially important microorganism:** Improvement of industrial microorganism; Isolation of auxotrophic mutants; Isolation of revertant mutants and use of recombinant systems for improvement of industrial microorganisms.
2. **Glycolysis:** Regulatory mechanism of metabolic pathways in industrial strains; Glycolysis and glycolytic enzyme regulation; ATP yield and calculations; solutions of numerical problems in biosynthetic pathways.
3. **TCA cycle and enzyme regulation:** Oxidative phosphorylation and enzyme regulation; ATP yield and calculations; solutions of numerical problems in biosynthetic pathways.
4. **Fatty acid metabolism:** ATP yield and calculations; solutions of numerical problems in biosynthetic pathways.
5. **Enzymology:** Source of enzymes; Production, isolation and purification of enzymes; Characterization in terms of pH, temperature, ionic strength, substrate and product tolerance, effects of metal ions etc.
6. **Enzyme kinetics:** Enzyme as biological catalysis; Enzyme action, active site, functional group, enzyme substrate complex, cofactors, Michaelis-Menten equation,  $K_m$  and  $V_{max}$ , enzyme inhibition; order of reaction, methods of plotting enzyme kinetics data; Enzyme turnover. Solution of numerical problems; Energy yielding and energy-requiring reactions; Calculation of equilibrium constants; Activation energy etc.; Multisubstrate enzymes and kinetics mechanisms; Enzyme induction, repression, covalent modification, Isoenzymes, allosteric effects.
7. **Immobilized enzyme technology:** Different techniques of immobilization of enzymes and whole cells; Advantages and disadvantages of immobilization; Kinetics of immobilized enzymes, design and operation of immobilized enzymes reactors; Calculations of diffusional resistances and Thiele's modulus, multi step immobilized enzyme systems; Solution of numerical problems; Application and future of immobilized enzyme technology.
8. **Enzyme in organic solvents and ionic liquids:** Various organic solvents and ionic liquids used in Biocatalysis; Potential in organic solvents and ionic solvents.
9. **Enzyme biosensors:** Applications of enzymes in analysis; Design of enzyme electrodes and case studies on their application as biosensors in industry; healthcare and environment.
10. **Enzyme engineering:** Random and rational approach of protein engineering; Directed evolution and its application in the Biocatalysis; various approaches of creating variant enzyme molecules; Future of Biocatalysis; Ideal biocatalyst.

#### **Recommended books:**

1. Lehninger's Principles of Biochemistry by Albert L. Lehninger, David Lee Nelson, Michael M. Cox
2. Biochemistry by Donald Voet, Judith G. Voet
3. Enzyme and Microbial Technology by J.Rehm and G.Reed
4. Biochemical Calculations: How to Solve Mathematical Problems in General Biochemistry by Irwin H. Segel

5. Biotol Series (This series has many books pertaining to all fields of Biotechnology students have to select the books as per the topics if interest)

## 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 haematological parameters.
4. **Specialization (70 hours):**

List of experiments:

  - i) To find out the  $K_m$  and  $V_{max}$  of an enzyme using various known plots.
  - ii) To study the type of inhibition (competitive and non-competitive etc) in an enzyme substrate reaction.
  - iii) To plot a growth curve of *S. cerevisiae*.
  - iv) To plot an standard curve of optical density vs. dry cell weight by cultivating *S. cerevisiae*.
  - v) To count bacterial cells by Hemacytometer counting method.
  - vi) To calculate the percentage viability of a culture by pour and spread plate method.
  - vii) To find out the growth yield coefficient ( $Y$ ) and maintenance coefficient ( $m$ ) of a yeast culture.
  - viii) To calculate the holding time and to determine the  $N_D$  factor in sterilization.
  - ix) To calibrate DO and pH probe in a bioreactor.
  - x) To demonstrate the fluid flow pattern in an aerated and agitated reactor.
  - xi) To determine the Mass Transfer Coefficient ( $K_L a$ ) at various aeration rates by Static Gassing out method.
  - xii) To determine the Mass Transfer Coefficient ( $K_L a$ ) at various mixing rates by Static Gassing out method.
  - xiii) To determine the  $K_L a$  by Sodium Sulphite method.

## General Courses

### 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 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 pharmaceuticals:** Experimental design in clinical trials; Parallel and crossover designs. Statistical test for bioequivalence. Dose response studies; Statistical quality control.

#### **Recommended books:**

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

### GE-520

#### Fundamentals of Intellectual Property (IP) and Technology Management (1 credit)

1. **Intellectual property:** Concepts and fundamentals; Concepts regarding intellectual property (IP), intellectual property protection (IPP) and intellectual property rights (IPR); Economic importance, mechanisms for protection of intellectual property-patents, copyrights, trademark; Factors effecting choice of IP protection; 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 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, brochures, periodicals, CD roms; Significance of copyright protection for researchers; Indian Copyright Law and digital technologies-Berne convention, WIPO copyright treaty (WCT), WIPO performance and Phonogram Treaty (WPPT); Protection for computer data bases, multi media works; Trade marks legislation and registration system in India-an introduction, meaning of trademark criteria for eligibility; filling application for trademark registration; Trade secrets-scope modalities and protection; Case studies-drug related patents infringements.
4. **Technology development / transfer / commercialisation related aspects:** Technology development-meaning; Drug related technology development; Toxicological studies, bioequivalence (BU), clinical trials-phase-I, phase-II and phase-III; Approved bodies and agencies; Scale-up, semi-commercialisation and commercialisation-practical aspects and problems; Significance of transfer of technology (TOT), bottlenecks; Managing technology transfer-guidelines for research students, scientists and related 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 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.

**Recommended books:**

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

**GE-511**

**Seminar**

(1 credit)

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

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

**Courses of Study 2016  
Semester-II**



# Medicinal Chemistry

## MC-610

### Drug Design

(2 credits)

1. **Electronic Structure methods:** Quantum chemical methods semi-empirical and ab initio methods. Conformational analysis, energy minimization, comparison between global minimum conformation and bioactive conformation. Predicting the mechanism of organic reactions using electronic structure methods. Complete and constrained conformational search methods, their advantages and disadvantages. Theoretical aqueous solvation calculations for design of ligands. Conformational interconversion, transition-state determination and their role in designing rigid analogs.
2. **Quantum chemical methods of analyzing drugs:** Metformin, its comparison to carbonates, 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 of CoMFA and CoMSIA.
6. **Molecular docking** :. Rigid docking, flexible docking, manual docking. Advantages and disadvantages of Flex-X, Flex-S, Autodock and Dock softwares, with successful examples.
7. **Molecular dynamics:** Dynamics of drugs, biomolecules, drug-receptor complexes, Monte Carlo simulations and Molecular dynamics in performing conformational search and docking. Estimation of free energy from dynamical methods.
8. **Pharmacophore concept:** Pharmacophore mapping, methods of conformational search used in pharmacophore mapping. Comparison between the popular pharmacophore methods like Catalyst/HipHop, DiscoTech, GASP with practical examples.
9. **De Novo drug design techniques:** Receptor/enzyme cavity size prediction. Predicting the functional components of cavities, designing drugs fitting into cavity.
10. **Informatics methods in drug design:** Brief introduction to bioinformatics, cheminformatics. Their relation to drug design as per the topics discussed in items 1-9 above.

**Recommended books:**

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

**MC-620**

**Logic in Organic Synthesis-II**

(3 credits)

1. **Metal/ammonia reduction:** Reduction of mono-, bi- and tri-cyclic aromatic systems and various functional groups, reductive alkylation, regio- and stereoselectivity; Reduction of alkynes; Complex metal hydrides and selectrides.
2. **Reaction of electron-deficient intermediates:** Carbene, nitrene and free radical, their stabilities and modes of generation; Addition and insertion reactions of carbenoids and nitrenoids - regio- and stereoselectivity, role of the metal catalysts in the 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 diastereoselection, asymmetric amplification; Asymmetric synthesis of amino acids and beta lactams.
6. **Concerted reactions and photochemistry:** Molecular orbital symmetry, frontier orbitals of 1,3-butadiene, 1,3,5- hexatrienes, allyl system, classification of pericyclic reactions; FMO approach, Woodward-Hoffman correlation diagram method and PMO approach to pericyclic reactions; Electrocycli-creactions-conrotatory and disrotatory motions, [4n], [4n+2] and allyl systems, secondary orbiatl interaction; Cycloaddition- antarafacial and the suprafacial additions, [4n] and [4n+2] sytems with stereo chemical effects, 1,3 -dipolar cycloadditions, chelotropic reactions; Sigmatropic 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 effeciency; Photochemistry of carbonyl compounds, norish type-I and type-II

cleavages, Paterno-Buchi reaction, photoreduction, photochemistry of enones and para-benzoquinones.

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

**Recommended books:**

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

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

## MC-630

### Structure and Function of Biomolecules

(2 credits)

1. **Methods for the determination of structure of biomolecules:** Biological crystallography-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 thermogravimetric analysis (TA) of biomolecules and other thermodynamics based instrumental methods estimating the structural features of biomolecules.
2. **Properties of amino acids and peptide bond:** End group determination of peptides, sequencing of peptides using various chemical and analytical techniques; Aptechiques with case studies like LHRH and TRH peptides.
3. **Protein structure building block to quaternary structure of proteins:** Ramachandran plots; Peptidomimetics; Protein-ligand interactions; Multiple binding modes.
4. Structure of lipoproteins and glycoproteins in relation to their function.
5. **Structure of lipids, polysaccharides and carbohydrates:** Relation-ship between their

- physico-chemical properties and their biological function.
- Detailed structure of nucleic acids and protein-nucleic acid interactions:** Nucleic acid and small molecule interactions; DNA damage and repair.
  - 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; Hyperlipidemia- HMG-CoA its structure and role in cholesterol manipulation.
  - Biological crystallography:** Crystallisation data collection, refinement, identification of active site, phase determination heavy atom derivatives, electron density maps. Differences in the small molecule and biomolecule crystallography.
  - Spectrofluorimetry and Optical methods:** Basic principles of fluorescence, intensity, fluorescent group, sensitivity of fluorescence to environment, biological applications. Optical activity measurements, ORD/CD applications to Nucleic acids and proteins.
  - Thermodynamical methods:** Differential Scanning Calorimetry (DSC) and Thermogravimetric analysis (TA) of biomolecules, Isothermal Titration Calorimetry (ITC). Various thermodynamics based instrumental methods for estimation of structural features of biomolecules, enthalpy vs entropy contribution to free energy.

**Recommended books:**

- Physical Biochemistry: Applications to Biochemistry and Molecular Biology by David Freifelder
- Methods in Modern biophysics, by B. Nolting
- Introduction to Biophysical methods in Protein and Neucleic Acid research, by J.A. Glasel
- Monosaccharides. Their Chemistry and Their Roles in Natural Products
- Essentials of Glycobiology by Varki
- Carbohydrates by Osborn
- Modern Methods in Carbohydrate Synthesis by Khan and O'Neill
- Organic Synthesis with Carbohydrates by Boons and Hale
- Enzymes in Synthetic Organic Chemistry by Wong and Whitesides
- Methods in Modern Biophysics by B. Nolting
- Introduction to Biophysical Methods in Protein and Neucleic Acid Research by J.A. Glasel.

## MC-650

### Stereochemistry and Drug Action

(2 credits)

- Molecular isomerism:** Molecular motion, time scales and energy; Conformation of open chain and saturated cyclic systems.
- Chirality and molecular symmetry:** Nomenclature and representations; Macromolecular stereochemistry; Dynamic stereochemistry.
- Group theoretical interpretation of chirality group:** Laws of group theory, symmetry elements and operations, classification of symmetry operation into groups, chiral and achiral point groups, determination of molecular structures into symmetry point groups,

platonic solids, disymmetrisation.

4. **Conformational analysis:**
  - a) Definitions: Internal coordinates, distinction between conformation and configuration.
  - b) Conformational analysis of cyclic compounds: carbocycles and heterocycles, bi- and tri-cyclic compounds.
  - c) Conformational analysis of acyclic compounds: potential energy diagrams of various acyclic systems, gauche effect, generalized anomeric effect.
5. **Assignment of configuration:** Various projectional formulae, molecular with chiral center, axis and plane.
6. **Front on projectional formula of conformers and configurational isomers:** rational with specific examples.
7. **Resolution procedures:** Biological and chemical; Analytical chiral integrity determinations; Pfeiffer rule and its violations; Recent attempts to develop continuous scale for chirality; Chiral ligands.
8. **Chirality and drug action:** Realization that stereoselectivity is a pre-requisite for evolution; Role of chirality in selective and specific therapeutic agents; Case studies; Enantioselectivity in drug absorption, metabolism, distribution and elimination.

**Recommended books:**

1. StereoChemistry of Organic Compounds by Ernest L. Eliel, Samuel H. Wilen, Lewis N. Mander
2. StereoChemistry of Carbon Compounds by Ernest L. Eliel
3. Chemical Application of Group Theory by F. Albert Cotton
4. Relevant research articles as suggested time to time during the progress of class room teaching.

## LS-610

### General Laboratory Experience 10 hours/week

(2 credits)

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

# Natural Products

## NP-610

### Natural Product and Bio-organic Chemistry

(2 credits)

1. **Importance of marine natural product chemistry in drug development:** Chemistry and biology of marine natural products, marine chemical ecology, marine bioactive compounds 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 & 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 & autocoids:** Classification, identification, biological activity and study of examples.

#### **Recommended books:**

1. Chemistry of Natural Products by S. V. Bhat, B. A. Nagasampagi, M. Sivakumar
2. Medicinal Natural Products: A Biosynthetic Approach by Paul M. Dewick
3. Organic Chemistry Vol. 1: The Fundamental Principles by I. L. Finar
4. Organic Chemistry Vol2: Stereochemistry and the Chemistry of Natural Products by I. L. Finar
5. The Flavonoids Advances in Research since 1986 by J.B. Harborne
6. Some Review Articles published related to chemistry and biological activities of natural products in Tetrahedron, Bioorganic & Medicinal Chemistry; and few research articles published on semi-synthesis and synthesis of bioactive natural products in Journals- Bioorganic & Medicinal Chemistry Letters, European Journal of Chemistry, Tetrahedron Letters, Journal of Natural Products and Phytochemistry.

## NP-620

### Natural Products-II

(2 credits)

1. **Chemotaxonomy:** 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:**

(a) anticancer, (b) anti-diabetic, (c) anti-haemorrhoids, (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 techniques for the removal of common secondary metabolites present in herbal/medicinal plant extracts with suitable examples.

**Recommended books:**

1. Natural Products: Drug Discovery and Therapeutic Medicine by L Zhang, AL Demain
2. Phytochemical Methods A guide to Modern Technique of Plant Analysis by J.B. Harborne
3. Some review articles published related to natural products with various therapeutic activities in Journals- Medicinal Research Reviews, Phytochemistry and Journal of Ethnopharmacology.

## NP-630

### Standardization of Natural Product Drugs / Formulation (2 credits)

1. **Standardization requirements of herbal medicines:** Traditional and folk-lore 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 & 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 & galenical changes, technical limitations, testing methods, combination products.
9. Bioavailability and pharmacokinetics aspects of herbal drugs with examples of well known documented clinically used herbal drugs. Phytoequivalence, pharmaceutical equivalence.
10. **Importance of monographs on standards of medicinal plants and their parts:** Comparative study of British Herbal Pharmacopoeia (BHP), Ayurvedic Pharmacopoeia of India (API), Chinese, Japanese and European Pharmacopoeias, US Formulary. WHO, EMEA and ESCOP guidelines for herbal medicinal products. Preparation of Drug Master File (DMF) for herbal medicines.

**Recommended books:**

1. Trease and Evans Pharmacognosy by William Charles Evans
2. Quality Control Methods for Medicinal Plant Materials by World Health Organization (WHO) Publication, Geneva; 1998.
3. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants, WHO Publication, Geneva; 2003.
4. National Policy on Traditional Medicine and Regulation of Herbal Medicines, A WHO Publication, Geneva; 2005.
5. Few review articles published on standardization/quality control and other aspects of herbal drugs in Journals such as Phytomedicine, Journal of Ethnopharmacology, Phytochemistry (about chemotaxonomy articles), Life Sciences.
6. Few research articles published on analysis of medicinal plants/herbal drug materials in Journals such Phytochemical Analysis, Journal of Pharmaceutical and Biomedical Analysis and Journal of Chromatography A and B.

## NP-640

### Structure Elucidation

(2 credits)

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

10. Structure elucidation - examples from coumarins, triterpenes, and xanthenes.

**Recommended books:**

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

## NP-650

### Medicinal Plants 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 organisation:** Gene families, genetic regulations in transcription and translation in plants.
4. **Mutation 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:** Micro-propagation 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.

**Recommended books:**

1. Introduction to Plant Tissue Culture by M. K. Razdan
2. Molecular Cell Biology by Lodish, Berk, Matsudairn, Kaiser, Kriegen, Scott, Zipursky, Darnell
3. Advanced Molecular Biology by R. M. Twyman
4. Ecology-Principles and Applications by J. L. Chapman and M. J. Reiss
5. Instant Notes in Ecology by Aulay Mackenzie, Andy S Ball, Sonia R, Virdee
6. Gene VIII by Lewin

## LS-610

### General Laboratory 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 triterpenes 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.

# Traditional Medicine

## TM-610

### Chemical Standardization of Herbal Drugs

(2 credits)

1. **Chemical standardization:** Need for standardization, issues related to herbal medicines, safety of herbal medicines, substitution and misidentification, toxicity, efficacy, standardization, and documentation of herbal medicines.
2. **Quality control methods for medicinal plant materials:** General considerations on measurements, storage, powder fineness, sampling, foreign matter.
3. **Determination of physical parameters:** Procedures, total ash, acid insoluble ash, water-soluble ash, extractive values of herbal drugs, moisture content determination and loss on drying of herbal drugs, determination of bitterness value, haemolytic activity, and foaming index, swelling index of gum and mucilage containing drugs.
4. **Volatile oil content:** Determination of volatile oil content herbal drugs, procedure, apparatus, methods, estimation of fixed oils and lipids of herbal drugs.
5. **Phytochemical assays:** Estimation of tannins, phenols and flavanoids, glycosides and vitamins in herbal drugs with methods and examples.
6. **Limit tests:** Heavy metals (arsenic, lead) in herbal drugs, microbial contamination of crude drugs and its detection, pesticide residues.
7. **Markers and biomarkers:** Concept and their importance in standardization of herbal drugs, analytical method development and estimation of alkaloids, steroids, carbohydrates, polypeptides/proteins of herbal drugs.
8. **Analytical methods:** Various methods for quantitative estimation of marker compounds such as HPTLC and HPLC, general methodology, quantitative analysis, validation of methods.
9. **Examples on standardization:** Discussion on research papers on standardizations of selected categories of Ayurvedic drugs, such as asavas, arishtas, churnas, ghritas, oils etc.
10. **Monographs:** Preparation of monographs for standardization purpose, selected examples from Ayurvedic Pharmacopoeia of India.

#### **Recommended books:**

1. WHO Guidelines on Quality Control of Medicinal Plants
2. Ayurvedic Pharmacopoeias of India
3. Various Research Publications

## TM-620

### Pharmacological Evaluation of Herbal Drugs

(2 credits)

1. Principles of drug evaluation: Methods of dose fixation and general data on laboratory animals.

2. Importance and study of in vitro and in vivo methods of drug screening.
3. Different therapeutic categories of botanical drugs: Pharmacological activities of these drugs and their correlation to therapeutic category.
4. Different in vitro and in vivo bioassays for evaluation of pharmacological activity of botanical/herbal drugs.
5. Pharmacodynamics and psychodynamic effects of herbal medicines.
6. Combined effects of pharmacodynamic and psychodynamic properties on the efficacy of herbal drugs.
7. Herbal-drug and food-drug interactions.
8. Interactions of herbal drugs and their derived compounds.
9. Safety aspects and adverse reactions of herbal medicines.
10. Toxicological evaluation of herbal drugs.

**Recommended books:**

1. Goodman & Gillman's, The Pharmacological Basis of Therapeutics, edited by Joel G. Hardman, Lee E. Limbird, Consulting editor, Alfred Goodman Gilman
2. Herbal Medicine-Science Embraces Tradition- A New Insight into Ancient Ayurveda, editors- Narendra Singh and Marilena Gilca

## TM-630

### Clinical Aspects of Herbal Drugs

(2 credits)

1. Challenges to scientific understanding of herbal medicines.
2. Effects of herbal medicines and their working with alternative medicines.
3. **Clinical proof, clinical reality of herbal drugs:** Evidence of clinical research carried out on herbal drugs.
4. **Clinical trial protocol development:** Phases of clinical trial, responsibilities of investigators and sponsor.
5. Comparison of clinical study data of pharmaceuticals versus herbal drugs.
6. **Ethical principles:** Design and broad objectives of clinical trials for herbal drugs, type and laying of protocol for clinical trial.
7. **Parallel and cross over design of clinical trial:** Placebo in clinical trials, sample size and objectives.
8. Limitations of clinical trials of herbal drugs.
9. Linkages between pharmacological and epidemiological studies carried on herbal drugs.
10. Determinants of adverse drug reactions and post marketing surveillance data available for herbal drugs.

**Recommended books:**

1. Pharmacoepidemiology, edited by Brian L. Strom
2. Clinical Trial Manual from the Duke Clinical Research Institute by Margaret B.Lin & Kate Davis
3. Clinical Pharmacology by D.R. Laurence, P.N. Bunnet
4. Principle and Practice of Clinical Trial Medicine by, Richard Chin and Bruce Y. Lee
5. GMP and GLP as per guideline of AYUSH, Ministry of Health and Family Welfare, Govt. of India.

## TM-640

### Herbal Formulation

(2 credits)

1. **Formulations based on crude herbs:** Product classification, tablets, capsules: Powdering of crude herbs, particle size, Carr's compressibility index and homogeneity of powdered herbs.
2. **Formulations based on plant extracts:** Total extracts and purified extracts. Conventional properties of extracts: appearance, pH, total solids, ash values.
3. Solubility of the soft and dry extracts in common formulation solvents, particle size with tolerance limits for fines.
4. **Injectable/Parenteral formulations:** Study of essential requirements such as solubility and sterility.
5. Different problems encountered in herbal formulations and their remedy.
6. Setting of Standard Operating procedures (SOPs) for each step of herbal formulations with emphasis on reproducibility.
7. **SOPS:** 3-4 Examples from herbal products.
8. Stability testing of herbal drugs.
9. Preparation of Drug Master File (DMF) for herbal formulations with examples.
10. **Regulatory aspects and quality control:** Regulatory requirements for herbal drugs, registration and licensing requirements.

**Recommended books:**

1. Review and research articles published on herbal formulations in the Journals, Fitoterapia, Phytomedicine, International Journal of Pharmaceutics, European Journal of Pharmaceutics and Biopharmaceutics, AAPS PharmaSciTech-USA and Indian Journal of Pharmaceutical Sciences.
2. Herbal Drugs Industry by R.D. Chaudhary

## LS-610

### General Laboratory Experience - 15 hours/week

(3 credits)

1. Standardization study of Herbal drugs/Medicinal plant materials/formulations by following the 'WHO guidelines' and 'The Ayurvedic Pharmacopoeia of India'.
  - a) Determination of Total Ash

- b) Determination of Aid-Insoluble Ash.
  - c) Determination of Water-Soluble Ash.
  - d) Determination of Sulphated Ash.
  - e) Determination of Alcohol- Soluble Extractive.
  - f) Determination of Water-Soluble Extractive.
  - g) Determination of Ether-Soluble Extractive (Fixed Oil Content)
  - h) Determination of Moisture Content (Loss on Drying)
  - i) Determination of Volatile Oils in Drugs
  - j) Estimation of Alkoloid
  - k) Estimation of Fatty Oil
  - l) Determination of Bitterness Value
  - m) Determination of Swelling Index
  - n) Determination of Foaming Index
  - o) Determination of Haemolytic Activity
  - p) Determination of Pesticides Residues
  - q) Determination of Aerobic Microorganisms
  - r) Determination of Anaerobic Microorganisms
2. Isolation of curcumin/lupeopl from *Curcuma longa* and *Crataeva nurvala* and their application as marker compounds in the Chemical Standardization and Chemoprofile matching study by
- a) UV-visible
  - b) HPLC
  - c) HPTLC
  - d) GC-MS
3. a. Preparation of one Ayurvedic Formulation from each segment.  
b. Concept of Rasashala and use of ancient purification method for crude drugs.  
C. Preparation of Kshar-sutra.

## Pharmaceutical Analysis

### PA-610

#### Pharmacopoeial Methods of Analysis

(2 credits)

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

1. **Physical tests:** Viscosity, melting point, boiling point/range, water content, osmolality/osmolarity, refractive index, loss on drying, loss on ignition, optical rotation, pH and specific gravity.
2. **Limit tests:** Tests for arsenic, lead, chloride, sulfate, and heavy metals.
3. **Special tests:** Inorganic impurities, residual solvents, etc.
4. **Microbiological assays:** Antimicrobial effectiveness testing, microbial limit tests, sterility test.
5. **Biological tests:** Antibiotics-microbial assays, bacterial endotoxins test.
6. **Dissolution tests:** Types of dissolution apparatus, dissolution test requirements for immediate release, delayed release, extended release dosage forms; coated, uncoated and enteric-coated tablets; gelatin capsules, etc.
7. **Miscellaneous tests:** Test for epianhydrotetracycline and epitetraacycline (USP).

#### **Recommended books:**

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

### PA-620

(2 credits)

#### Modern Instrumental Techniques for Evaluation of APIs and Drug Products

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 application, derivative differential thermal analysis (DDTA).

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

3. **Particle sizing:**

Light interaction methods: Rayleigh or static laser light scattering, photon correlation spectroscopy or dynamic laser light scattering, single particle light scattering, multi-angle light scattering.

4. **Electrophoresis:**

Capillary electrophoresis: Basic principle (zeta potential), instrumentation, different modes of CE, advantages and disadvantages, pharmaceutical applications.

5. **Chromatographic techniques:**

a) HPLC: Principle, instrumentation, pharmaceutical applications.

b) UPLC: Principle and applications.

c) LC-MS and LC-NMR: Nature of interfaces, applications.

**Recommended books:**

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

## PA-630

### Stability Testing

(1 credit)

1. **Drug development cycles and stability testing:** Role and types of stability studies during different stages of drug and product development.
2. **Stress testing:** Role, regulatory aspects, protocols/approaches, practical considerations.
3. **Stability-indicating methods:** Definition, regulatory requirement, steps in development, practical considerations.
4. **Role of kinetics studies:** Important mechanistic and stability-related information provided by results of study of factors like temperature, pH, buffering species, ionic strength, dielectric constant, etc. on the reaction rates.
5. **Stability testing protocols:** Selection of batches, container orientation, test parameters, sampling frequency, specifications, storage conditions, recording of results, concept of stability commitment, etc.
6. **Retest period/shelf life determination:** Evaluation of stability data.

7. **Photostability:** Photostability testing of new active substances and medicinal products, light sources and options, types of chambers, presentation of samples, practical considerations, confirmatory testing.
8. **Stability testing of biotechnological products:** Typical stability testing issues of biotechnological vis-à-vis conventional products, considerations in ICH Q5C guideline.
9. **Stability testing of phytopharmaceuticals:** Regulatory requirements, protocols, HPTLC/HPLC finger printing, Interactions and complexity.
10. **Post-approval changes:** Nature of post-approval changes. Regulatory requirements of stability re-workup.
11. **Reduced stability-testing plans:** Bracketing and matrixing designs for multiple strength, packaging, etc.
12. **Ongoing and follow-up stability testing:** Definitions, applicability, requirements in WHO 2009 stability testing guideline.
13. **Stability test equipment:** Types of stability chambers (walk-in, stand-alone, photostability), design considerations, qualification and other critical issues.

**Recommended books:**

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

## PA-640

### Quality Control and Quality Assurance

(2 credits)

1. Good manufacturing practices and its applications to pharmaceutical industry.
2. Basic principles and concepts of quality management viz. quality control, quality assurance, quality auditing and ISO system etc.
3. Sampling, finished products 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.

**Recommended books:**

1. Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials
2. Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials by *D.H. Shah, Q.A. Manual*
3. Good Pharmaceutical Manufacturing Practice: Rationale and Compliance by *John Sharp*
4. WHO Expert Committee on Specifications for Pharmaceutical Preparations

**LS-610****General Laboratory Experience-10 hours/week****(2 credits)****Practicals in lab:**

1. Analysis of a drug sample by a pharmacopoeial method and preparation of its certificate of analysis.
2. Determination of viscosity of given samples using Ostwald viscometer and rotoviscometer.
3. Estimation of the given drug in urine and blood samples using HPLC and identification of metabolites.
4. Stress study of a drug sample in proposed conditions and 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 behaviour 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

### 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.

#### *Recommended books:*

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

### PC-611

#### Pharmacological Screening and Assays

(1 credit)

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

#### *Recommended books:*

1. Drug Discovery and Evaluation: Pharmacological Assays by Vogel
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:** Benzodiazepines and its antagonists. Barbiturates, local 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 antiepileptics.
6. Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of drugs used in the treatment of Parkinsonism.
7. Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of centrally acting muscle relaxants.
8. Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of narcotic analgesics.
9. Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of psychomotor stimulants and psychotomimetic drugs, antipsychotic drugs.
10. Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of drugs used in Alzheimer's disease,
11. Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of: respiratory stimulants, bronchodilators and anti-inflammatory agents used in asthma, cough suppressants.

**Recommended books:**

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

**PC-630**

**Autonomic, CVS, Blood, Renal, and GI Pharmacology**

(2 credits)

1. Chemical transmission of the autonomic nervous system.
2. **Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of the followings:** Muscarinic cholinergic receptor agonists and antagonists. Ganglionic stimulants and blocking agents, neuromuscular blocking agents, drugs acting and adrenoceptors.
3. **Cardiac glycosides and other cardiotonic agents:** Anti dysrhythmic drugs, antianginal drugs.
4. **Antihypertensives:** Calcium channel antagonists, ACE inhibitors, endothelium derives 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 hemostatic agents.
8. **Factors necessary for erythropoiesis:** Homopoietic growth factors.
9. H2 receptor antagonists: Proton pump inhibitors, antacids, emetics, antiemetics and cancer chemotherapy, purgatives,

10. **Drugs regulate the GI motility:** Cholagogues and drugs used in cholelithiasis.

**Recommended books:**

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

## PC-640

### Autacoids and Endocrine Pharmacology

(1 credit)

1. Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of the following Histamine and brady kinin agonist and antagonists.
2. Drugs acting through eicosanoids and platelet activating factor.
3. Adenohypophyseal hormones and related substances.
4. Thyroid and antithyroid drugs.
5. Insulin and oral hypoglycemic agents.
6. Endocrine pancreas.
7. Adrenocortical hormones: adrenocortical steroids and inhibitors of the synthesis.
8. Agents affecting the clacification, estrogens and progesterone and their antagonists.
9. Oral contraceptive.
10. Androgens.

**Recommended books:**

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

## PC-650

### Clinical Pharmacology and Regulatory Toxicology

(2 credits)

1. **Introduction to clinical pharmacology:** Importance of clinical pharmacokinetics, therapeutic monitoring of important drugs.
2. **Drug-drug interactions:** Drug-food interactions; Drug-pollutant interaction.
3. Investigational new drug application, new drug application requirements; FDA requirements.
4. Preclinical testing strategy; Vis a-vis envisaged clinical studies; Experimental clarification of possible human risk; Technical details of experiments; Flow chart for development of preclinical testing.
5. Design and organisation of phase-I to phase-IV clinical studies.
6. **Single dose and repeat dose toxicity studies:** Factors influencing such studies such as species, sex, size, route, dose level; Data evaluation and regulatory requirements.
7. **Reproductive toxicology assessment of male reproductive toxicity:** Spermatogenesis; Risk assessment in male reproductive toxicity; Female reproductive toxicology; Oocyte toxicity; alterations in reproductive endocrinology; relationship

between maternal and developmental toxicity.

8. **Mutagenicity:** Mechanisms of mutagenesis, point mutations; Individual chromosomes and complete genome mutations, germ cell mutations, somatic cell mutation; Tests systems in vitro, test for gene mutation in bacteria, chromosome damage, gene mutation, in vivo micronucleus tests in rodent, metaphase analysis.
9. **Carcinogenicity:** Principles of carcinogenicity, prechronic studies for dose-setting, chronic study, transplacental carcinogenesis; Cocarcinogenesis/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; Stereoisomerism vis-à-vis regulatory requirements; Single enantiomers; Racemate enantiomer switch; Regulatory requirements.
11. **Toxicokinetic methods validation:** Assay development; Assay validation, study monitoring, calibration of standards; validation report.
12. **Preclinical toxicological requirements for biologicals and biotechnological products:** safety analysis; problems specific to recombinant products secondary pharmacology, antibodies, transmission of viral infections, residual DNA, etc.

**Recommended books:**

1. Clinical Pharmacology by Lawrence
2. Basic and Clinical Pharmacology by Katzung
3. ICH Guidelines
4. Schedule Y
5. OECD Guidelines
6. US FDA Guidelines

## 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 antimalarial agents, antiparasitic drugs
8. Spectrum of activity, mechanism of action, ADME and therapeutic aspects of the antiviral drugs, drugs used in the treatment of AIDS
9. Spectrum of activity, mechanism of action, ADME and therapeutic aspects of the

antineoplastic agents.

**Recommended books:**

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

**LS-610**

**General Laboratory Experience in the area of Specialization-**

**10 hours/week**

**(2 credits)**

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

# Regulatory Toxicology

## RT-630

### Molecular Toxicology

(2 credits)

1. **Cell signaling and receptor mediated toxicity- Ion channels:** Receptors linked to protein kinases and phosphatases, intracellular receptors.
2. **Second messengers:** Signaling to the nucleus, general overview of mechanisms of cell death.
3. **Calcium- mediated toxicity:** Excitatory amino acid toxicity. No toxicity.
4. **Cytokines toxicity:** Steroid hormone induced toxicity.
5. **Signaling and apoptosis:** Methods of studying receptors.
6. **Methods for studying cell signaling:** Mechanism of chemical toxicity.
7. **Oxidative stress:** Apoptosis, necrosis, comparison and significance in toxicity evaluation.
8. **Toxicogenomics and microarray:** Expression profiling in prediction of toxicology, principles problems and prospects. Early predictions, impact to reduce attrition in drug development.
9. **New assays:** New procedures of evaluation, phototoxicity, comet assay, modified *Salmonella* assay, transgenic bioassays, neonatal bioassays, validation procedures, uses and limitations.
10. **In- vitro bioassays:** Predictive and mechanistic toxicology, different cell lines their use and limitations.

#### **Recommended books:**

1. Molecular Toxicology by P. David Josephy
2. Advances in Molecular Toxicology by James C. Fishbein
3. Cellular and Molecular Toxicology and In Vitro Toxicology by Daniel Acosta
4. Lehninger Principles of Biochemistry (5th Edition) by M.M. Cox and DL Nelson

## RT-640

### Target Organ Toxicology

(2 credits)

1. Haematotoxicity: Blood pictures, cell types and pathology.
2. Hepatotoxicity: Liver structure, functions and pathology.
3. Nephrotoxicity: Kidney morphology and pathology.
4. Local toxicity: Skin morphology and pathology.
5. Cardiotoxicity: Cardiovascular structure and pathology.
6. Neurotoxicity: Structure and pathology. Bone marrow toxicity.
7. Targets of toxic drugs: Toxicity of chemotherapeutic drugs, antibiotics, antiviral agents.
8. Toxicity of drugs used for chronic treatment: Drug pollutant interactions.

9. Endocrine disruptors: Emphasis on neurotoxic, genotoxic and carcinogenic agents.
10. Historical control data: Importance in generation of quality data, back ground lesions, Use of suitable animal models in toxicity evaluation.

**Recommended books:**

1. Robins Basic Pathology, by Saunders, Elsevier
2. Text Book of Pathology, by Harish Mohan, Jaypee

## **RT-650**

### **Good Laboratory Practices**

(2 credits)

1. Good Laboratory Practices (GLP).
2. Quality control and Quality Assurance.
3. SOP writing and implementation: GLP Establishment.
4. Study plans: Study protocols.
5. Master schedule: Responsibility of study directors.
6. Multisite management and principles investigators responsibility.
7. Reporting of study results.
8. Storage and retention of records and materials.
9. GLP audits and inspections.
10. Cost benefit comparisons, in regulatory set ups.

**Recommended books:**

1. Good Laboratory Practice, 2nd Edition, by Jurg P Seiler, Springer
2. WHO/TDR Manual for Good Laboratory Practice, WHO/TDR, Geneva, Switzerland

## **RT- 660**

### **Bioethics**

(1 credit)

1. Ethics moral and laws relative to animals.
2. Trade regulations.
3. Market requirement.
4. Import and export rules.
5. Social pressure and friendly use of animals in higher research.
6. Approval process for use of animals in experiments.
7. Precautions in biological experiments.
8. Labeling: Identification, cage cards.
9. Handling of experimental animals.

10. Disposal of dead animals after experiments.

**Recommended books:**

1. Animal bioethics Principles and Teaching Methods, edited by M. Marie, S. Edwards, G. Gandini, M. Reiss and E. von Borell
2. The Palgrave Macmillan Series on Animal Ethics, edited by Andrew Linzey and Priscilla Cohn
3. Nonhuman Primates in Biomedical Research, Diseases by Taylor Bennett, Christian R. Abee, Roy Henrickson

## **LS-610**

### **General Laboratory Experience in the area of Specialization-10 hours/week**

(2 credits)

1. Route of administration (ip, iv, po)
2. Blood collection and plasma separation.
3. Blood cell counting (manual and 5 part automation).
4. Tissue isolation and fixation.
5. Tissue processing and histological slide preparation.
6. Blood smear and histological slide staining (manual and automation).
7. Aseptic techniques.
8. Cell culture techniques.
9. Cytotoxicity determination by MTT, LDH and neutral red uptake assay.
10. Use of statistics.
11. Data collection, interpretation and calculations. Health check ups, acclimatization, grouping, animal marking; Cage cards, dose calculation for mice and rats; Common solvents, uses, storage conditions, dosing procedures (oral, intraperitoneal); Common toxic symptoms- definitions and observation, feed intake measurements, water intake measurements, urine output, anesthesia and gross necropsy; Blood removal from mice and rats and anticoagulants. Separation and isolation of plasma, case of hemolysis sample. Body weight, organ weight, body to organ ratio calculation, different target organs isolation, fixative, preservations, autolysis, raw data collection, computation, statistics and report preparation.

# Pharmaceutics

## 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 effecting 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 drug products, polymer microspheres and their biocompatibility and dispersed DDS.
5. **Transdermal/skin drug delivery systems:** Principles of skin permeation, factors affecting percutaneous absorption of 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 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 pharmacodynamic and bioavailability problems of oral controlled release products, dissolution rate assessment, biopharmaceutic considerations in the regulatory assessment.

#### **Recommended books:**

1. Drug Delivery Systems, by K K Jain.
2. Pharmaceutical Perspectives of Cancer Therapeutics, by Y Lu and R.I. Mahato.
3. Targeted Delivery of Small and Macromolecular Drugs, by A.S. Narang and R.I. Mahato.
4. Controlled Drug Delivery, Fundamentals and Applications, by Robinson and Lee.



## PE-640

### Pharmaceutical Product Development-II

(2 credits)

1. **Formulation additives:** Study of different types of additives e.g. antioxidants and preservatives, coloring and flavouring 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. **Liquid 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.

#### **Recommended books:**

1. Handbook of Pharmaceutical Excipients, by Rowe, R.C., P. J. Sheskey
2. Pharmaceutical Excipients: Characterization by M. Dekker. Bugay, D. E. and W. P. Findlay
3. Pharmaceutical Manufacturing Handbook: Production and Processes, by Gad, S. C
4. Selected Pharmaceutical Excipients: Physicochemical Properties, Analytical Techniques Utilized and their Excipient-Excipient Interactions by Rane, S. C.
5. Encyclopedia of Pharmaceutical Technology, by Swarbrick, J. and J. C. Boylan

6. Packaging of Pharmaceuticals and Healthcare Products, by Lockhart, H. and F. A. Paine
7. Pharmaceutical Packaging Technology, by Dean, D. A., R. Evans
8. Pharmaceutical Packaging Handbook, Informa Healthcare by Bauer, E. J.
9. Pharmaceutical Manufacturing Handbook: Regulations and Quality, Wiley-Interscience by Gad, S. C. WHO Publications:
10. Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials.
11. Good Manufacturing Practices and Inspection, World Health Organization.
12. Modern Pharmaceutics, Marcel Dekker by Banker, G.S. and C. T. Rhodes
13. Pharmaceutical Dosage Forms, by Lieberman, H. A. and L. Lachman
14. Pharmaceutical Dosage Forms: Parenteral Medications, by Avis, K. E., H. A. Lieberman

## 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 of biomaterials:** 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, *in vivo* 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.

#### **Recommended books:**

1. Handbook of Biodegradable Polymers, by Abraham J. Domb, David M. Wiseman
2. Biodegradable Polymers in Clinical Use and Clinical Development, by Domb, Kumar and Azra
3. Surface modification of Biomaterials: Methods Analysis and Applications, Edited by R Williams

## 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, packing / conformational polymorphism, thermodynamics of polymorphs, enantiotropy / 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 (T<sub>g</sub>), thermodynamic necessity for T<sub>g</sub>, 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 stabilization of amorphous form, amorphous solid dispersions.
8. **Particulate 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.

#### **Books recommended:**

1. Polymorphism in Pharmaceutical Solids Edited by Harry Brittain
2. Solid State Characterization of Pharmaceuticals Edited by Angeline and Mark Zarkrzewski
3. Crystal Engineering: A textbook, Edited by G. R. Desiraju, J. J. Vittal and A. Ramanan

## 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.

# Biotechnology

## 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-dependant and 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.

**Recommended books :**

1. Genes VIII by Benjamin Lewin
2. Principles of Genetics by Gardner, Simmons and Snustard

**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 P* system, knock-out mice.
9. **Transgenic animals:** Principle, 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* gene therapy, prospects and limitations.
12. **Nucleic acid therapeutics:** Antisense technology, siRNA, trans-splicing, ribozymes, aptamers, case studies, advantages and challenges.

**Recommended books:**

1. Principles of Gene Manipulation and Genomics (7/e) by Sandy 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

## BT-630

### Immunology and Immunotechnology

(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 subsets and surface markers, 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, immunodeficiency disorders (AIDS), tumor immunology.
10. **Immunobiotechnology:** Hybridoma, phage display technology, vaccines, Antibody engineering, second generation antibodies a brief outline.

#### **Recommended books:**

1. Cellular and Molecular Immunology by Abdul K. Abbas, Andrew H. Lichtman and Shiv Pillai
2. Kuby Immunology by Thomas J. Kindt, Barbara A. Osborne, and Richard A. Goldsby

## 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 MTT 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.
8. **Cell-based screening assays:** Advantages over in vitro assays. Different formats: radioactive, luminescence, fluorescence, etc. Assays compatible with cell membranes: GTP $\gamma$ S, cAMP accumulation.
9. **Yeast two-hybrid system:** Different Y2H systems, their advantages and disadvantages, examples.
10. **GPCRs as targets:** Identification of drug molecules; Important parameters: intracellular calcium, cAMP,  $\beta$ -arrestin, receptor internalization, reporter gene assays; orphan GPCRs; desensitization and internalization.

**Recommended books:**

1. The Immunoassay Handbook by David Wild
2. High Throughput Screening: The Discovery of Bioactive Substances by John P. Devlin

## 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 PartII:** 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.
6. Methods for discovering conserved patterns in protein sequences and structures and protein motifs.

7. **BLAST, various methods of DNA and protein BLAST and interpretation of output:** Sequence alignment, Pairwise alignment, Techniques, Multiple Sequence Alignment.
8. **Predicting secondary structure from protein sequences:** Protein structure prediction, homology modelling. 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.

**Recommended books:**

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. Wierling, H. Lehrach
5. Relevant Research and Review Papers

## 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  $\alpha$ -amylase from wheat germ and its partial purification

**Enzyme biochemistry:**

Day-1-9: Expression, partialpurification 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.

# Pharmacoinformatics

PI-610

**Bioinformatics**

(2 credits)

1. **Bioinformatics basics:** Computers in biology and medicine, Information Chaos, Challenges in post genomic era, Data base concept, Protein and nucleic acid databases.
2. **Databases and search tools:** Structural databases, Gene databases, Protein data bases, Searching data bases, The NCBI; Publicly available tools, Resources at EBI, Resources on the web; Database mining tools.
3. **Protein folding:** Diversity in proteins function and protein structure, Link between sequence, structure and function Misfolding problem, Anfinsen's dogma, Levinthal's paradox, Challenges in understanding structure, Methods for determining 3D structure, Protein data bank, Visualization of macromolecules.
4. **Protein Flexibility:** Dynamic motion in biological processes, Motion and function, Examples, Types of molecular motions, Time scale of protein motion, Methods to study protein motion, Data base of macromolecules, Online servers and software tools.
5. **Molecular recognition:** Process of recognition, Complementary features upon binding, Tolerance upon binding, Induced fit theory, Adaptation of enzyme and ligand, Domino effect, Ensemble of conformations, Forces involved in recognition, Solvent effect, Hydrophobic effect.
6. **Secondary and tertiary structure of proteins:** Protein architecture, Conformation, Ramachandran plot, Characteristics of secondary structural elements, Alpha helices, Beta sheet and reverse turns, Super secondary structure, Domains, New levels of protein architecture.
7. **Classification of protein folds and topology:** All alpha topology, All beta topology, Alpha-beta topology, Alpha + beta topology, Classification of proteins, CATH, SCOP.
8. **Sequence Alignment:** DNA/protein sequences analysis, Alignment, pairwise and global alignment, Multiple alignment, structure based alignment, software tools, BLAST, FASTA, CLUSTAL, Scoring matrices, Algorithms, Needleman-Wunsch and Smith-Waterman algorithms, Dynamics programming.
9. **Structure prediction of proteins:** Homology modeling, Template selection, Sequence alignment, Secondary structure prediction methods, On line servers and software, Protein main chain and side chain modeling, Loop modeling, Refinement and evaluation of models, Structure prediction of GPCRs.
10. **Applications of bioinformatics:** Proteins history, Proteins and pharmaceutical industries, Disease areas, Complex proteins, Applications, structure based drug design.

**Recommended books:**

1. Essentials of Genomics and Bioinformatics by Sensen, Christoph W. D.
2. Essential Bioinformatics by Xiong, Jin
3. Sequence Analysis in a Nutshell : A Guide to Common Tools and Databases by Markel, Scott
4. Structural Bioinformatics by Bourne, Philip E.

5. Computational Biology and Genome Informatics by Wang, Jason T. L.
6. Computational Molecular Biology : An Introduction by Clote, Peter
7. Introduction to Bioinformatics by Lesk, Arthur M.
8. Structural Bioinformatics by Bourne, Philip E.
9. Bioinformatics : A Primer by Narayanan, P.
10. Bioinformatics : Concepts, Skills & Applications by Rastogi, S. C.
11. Beginning Perl for Bioinformatics by Tisdall, James
12. Mastering Perl for Bioinformatics by Tisdall, James D.
13. Perl Programming for Bioinformatics by Bal, Harshawardhan P.
14. Discovering Genomics, Proteomics and Bioinformatics by Campbell, A. Malcolm

## PI-620

### Chemoinformatics

(2 credits)

1. **Structure prediction methods:** 2D, 3D, representing chemical structures in 1D notations searching analyzing. 4D-7D definition of structure. Morgan algorithm.
2. **Similarity searching:** Tanimoto coefficient, Sorensen coefficient, Carbo coefficient, Euclidean distance, power distance, Soergel distance, Hamming distance. Full structure search and partial structure search.
3. **Matrices of chemical structures:** Adjacency matrix, bond matrix, distance matrix, etc., Hash codes, bitmap generation, fragment based methods. Coordinate matrix, z-matrix; their interconversion.
4. **Descriptor generation:** Molecular graphs and molecular trees, 2D QSAR: structure-activity relationships; Weiner index, Hosoya index, Randic index, Balaban index, etc. topological descriptor generation.
5. **Chemoinformatic tools:** CDK tools, Scifinder tools and algorithms associated with these tools.
6. **Crystallography tools:** CCSD tools; web based applications, algorithms associated with search tools in CCSD. PDB tools, web application.
7. **Combinatorial library:** Design and molecular diversity; Applications in structure-based drug design, enumeration techniques.
8. **Algorithms in chemoinformatics:** C++ code generation for smiles notation, matrices, linear regression, Newton-Raphson method, conformational search. Genetic algorithms.
9. **Chemoinformatic databases:** Creation, analysis of chemoinformatic databases. Generate reports from the chemical databases.
10. **Web applications of Chemoinformatics:** MolEngine, ChemAxon, sysment reaction tool.

#### **Recommended books:**

1. J. Gasteiger, Chemoinformatics
2. A.R. Leach, Introduction to Chemoinformatics

3. J. Bajorath, Chemoinformatics: Concepts, Methods, and Tools for Drug Discovery
4. J. Bajorath, Chemoinformatics and Computational Chemical Biology

## PI-630

### Metabolomics and Toxicoinformatics

(2 credits)

1. **Metabolomics:** Definition, metabolomics Vs metabonomics, identification of target organ, severity, onset, duration and reversal effects.
2. **Optimizing drug candidates-Phase I metabolism:** Reaction phenotyping of CYPs (in silico/in vitro/in vivo), identification of site of metabolism (SoM), structure metabolism relationships, nucleophilicity, hardness and quantum chemical parameters in determining SoM, case studies.
3. **Optimizing drug candidates-Phase II metabolism:** Reaction phenotyping of UGTs (in silico/in vitro/in vivo), identification of site of metabolism (SoM), structure metabolism relationships, nucleophilicity, hardness and quantum chemical parameters in determining SoM, case studies.
4. **Optimizing drug candidates-Phase III metabolism:** Substrate identification by transporters (influx and efflux) (in silico/in vitro/in vivo), structure transporter relationships, case studies
5. **Optimizing drug candidates- Non CYP metabolism:** aldehyde oxidase as drug metabolising enzyme, prediction of SoM, case studies.
6. **Techniques of metabolite elucidation:** LCMS/HRMS/NMR.
7. **Mechanism of drug induced toxicity:** Metabolic activation and idiosyncratic drug reactions.
8. **Reactive metabolites and drug safety:** Adverse drug reaction (ADR), drug attrition, bioactivation/reactive metabolite formation, metabolites in safety testing (MIST), structural alerts, experimental techniques to detect reactive metabolites, strategies to avoid reactive metabolites, human hepatocytes in evaluation of adverse drug properties.
9. **Pharmacokinetic DDI:** Mechanisms of drug interaction, CYP inhibition/induction, UGT inhibition/induction, nuclear receptors in DDI.
10. **Drug metabolism and disposition profile of drugs:** Non clinical and clinical aspects, integrating in silico models for disposition profile of drugs.

#### **Recommended books:**

1. Drug Metabolism in Drug Design and Development, edited by Donglu Zhang, Mingshe Zhu, W. Griffith Humphreys
2. Evaluation of Drug Candidates for Preclinical Development. Pharmacokinetics, Metabolism.
3. Pharmaceutics and Toxicology, edited by Chao Han, Charles B. Davis, Bringhe Wary
4. Early Drug Development: Strategies and Routes to First-in-Human Trials, edited by Mitchell N Cayes
5. Handbook of Drug Metabolism, edited by Paul Gerard Pearson, Larry C Wienkers

## PI-640

### Comparative Genomics, Transcriptomics, Immunoinformatics

(1 credit)

1. **Pharmacogenomics:** Interindividual differences in therapeutic response to drugs, susceptibility to adverse effects, polymorphism of drug metabolising enzymes, sub-therapeutic and supra-therapeutic concentration of drugs.
2. **Pharmacogenomics in PK and PD:** Species difference, extrapolation to humans, selection of animal models.
3. **Pharmacogenomics of Phase I metabolism:** CYP 450 enzyme polymorphism, poor/rapid/ultrarapid metabolisers, case study of CYP2D6 and CYP3A3/4 polymorphism.
4. **Pharmacogenomics of Phase II metabolism:** Expression of different UGT isoforms, change in drug glucuronidation parameters, polymorphism of UGTs, atypical kinetics exhibited by UGTs, IVIVC/in silico modeling.
5. **Pharmacogenomics of Phase III metabolism:** Expression of efflux/influx transporters, drug resistance due to over expression of efflux transporters, substrate/inhibitor selectivity for efflux transporters.
6. **Toxicity profiles of PPAR agonists:** PPAR mediated adverse events, different isoforms of PPAR, development of dual PPAR  $\alpha/\gamma$  agonists, case study.
7. **Toxicity profiles of PXR agonists:** PXR mediated expression of P-gp and CYP3A4, enhanced metabolism and efflux of drugs, PXR in drug development, neurological disorders and PXR.
8. **Toxicity profiles of CAR agonists:** Target genes, expression of CYPs and UGTs due to induction of CAR, case study.
9. **Toxicity profiles of AhR agonists:** Target genes, expression of CYPs and UGTs due to induction of CAR, case study.
10. **Immunoinformatics:** immunoinformatics and system biology integration for personalized medicine.

#### **Recommended books:**

1. Immunoinformatics: Bioinformatics Strategies for better understanding of Immune Function Vol. 254, by Gregory Bock, Jenie Goode
2. Immunoinformatics: Predicting Immunogenicity in Silico by Darres R Flower
3. Immunoinformatics by Shobha Ranganathan, Vladimir Brusic
4. In Silico Genomics and Proteomics
5. Functional Annotation of Genomes and Proteins
6. Chemical Genomics and Proteomics by Zanders Edward .D.

## PI-650

### Pharmacoinformatics Database Management

(1 credit)

1. **Database Management:** Data, Database, Database Management System, Types of databases, Conceptual and physical schema, Terminology, Relationships, ER-Diagram, Normalization forms

2. **SQL:** Data Definition Language, Creating database, Creating tables, Constraints, Alter table, Drop table, Creating views, Data Manipulation Language, Inserting records, Deleting records, Modifying records, Queries, Types of join, Grouping, Data integrity and security.
3. **Derived Databases:** Basic concept of derived databases, sources of primary data and basic principles of the method for deriving the secondary data, organization of data, identification of patterns
4. **System Development Life Cycle:** System Analysis and Design, Development, Testing, Implementation, Maintenance, SDLC Models.
5. **File Organization:** Heap, Sequential, Indexing and Hashing.
6. **Data Structures and Algorithm:** Arrays, Link Lists, Stacks, Queues, Graphs, Trees, Sorting, Searching
7. **Pharmacoinformatic data Resources:** NCBI, EBI, ExpASY, RCSB: architecture of these databases, application tools, etc.
8. Open access bibliographic databases related to Life Sciences viz., PubMed, BioMed Central, Public Library of Sciences (PloS), their architecture, application tools.
9. **Sequence databases:** Formats, querying and retrieval, Nucleic acid sequence databases
10. **3D Structure Database:** PDB, NDB; Chemical Structure database: Pubchem; Gene Expression database: GEO, SAGE

**Recommended books:**

1. Learning SQL by Alan Beaulieu
2. Database Systems By Rob Coronel
3. Principles of Databases by JD Ullman

**LS-610**

**General Laboratory Experience-10 hours/week**

(2 credits)

**Total 180 hours:**

1. Bioinformatics basics (45 hours)
2. Computer programming (50 hours)
3. Pharmacy practice informatics (20 hours)
4. ADME/ Tox. Informatics (20 hours)
5. Molecular modeling / drug design (45 hours)

## Pharmacy Practice

### PP-610

#### Pharmacy Practice-II

(1 credit)

1. **Healthcare measures and evaluation methods:** Approaches to healthcare measurement and evaluation: QoL factors affecting it, QoL measurement; QALY; Outcome measurement and instruments of measurement; Applications of general health survey; Rational drug use; healthcare policy/policy making and implementation.
2. **Health and pharmacoconomics:** Health economic theory and relevance to pharmacy practice, priority setting, economic evaluation; Concepts of economics (cost benefit, cost effectiveness, cost minimization); Cost analysis; Aiming towards prescribing on these principles.
3. **Medicine management:** Its policies and implementation; Formulary preparation and implementation; Requirements to ensure compliance with agreed guidelines.
4. **Pharmacoepidemiology:** Population approaches and their application in health care and drug use; Types of epidemiological studies, advantages, disadvantages and applications in drug use research.
5. **Medication errors, ADR and prescription event-monitoring:** Medication errors, types and sources of medication errors, methods of studying medication errors and methodological issues; Risk and its measurement.
6. **Defining adverse drug reaction:** Role of pharmacists in ADR reporting, WHO ADR reporting programme in India.
7. **Prescription event monitoring (PEM) with respect to prescribed medicines:** Method of monitoring safety of marketed drugs; Methods of monitoring safety and effectiveness profile of drugs recently introduced/marketed in India.

#### **Recommended books:**

1. Quality of Life: The Assessment, Analysis and Interpretation of Patient-Reported Outcomes by Peter Fayers and David Machin
2. Quality of Life Outcomes in Clinical Trials and Health-Care Evaluation: A Practical Guide to analysis and interpretation (Statistics in Practice) by Stephen John Walters (Nov 17, 2009) Wiley, Editors- Stephen Senn, Vic Barnett
3. Essentials of Pharmacoconomics, Karen Rascati (Author), Lippincott Williams and Wilkins, Editor- Barrett Koger
4. Understanding Health Outcomes and Pharmacoconomics by George E. MacKinnon III
5. Principles of Pharmacoconomics, edited by J. Lyle Bootman, Raymond J., Townsend, William F. McGhan
6. Pharmacoepidemiology, edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy, Wiley Blackwell
7. Introduction to Epidemiology by Ray M. Merrill, Jones and Bartlett
8. An Introduction to Pharmacovigilance by Patrick Waller
9. Cobert's Manual of Drug Safety and Pharmacovigilance by Barton L. Cobert
10. Pharmacovigilance from A to Z: Adverse Drug Event Surveillance by Barton L. Cobert

### PP-611

#### Pharmacy Practice-III (Community and Rural Pharmacy)

(1 credit)

1. **Community pharmacy:** Overview of organization, administration, computerization and functioning (supply and control, stock control, suppliers, control on price and purchase, receipt/return of goods, financial management); Need for a pharmacist within the pharmacy; Dispensing {prescription for drugs and presentation of dispensed medicines,

prescription for non-drugs, OTC products (and self-medication), drugs other than actual OTC products dispensed without prescription in India: legislation, prescription for/supply of alternative medicines, dispensing of medicinal gases}, counseling, records; Home Care; Health education.

2. **Rural pharmacy:** Need; Provision of pharmacy services in rural areas (issues around accessibility, availability, adequacy, efficiency, equality): where, how, what services, how long, through whom/what (e.g. through the community pharmacies, clinics, camps, home visits by pharmacists), how often; Economic issues; Need for a set number of pharmacies (with a certain number of pharmacists covering the pharmacy and area) within a specified area covering a particular part (number) of the population of rural India; Health education; Pharmacists' responding to symptoms (mnemonics e.g., WHAM, AS METHOD), counselling, referral to a medicinal practitioner.

**Recommended books:**

1. Community Pharmacy Practice Case Studies by Jean-Venable R. Goode, Lynne M. Roman and Kristin W. Weitzel
2. Community Pharmacy Handbook by Jon Waterfield
3. Pharmaceutical Practice by- A.J Winfield, R.M.E Richards. Churchill Livingstone
4. Pharmacy Practice by- Patricia Stone, Stephen J Curtis

**PP-620**

**Clinical and Applied Therapeutics-II**

(3 credits)

1. **Psychiatry:** Pharmacists' contribution in the management of schizophrenic patients, anxiety and mood disorders (monitoring therapy, dosing, initiation and withdrawal of therapy, need to exclude administration of specific drugs post withdrawal of these drugs used in these disorders, effectiveness, compliance, counseling, discharge planning).
2. **Parkinson's disease:** Differentiation between Parkinson's disease and drug-induced Parkinson like syndrome and drug induced extrapyramidal side effects; therapeutic options and drawbacks, issues around levodopa combinations; alternative therapies, recent additions to drug treatment options.
3. **Rheumatology and inflammatory disease:** Rheumatoid arthritis; Systemic Lupus Erythematosus; Ankylosing spondylitis; Osteoarthritis; Osteoporosis and Osteomalacia; Gout and Hyperuricemia (treatments, monitoring and modifications in therapy as and when required, home care plan, provision of adequate devices to aid rheumatic patients).
4. **Oncology:** Principles of therapy; consequences of regimens in use in India as against in developed countries; incidence; cytotoxic reconstitution; patient and treatment monitoring (acute leukaemias, lung cancer, breast cancer, malignant lymphomas, head and neck cancers, prostate cancer).
5. **Liver disorders:** Viral Hepatitis (types, antiviral treatment, other treatment options; Cost constraints and availability of different vaccines and treatments; Recent advances in therapy; Prophylaxis and prevention; Drug induced Hepatitis; Cirrhosis (Management of Cirrhosis and its complications; FHF and its management).
6. **Gastroenterology:** Peptic Ulcer disease; Inflammatory Bowel disease; Gastroesophageal Reflux Disorder; Diarrhea and Constipation.
7. **Pharmaceutical care in a surgical patient:** Surgical prophylaxis; Pain control; Sedation; Antiemesis; Implications for prescribing in 'Nil by Mouth' Patients.
8. **Neurology:** Epilepsy types, incidence and prevalence in different age groups, toxic effects, DIs; Choice of drugs (mono- or poly- therapy); Initiating, adjusting and monitoring AED treatment, withdrawal of drugs; TDM; Newer AEDs - advantages and drawbacks; Drug-induced seizures and management; Pregnancy and epilepsy.

**Recommended books:**

1. Koda-Kimble and Young's Applied Therapeutics: The Clinical Use of Drugs by Brian K. Alldredge, Robin L. Corelli, Michael E. Ernst, and B. Joseph Guglielmo
2. Pharmacotherapy: A Pathophysiologic Approach, by Joseph DiPiro, Robert L. Talbert, Gary Yee and Gary Matzke
3. Clinical Pharmacy and Therapeutics by Eric T. Herfindal and Joseph L. Hirschman
4. Clinical Pharmacy and Therapeutics, by Roger Walker and Cate Whittlesea
5. Goodman and Gilman's Manual of Pharmacology and Therapeutics by Laurence Brunton, Donald Blumenthal, Iain Buxton and Keith Parker
6. Goodman and Gilman's The Pharmacological Basis of Therapeutics, by Laurence Brunton, Bruce Chabner and Bjorn Knollman

**PP-630**

**Evidence Based Medicine and Critical Appraisal**

(2 credits)

1. **Explain:** Evidence based medicine what it is and what it is not?
2. **Literature search and analysis:** Searching and finding the current best evidence. Keeping up to date and improving the clinical and other skills and run a better, more efficient pharmacy practice.
3. **Reading the medical literature:** "Significant" relations and their pitfalls; Different types of data and different statistical tests; Assessing methodological quality of published papers; Identifying the authenticity of the published article, evaluating and assessing the type of clinical studies in medical sciences.
4. **Evaluation of literature:** Explaining the role of, key features to examine in, and possible indicators of biases in the primary literature. Data evaluation, tables, graphs, internal validity, per protocol analysis and intention to treat (ITT) analysis of a study. Causal and non-causal relationships. Population size, cause, strength, randomization, and generalizability play in determining the importance of a study.
5. **Understanding terminologies and concepts:** Absolute risk reduction, bias, confounding, confidence interval, odds ratio, predictive value, prognostic factor, relative risk, likelihood ratio, sensitivity, specificity, p value, confidence interval; Number needed to treat; Number needed to harm; Patient expected event rate, survival curve, Kaplan-Meier product limit theorem, Kappa statistic; Clinical significance and systematic review.
12. Measuring the accuracy of diagnostic procedures.
13. Experience in advanced statistical programs (Like SAS, SPSS etc. for decision analysis)

**Recommended books:**

1. Evidence Based Medicine (3rd Edition) by Sharon E. Straus, W. Scott Richardson, Paul Glasziou and R. Brian Haynes
2. Evidence-Based Medicine: How to Practice and Teach it, (Straus, Evidence-Based Medicine) by Sharon E. Straus MD, Paul Glasziou, W. Scott Richardson MD and R. Brian Haynes
3. How to Read a Paper: The Basics of Evidence-Based Medicine by Trisha Greenhalgh
4. Essential Evidence-based Medicine (Essential Medical Texts for Students and Trainees) by Dan Mayer
5. Pharmacists Guide to Evidence-Based Medicine for Clinical Decision Making by Dr. Patrick J. Bryant and Heather A. Pace
6. Introduction to Meta-Analysis (Statistics in Practice) by Michael Borenstein, Larry V. Hedges, Julian P. T. Higgins and Hannah R. Rothstein
7. Research Synthesis and Meta-Analysis: A Step-by-Step Approach (Applied Social Research Methods) by Harris M. Cooper
8. Systematic Reviews and Meta-Analysis by Julia H. Littell, Jacqueline Corcoran and Vijayan Pillai

9. Systematic Reviews in Health Care: Meta-Analysis in Context by Matthias Egger, George Davey Smith and Douglas Altman

## PP-631

### Clinical Biostatistics

(1 credits)

1. Statistical methods for multiple variables.
2. Assessing the quality of clinical trials.
3. Design and interpretation of clinical trials.
4. Per protocol and intention to treat analysis.
5. Missing values and outliers.
6. Type of comparison of clinical trials.
7. Analyze survival data.
8. Relationships among variables.
9. Bias and Confounders.
10. Pooling data in Meta analysis.
11. Advantages and disadvantages of different survey methods.
12. Measuring the accuracy of diagnostic procedures.
13. Experience in advanced statistical programs (Like SAS, SPSS etc.for decision analysis)

#### **Recommended books:**

1. Epidemiology and Biostatistics: An Introduction to Clinical Research by Bryan Kestenbaum
2. Biostatistics and Epidemiology: A Primer for Health and Biomedical Professionals by Sylvia Wassertheil-Smoller
3. Basic & Clinical Biostatistics (LANGE Basic Science) by Beth Dawson and Robert Trapp
4. Clinical Trial Methodology (Chapman & Hall/CRC Biostatistics Series) by Karl E. Peace and Ding-Geng (Din) Chen

## LG-611

### Clinical Placement

(5 credits)

1. Prescription and patient monitoring for treatment effect, drug interactions, adverse drug reactions.
2. **Self-study and time management:** Time spent on a case and ability to gather relevant information in relation to time.
3. Patient profiles (Two).
4. Case presentations (Two).
5. Group discussions for 'real' patient issues (6 per semester).
6. Contribution during pharmacist and medical rounds: In relation to patient and/or drug information, recent advances, relevance in practice.
7. Practice with ethics in view and without interfering with the work of the other professionals but proving to be an aid to the overall care.

## Clinical Research

### CR-610

#### Bioavailability and Bio-Equivalence Testing

(2 credits)

1. Overview of bioavailability, drug product, pharmaceutical equivalents, pharmaceutical alternatives, bioequivalence, bioequivalent drug products.
2. Factors modifying bioavailability; physiologically modified bioavailability, dosage form modified bioavailability.
3. Bioavailability of new drugs.
4. Bioequivalence requirements; criteria and evidence to establish a bioequivalent requirement.
5. General guidelines for the determination of in vivo bioavailability.
6. Criteria for waiver of in vivo bioavailability.
7. Selection of a standard for bioavailability testing.
8. In vitro and in vivo methods for bioavailability testing.
9. Methods to assess bioavailability.
10. Types of bioavailability, absolute bioavailability or fraction of drug absorbed, bioavailability in presence of first-pass effect, relative bioavailability and bioequivalence, relative optimal bioavailability, determination of rate of bioavailability.
11. Evaluation of bioavailability studies: single dose studies, multiple dose studies, routes of administration, blood sampling, placebos, investigation of efficacy, adverse effects, risks.
12. Estimate on bioavailability from in vitro and extravascular data.
13. Overview of the analysis and interpretation of bioavailability studies in man.

#### **Recommended books:**

1. Handbook of Bioequivalence Testing by Sarfaraz K. Niazi.
2. Drugs and Pharmaceutical Sciences, Vol. 171, Informa Healthcare, London.
3. Design and Analysis of Bioavailability and Bioequivalence Studies by S.C. Chow, J. P. Liu.
4. Bioequivalence and Bioavailability Studies in Human Volunteers: Clinical Pharmacokinetic Evaluation by Vivek Paithankar

These are just the indicative books. Students are advised to update themselves with recent regulatory guidelines issued by different agencies like USFDA, ICH, EMEA, CDSCO

### CR-620

#### Clinical Research Management

(2 credits)

1. **Introduction to clinical project management:** Project management systems.
2. **Project management process:** Project organization, planning and scheduling, network, resources estimates, resource planning, resource levelling, project control, progress, reporting and validation.
3. Project and business management theory in the context of a clinical trial.
4. Implementation and co-ordination of the project plan with an emphasis on communication and project promotion and monitoring.

5. Choice of a project management system.
6. Modern methods for managing multiple small projects.
7. Initiating and managing a clinical trial; follow up.
8. Project management: Combining technical and behavioural approaches for effective Implementation.
9. Marketing strategy in the pharmaceutical industry.
10. The international project plan: Creating the development plan, project planning, development time, central planning and planning in line departments.

**Recommended books:**

1. A Guide to Patient Recruitment and Retention by Diana L. Anderson
  2. Principles and Practice of Clinical Trial Medicine by Richard Chin and Bruce Y. Lee
  3. A Manager's Guide to the Design and Conduct of Clinical Trial by Phillip I. Good
- These are just the indicative books. Students are advised to update themselves with recent regulatory guidelines issued by different agencies like USFDA, ICH, EMEA, CDSCO

**CR-630**

**Safety in Clinical Trials**

(1 credit)

1. Principles of drug safety evaluation.
2. **Classification of adverse reactions:** Hypothesis generation and testing.
3. The advantages / disadvantages and principles of spontaneous reporting: Monitoring strategies during the post marketing period, methods used to evaluate signals.
4. **The principles of causality assessment:** Limitation of clinical trials.
5. Pharmacoepidemiological principles and methods.
6. Patient and case control studies and the principles of record-linkage.
7. **Pharmacovigilance:** Monitoring drug safety in clinical practice, identification of drug safety hazards, actions to improve drug safety, responding to drug safety hazards, post marketing, monitoring and decision making, lessons learned from previous problems, the pharmaceutical physician and drug safety.
8. **Regulatory requirements for pharmacovigilance:** India, Europe, Japan and USA, International Harmonisation, Global assessment of drug safety including risk benefit.
9. Commercial consequences of drug failure.
10. Adverse events: Reaction and side effects, laboratory parameters requiring monitoring

**Recommended books:**

1. Textbook of Pharmacoepidemiology, Edited by Brian L. Strom and Stephen E. Kimmel.
  2. Pharmacovigilance Edited by Ronald D. Mann, Elizabeth B. Andrews
- These are just the indicative books. Students are advised to update themselves with recent regulatory guidelines issued by different agencies like USFDA, ICH, EMEA, CDSCO

## CR-640

### Documents for Clinical Trials

(2 credits)

1. **The protocol:** Functions of sponsors and investigators, protocol content and administration.
2. Biostatistical unit and their role
3. Regulatory affairs department.
4. **Drug supply department:** QA group, supporting centres and Hospital administration.
5. Personnel identification, source data verification, inventory management
6. **Trial summary:** Trial design, treatment materials, patient management, trial administration, reference information.
7. **Design & Development of case report forms:** Purpose and amount of data collection required. C
8. **Choice of question format:** Analogue scales, transcription issues, essential data, validation.

#### **Recommended books:**

1. Design and Analysis of Clinical Trials edited by Shein-Chung Chow ,Jen-Pei Liu
  2. A Manager's Guide to the Design and Conduct of Clinical Trials by Phillip Good
- These are just the indicative books. Students are advised to update themselves with recent regulatory guidelines issued by different agencies like USFDA, ICH, EMEA, CDSCO

## CR-650

### Clinical Data Management

(2 credits)

1. Data items and data collection forms, logistical and budgetary issues, and procedures of different funding bodies.
2. Collection of data and their subsequent management (edit checks, datalock) prior to analysis.
3. Clinical Trial sample size calculation.
4. Statistical Analysis Plan (SAP) and management of the plan.
5. Use of different computer packages to implement the plan in practice.
6. Data management including electronic data capture and transmission of data.
7. Quality assurance, quality control, audit and regulatory inspection.
8. Context of decisions about whether or not to continue recruitment of patients into clinical trial. Role of data safety monitoring board.
9. Different statistical approaches to analyze clinical trial data.
10. Role and conduct of data monitoring committees

#### **Recommended books:**

1. Clinical Data Management, edited by R. K. Rondel, S. A. Varley, C. F. Webb
2. Practical Guide to Clinical Data Management by Susanne Prokscha

3. Introduction to Statistical Methods for Clinical Trials, edited by Thomas D. Cook and David L. DeMets.
  4. Clinical Data Management by Richard K. Rondel, Sheila A. Varley, Colin F. Webb
  5. Clinical Data Management by McFadden Practical Guide to Clinical Data Management by Porksha
  6. Electronic Record Interpharm by David Nettleton & Janet Gough
- These are just the indicative books. Students are advised to update themselves with recent regulatory guidelines issued by different agencies like USFDA, ICH, EMEA, CDSCO

## **CR-660**

### **Medical Writing and Reporting**

(1 credit)

1. Use of written English in science.
2. Basics of writing scientific / medical reports.
3. Narrative writing.
4. Methods of referencing.
5. Writing clinical study reports.
6. Writing for publishing results of trials.
7. Skills for medical writing.
8. Reporting skills for regulatory bodies.

#### ***Recommended books:***

1. Essentials of Writing Biomedical Research Papers Edited by Mimi Zeiger
2. Scientific Writing: A Reader and Writer's Guide
3. Medical Writing: A Prescription for Clarity by Neville W. Goodman

## **CR-670**

### **Clinical Trials in Special Populations**

(2 credits)

1. Considerations for conducting clinical trials in special populations and precautions to be observed.
2. Involvement of social communities.
3. Case studies in special situations like oncology
4. Case studies in pediatrics.
5. Case studies in special situations like Alzheimer patients
6. Case studies in special situations like parkinsonian patients.
7. Case studies in special situations like elderly patients.

The students will be expected to present case studies on various special populations discussing the complexities involved.

#### ***Recommended books:***

1. Textbook of Clinical Trials Edited by David Machin, Simon Day, Sylvan Green
2. Clinical Trials: A Methodologic Perspective Edited By Steven Piantadosi

## CR-680

### Research Designs

(2 credits)

1. **Introduction to Research Methodology:** Meaning and objectives of research
2. Types of research; Approaches to research, Research methods versus methodology; Research Process; Criteria of good research
3. Common problems encountered in research; Quantitative and qualitative research methods.
4. Epidemiological research methods versus clinical trials
5. Defining the research problem: Selecting a problem; Necessity of defining the problem.
6. **Research design:** Meaning and features of research design; Concepts related to research design; Basic principles of experimental designs; Developing a research plan.
7. **Methods of data collection:** Primary data collection methods, use of questionnaires; Secondary data collection; Selection of appropriate method of data collection; Interviewing and principles of good interview.
8. **Processing & analysis of data:** Processing operations; Elements of analysis; Measures of asymmetry, relationships, associations; Summary chart concerning analysis data collection.
9. **Fundamentals of sampling:** Need for sampling; Sampling distributions, central limit theorem; Sampling theory; Sandler's A-test; Standard error; Estimating population proportion; Sample size and its distribution; Determination of sample size based on various basis.
10. **Interpretation of results:** meaning of interpretation; technique of interpretation; scientific writing & report preparation; fundamentals of scientific writing; steps in report preparation; layout of reports; types of reports; precautions in writing research report.

#### **Recommended books:**

1. Schedule-Y of D&C Act 1948
2. ICH E6-GCP Guideline
3. Ethical Guidelines For Biomedical Research On Human Participants, ICMR, New Delhi, 2006
4. Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary, edited by Ezekiel J. Emanuel, Robert A. Crouch, John D. Arras, Jonathan D. Moreno, Christine Grady  
These are just the indicative books. Students are advised to update themselves with recent regulatory guidelines issued by different agencies like USFDA, ICH, EMEA, CDSCO.
5. Research Methodology in the Medical and Biological Sciences by Petter Laake, Haakon Breien Benestad and Bjørn Reino Olsen
6. Clinical Trials: A Methodologic Perspective by Steven Piantadosi

## Pharmaceutical Technology (Formulations)

### PT-620

#### Pharmaceutical Production Technology

(1 credit)

1. **Design of Pharmaceutical Plants- HVAC systems:** Introduction, Clean room, US Federal Standards, European community guidelines and ISO guidelines and requirements for clean rooms; factors to be considered in designing HVAC in pharmaceutical plant
2. Improved tablet production systems. Benefits, tablet production, production process, improvement in unit processes; development in the area of granulation
3. Tablet coating- process, coating equipment, fluid bed coating, particle coating, application techniques and applications
4. **Parenteral production design:** Design concepts, area planning and environmental control, wall and floor treatment, fixtures, personnel flow, utilities and equipment location.
5. Latest advancements such as isolator barrier technology, trends in aseptic filtration, blow fill seal and pre-filled syringe technology
6. **Lyophilization:** Advantages and application of lyophilization, Principles of lyophilization, process of freeze-drying, equipment used- its principle and working
7. **Advances in dispersion technology:** Nano-systems (R), Dissocubes (R), Nanoedge (R) technologies, Dynamill principle and working
8. **Specialized solid dosage form technologies:** Zydis (R), Orasolv and Durasolv
9. Supercritical fluid technology and application in pharmaceutical field

#### **Recommended books:**

1. Pharmaceutical Dosage Forms: Disperse Systems by Herbert A. Lieberman, Leon Lachman, Kenneth E. Avis.
2. Pharmaceutical Dosage Forms: Tablets by Herbert A. Lieberman, Leon Lachman, Kenneth E. Avis.
3. Pharmaceutical Dosage Forms: Parenteral Medications by Herbert A. Lieberman, Leon Lachman, Kenneth E. Avis
4. Modern Pharmaceutics, Marcel Dekker by Banker, G.S. and C. T. Rhodes
5. The Theory and Practise of Industrial Pharmacy by Lachman, Lieberman and Kanig

### PT-660

#### Formulation Development Concepts as Applied in Industry

(2 credits)

1. **Systems in formulation development:** Components of project initiation; Global versus market specific products; SOPs; Stages of development; Inputs and outputs at each stage.
2. **Prototype formulation development:** Strategy for generics and drug products for NCEs; Innovator product characterization

3. **API sourcing; Formulation additives:** Study of different types of additives e.g. antioxidants and preservatives, coloring and flavouring agents, emulsifying and suspending agents, basic materials for ointment bases, diluents and pharmaceutical solvents, regulatory perspectives: GRAS, IIG;
4. New developments in excipient science, functional and co-processed excipients, international patented excipients.
5. **Drug-excipient interaction:** Drug-excipient interaction and incompatibilities, physical, chemical, pharmaceutical and therapeutic, analytical techniques to characterize drug-excipient incompatibility. Implication of quantitative selection of each excipient in product development
6. Optimization studies for tablets, capsules, injectables, liquid orals, topicals, aerosols and NDDS products
7. **Product and Process development:** Pack strategies; Documentations- MFC, MF, specifications, development report, technology transfer dossier.
8. **Early clinical trial formulations:** Composition and further development stages during product development.
9. **Design of experiments:** Factorial design for product and process development. Fundamentals with case studies from literature.
10. **Stability protocols:** Formulation development based stability protocols; Stability reports.

**Recommended books:**

1. Modern Pharmaceutics by Gilbert S. Banker, Christopher T. Rhodes
2. Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems by L.V. Allen, N.C. Popovich and Howard C. Ansel
3. Remington's Pharmaceutical Sciences
4. Pharmaceutical Dosage Forms: Disperse Systems by Herbert A. Lieberman, Leon Lachman, Kenneth E. Avis.
5. Pharmaceutical Dosage Forms: Tablets by Herbert A. Lieberman, Leon Lachman, Kenneth E. Avis.
6. The Theory and Practise of Industrial Pharmacy by Lachman, Lieberman and Kanig

**PT-670**

**Industrial Pharmaceutical Processing (Scale up and Validation) (1 credit)**

1. Pilot Plant Scale-up: Introduction, stages of product development, stages of scale-up and pilot plant scale up.
2. Process scale-up for solid, liquid, topical and sterile dosage forms.
3. Scale up and Post Approval Changes (SUPAC) guidelines and Change- Control
4. Process Validation: General Principles and Practices ( 2011) guidelines, salient features of process validation and stages of process validation
5. Introduction to Quality by Design in development of pharmaceutical dosage forms, Design

- space definition and implication
6. Introduction to Risk Analysis-Salient features of risk analysis tool such Failure Mode and Risk Analysis (FMEA) in identification of critical process controls.
  7. Pharmaceutical Equipment Qualification: Introduction, stages of equipment qualification, Design qualification, Installation qualification, operational qualification, performance qualification and installation qualification
  8. Cleaning Validation: Introduction, validation methodology of pharmaceutical equipment; guidelines and essential requirement of good cleaning validation
  9. Case studies of Quality by design in formulation of dosage forms

***Recommended books:***

1. Pharmaceutical Process Validation by Ira R. Berry and Robert Nash
2. The Theory and Practise of Industrial Pharmacy by Lachman, Lieberman and Kanig
3. [www.fda.gov](http://www.fda.gov)
4. [Www.who.org](http://www.who.org)

**LS-610**

**General Laboratory Experience 10 hours/week**

(2 credits)

Development and evaluation of drug delivery systems, formulation development and evaluation, transdermal drug delivery system development of control release delivery systems, HPLC method development, generation and characterisation of solid state forms, permeability studies.

## Pharmaceutical Technology (Process Chemistry)

### PT-610

#### Topics Relevant to Drugs and Pharmaceutical Industry

(1 credit)

1. **Drug and pharmaceutical plants:** Building layout, equipment layout, regulatory requirements for the same.
2. **Safety aspects:** Fire, explosion, toxicity, hazards of some selected organic/ inorganic chemicals and methods to handle them safely.
3. **Disaster planning:** Hazard appraisal and control, "on-sight" and "off-sight" disaster planning.
4. **Corrosion and its prevention:** Corrosion characteristics of selected organic/ inorganic chemicals and compatible materials of construction.
5. **Documentation and regulatory record keeping:** Record keeping as required by different statutory bodies.
6. **Management information systems (MIS):** Information management, need, users, systems.
7. Concept and type of pollution, ecology and ecological balance, pollution and health hazards, gaseous pollution and control, water pollution and control.
8. **Waste Management:** Waste minimization technology used in pharma plants.
9. **Instrumentation and process control:** Fundamentals of automatic control, process measurements -concept of accuracy, sensitivity and precision, measurement and control of temperature, pressure level, density, pH, dis-solved oxygen and carbon dioxide.
10. **Use of computers in process control:** Basics and recent computer developments in automation

#### **Recommended books:**

1. Fire Safety Management by Satish Tandon
2. Pollution Prevention of Chemical Processes by Allen David T.
3. The Treatment and Handling of Wastes by Bradshaw, A.D.
4. Good Pharmaceutical Manufacturing Practice: Rationale and Compliance by Sharp John
5. Management Information Systems by Laudon Kenneth C.
6. Plant Design and Economics for Chemical Engineers by Peters, Max S.

### PT-630

#### Synthetic Bulk Drug Technology

(2 credits)

1. **Unit Processes:** Oxidation, Reduction, Sulfonation, Nitration, Halogenation and their applications to the manufacture of known drugs
2. **Bond formation and cleavage:** Industrially feasible C-C bond formation and cleavage reactions, Epoxide and Aziridine ring formation and opening.

3. **Application of new synthetic methodologies in bulk drug synthesis:** Modern peptide coupling reagents, applications of Weinreb's amide in bulk drug synthesis, RAMP/SAMP methodology.
4. **Industrial synthesis of chiral drugs:** Commercial synthesis of (S, S)-Reboxetine, commercial route to Rizatriptan, commercial production of Oseltamivir, their medicinal chemistry approaches and subsequent chemical development.
5. **Process development of a chiral drug:** Project development, medicinal chemistry route, Pros and cons of the early route, process development, chemistry development.
6. **Bulk organic chemicals as building blocks for drugs and drug intermediates:** List of raw materials, their manufacturer in India and abroad and their uses.
7. **Bulk drug or drug intermediate synthesis based on named organic reactions:** Proline-catalyzed Aldol reaction, Mukaiyama Aldol reaction, Baylis-Hillman reaction, Claisen rearrangement, Mitsunobu reaction, Horner-Wadsworth-Emmons Olefination.
8. **Use of protecting group in bulk drug synthesis:** Protecting groups for different functional groups, their applications in bulk drug synthesis.
9. **Catalysis in industrial organic synthesis:** Use of achiral and chiral heterogeneous and homogeneous catalysts, their recovery and reuse.
10. **Biocatalysis in bulk drug synthesis:** Use of enzymes, immobilized enzymes/cells in bulk drug synthesis, deracemization of amines, biocatalytic dynamic kinetic resolution

**Recommended books:**

1. Organic Chemistry by J. Clayden, N. Greeves, S. Warren and P. Wothers
2. Advanced Organic Chemistry, Part A: Structure and Mechanisms by F.A. Carey and R.A. Sundberg
3. Advanced Organic Chemistry, Part B: Reactions and Synthesis by F.A. Carey and R.A. Sundberg
4. Advanced Organic Chemistry. Reactions, Mechanisms and Structure by J. A. March, M. B. Smith
5. Modern Methods of Organic Synthesis by W. Carruthers and I. Coldham
6. Strategic Applications of Named Reactions in Organic Synthesis by L. Kurti and B. Czako
7. Organic Syntheses Based on Name Reactions by A. Hassner and C. Stummer
8. The Art of Process Chemistry by Nobuyoshi Yasuda

**LS-610**

**General Laboratory Experience (10 hours/week)**

(2 credits)

Synthesis of a complex molecule/ drug intermediate or a catalyst which may include 5 or more steps to isolate, purify (chemical methods and through chromatography) and characterize the product from each step. To be familiar with modern analytical methods like UV, IR, NMR, GC-MS, LC-MS, & HPLC methods. To learn about unit processes (hydrogenation, oxidation etc.). Chiral resolution of racemic mixtures and their characterization using polarimeter and chiral HPLC methods.

## Pharmaceutical Technology (Biotechnology)

PT-640

### Bioprocess Technology

(1 credit)

1. **Industrially important primary metabolites:** Process technology for the production of primary metabolites e.g. baker's yeast, ethanol, acetone- butanol, citric acid, lactic acid, amino acids, polysaccharides nucleotides and bioplastics.
2. **Industrially important secondary metabolites:** Production of secondary metabolites- penicillin, cephalosporins, streptomycin, vitamins etc and their uses.
3. **Organic acids:** Production of Citric acid; Gluconic acid; Gluconolactone; Acetic acid; Lactic acid; Kojic acid; Itaconic acid, there uses etc.
4. **Enzymes:** Production and use of glucose isomerase; amidase/aminopeptidase Amylase; Cellulase; Penicillin acylase; Lipase; Oxido-reductase; Protease Hydantoinase; Epoxide hydrolase; Nitrilase hydroxylase; Aldolases; Decarboxylase etc. for the production of different types of drugs and drugs intermediates, future directions; Commercial applications of enzymes in food, pharmaceutical and other industries; enzymes for diagnostic applications.
5. **Amino acids:** Methods of production; Strains for amino acid production; Process control; Product recovery; Production of individual amino acids viz., L-Glutamic acid, L-Lysine, L-Tryptophan etc.
6. **Antibiotics:** b-lactam antibiotics; Amino acid antibiotics; Peptide antibiotics; Carbohydrate antibiotics; Macrocyclic lactone antibiotics; Tetracycline, Anthracycline; Nucleoside antibiotics; Aromatic antibiotics.
7. **Single cell protein:** Production of single-cell protein from alkanes; Bacteria which utilise methane; Menthol fermentations; Single-cell protein from carbohydrates; Single-cell protein from sewage.
8. **Ergot alkaloids:** Occurrence and significance; Structure; Biosynthesis; Production of ergot alkaloids; Regulation of alkaloid production in cultures; Strain development.
9. **Vaccines:** General considerations in vaccine production; Semple-type vaccine; Fermi-type vaccine; Phenolized freeze-dried sheep brain vaccine; Vaccine for Man prepared in human diploid cells; Production of vaccines using animal cell culture.
10. **Biotransformation and stereoselective production of drug intermediates:** Definition of biotransformation; Advantages and disadvantages of Biocatalysis over chemical catalysis; Biocatalysis for the synthesis of some chirally pure pharmaceutical intermediates etc.

#### **Recommended books:**

1. Bioprocess Engineering Principles by Pauline M. Doran
2. Principles of Fermentation Technology by Peter F. Stanbury, Allan Whitaker, Stephen J. Hall
3. Biotechnological Innovations in Chemical Synthesis (Biotol series) by J. A. M. van Balken
4. Biotol Series (This series has many books pertaining to all fields of Biotechnology, students have to select the books as per the topics of interest)

## PT-690

### Downstream Processing of Biological Products

(1 credit)

1. **Pre-treatment:** Importance of pre-treatment; Dealing with high viscosity fermentation broth; Coagulation; Flocculation; Pasteurization; Sterilization; Adsorption on filter aids; heating etc.
2. **Filtration:** Theories of filtration, Conventional and Non-conventional filtration Darcy's equation, Various forms of Darcy's equation, Batch filters, continuous rotary filters, Microfiltration, Ultrafiltration, Reverse Osmosis; Symmetric and asymmetric membranes.
3. **Centrifugation:** Gravity sedimentation, Centrifugal sedimentation; Stoke's equation; Batch and continuous centrifuges; Various types of centrifuges; Centrifugation theory; Determination of molecular weight and particle size from centrifugation data; Sedimentation coefficient; Various forms of Stoke's equation; Scale-up of centrifuge.
4. **Cell disruption:** Different methods of cell disruption, advantages, disadvantages, solid shear method and liquid shear method; Factors affecting the rate of cell disintegration and solving of numerical thereof.
5. **Solvent-solvent extraction:** Theories of solvent-solvent extraction; co-current and counter-current extraction; separation factor; solid yield; Aqueous two phase extraction; Supercritical fluid extraction; pervaporation and numerical thereof.
6. **Adsorption:** Langmuir adsorption isotherm; Equilibrium relationship for adsorption; Adsorbate; Freundlich adsorption isotherm; Fixed bed adsorber, analysis thereof; Antibody recovery by adsorption; case studies.
7. **Evaporation:** Theories of evaporation; Evaporator cum crystallizer; Economics of evaporator design; Evaporative equilibrium; Factors influencing the rate of evaporation; Solving of numericals associated with evaporation.
8. **Crystallization:** Crystallization theory; Rate of nucleation and rate of crystal growth; Particle size distribution of crystals; Solving of numericals associated with crystallization; Batch and continuous crystallizers.
9. **Distillation:** Theories of distillation; Batch and continuous distillation; Azeotropic distillation; Distillation in food processing; Simple distillation; Fractional distillation; Steam distillation; Vacuum distillation etc.
10. **Drying:** Drying of bioproducts; Drying mechanism; Freeze drying; Supercritical drying; Natural air drying; Spray drying; Equipment for drying; Equilibrium moisture content of bioproducts; Rate of drying curves.

#### **Recommended books:**

1. Process Biotechnology Fundamentals 2nd/ed by S. N. Mukhopadhyay
2. Bioprocess Engineering Principles by Pauline M. Doran
3. Principles of Fermentation Technology Biotol series by Peter F. Stanbury, Allan Whitaker, Stephen J. Hall
4. Biotol Series: Biotechnological Innovations in Chemical Synthesis by J. A. M. van Balken
5. Biotol Series, Product recovery in Bioprocess Technology by Butterworth Heinemann
6. Industrial sterilization by Richards

## **LS-610**

**General Laboratory Experience -10 hours/week**

(2 credits)

### **Fermentation technology:**

Experiment-1: Immobilization of whole cells and enzymes and compare the activities.

Experiment-2: To determine the mass transfer coefficient (KL a) by sodium sulphite method in a stirred tank reactor.

Experiment-3: To determine the mass transfer coefficient (KL a) by static and dynamic gassing out method. Discussion of the results and viva.

### **Enzyme biochemistry:**

Day-1 & 2: Mitochondrial preparation and assay.

Day-3 & 4: Enzyme purification and assay.

### **Recombinant DNA technology:**

Day-1: Preparation of E. coli growth medium. Preparation solutions for plasmid isolation inoculation for miniprep.

Day-2: Mini preparation of restriction digestion.

Day-3: Gel electrophoresis. Molecular weight calculation.

Day-4: Discussion of result and viva.

## General Courses

### GE-611

#### Seminar

(1 credit)

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

**Courses of Study 2016**  
**Semester-III**

## Pharmacoinformatics

### PI-560

#### Pharmacoinformatics-The Tools

(1 credit)

1. **Introduction to PERL:** History, Built in functions; Applications.
2. **Data types and operator:** Scalar data type, array data types, hash data types, subroutines, array and hash operators, perl data structures.
3. **Perl operators:** Arithmetic operators; Relational operators; Logical operators, assignment, Bitwise operators.
4. **Control structures:** Statement blocks, branching structures, loops, for loop, for each loop, do... until etc.
5. **Subroutines:** Subroutine data types; Writing subroutine; Return function; Calling subroutine; Global and lexical variable.
6. **File handles:** STDIN, STDOUT; Formatted output; Here strings; File tests, handling file opening errors, examples.
7. **Pattern matching:** Writing regular expressions; Simple meta characters; Pattern matching.
8. **Biocomputing:** Introduction to Bioperl; Retrieval and alignment of sequences; Applications.
9. **3D database searching algorithms:** Constrained systematic search; Ensemble distance geometry method, ensemble molecular dynamics methods; Clique detection methods.
10. **Pattern recognition techniques:** Artificial intelligence, logical programming, expert systems, artificial neural networks (ANN); Genetic algorithms.

#### *Recommended books:*

1. Chemoinformatics by Gasteiger
2. Virtual Screening in Drug Discovery by Juan Alvarez, Brian Shoichet (Editors)
3. Molecular Modelling: Principles and Applications by Andrew Leach
4. QSAR and Molecular Modeling by Satya P. Gupta
5. 3D QSAR in Drug Design: Theory, Methods and Applications
6. Neural Networks in Chemistry and Drug Design by J. Gasteiger

### PI 570

#### Pharmacoinformatics- The Methodology

(1 credit)

1. **Pharmacoinformatics:** Integration of Bioinformatics, Chemoinformatics, genomics and proteomics. In silico identification and validation of novel therapeutic targets:
2. Bioinformatics followed by computational biology, Homology modeling. Pattern searching methods in drug identification. 3D database search methods: Artificial neural network methods, Genetic algorithm methods in chemoinformatics.

3. **Databases in pharmacoinformatics:** Evaluation of diverse compound subsets from chemical structure databases. Recognition of hypotheses, validation of hypotheses using pharmacophore pattern searching methods in chemoinformatics. Spectral and Crystallographic databases.
- 4) Ab initio gene prediction techniques to predict novel gene targets. Case studies.
- 5) **In silico combinatorial and high-throughput methods:** Computational methods of library design.
- 6) **Virtual screening:** Lead compound selection and lead optimization using virtual screening. Filtering methods. Rapid QSAR methods for virtual screening, Rapid molecular docking methods for virtual screening.
- 7) **Receptor selectivity mapping:** Testing the lead drug candidates (from chemoinformatics methods) for their selectivity across a broad panel of targets (from bioinformatics methods). Scoring functions and their importance in virtual screening. Case studies. Internet computing in drug discovery.
- 8) **In silico ADME Analysis:** Modeling ADME properties, pattern recognition, regression, ANN, GA, Quantum mechanical methods.
- 9) **Algorithms in pharmacoinformatics:** Development of small packages for Pharmacoinformatics analysis. Advanced algorithms in descriptor development. Algorithms for QSAR.
- 10) **Case studies:** Pharmacoinformatics in anti-diabetic drug design, Pharmacoinformatics in anti-malarial drug design.

***Recommended books:***

1. J. Gasteiger, Chemoinformatics
2. A.R. Leach, Introduction to Chemoinformatics
3. J. Bajorath, Chemoinformatics: Concepts, Methods, and Tools for Drug Discovery
4. J. Bajorath, Chemoinformatics and Computational Chemical Biolog

## Pharmacy Practice

**PP-551**

### **Pharmacy Informatics**

(1 credit)

1. **Introduction to pharmacy informatics:** Role of informatics to enhance the services provided by pharmaceutical care givers.
2. Health information systems architecture, health data management.
3. Medical coding and classification.
4. **Medical databases:** Clinical data collection and acquisition and evaluation. methods; Privacy and security of clinical data.
5. Clinically relevant drug-drug interactions and databases.
6. Telemedicine and telehealth.
7. Ethics in medical informatics.
8. Pharmacy systems and automation.
9. **Drug information systems:** Electronic records, informatics applications in pharmacy, survey and evaluation of on-line resources.

#### ***Recommended books:***

1. Introduction to Clinical Informatics by Degoleut Patrice and Feischi Marius
2. Information Technology for Integrated Health Systems by Kissinger K & Borchard S. John Wiley
3. Medical Data Management A Practical Approach, Leiner, Gaus and Faux

## Clinical Research

### CR-551

#### Clinical Trials Documentation

(3 credits)

1. Writing Informed consent and translation in local languages.
2. Investigator Brochure preparation.
3. Patients' diaries.
4. Understanding of various documents required for conduct of a good clinical trial.
5. Maintaining Essential Documents of clinical trials.
6. Managing Essential Documents of clinical trials.

#### **Recommended books:**

1. Informed Consent: Legal Theory and Clinical Practice by Jessica W. Berg, Paul S. Appelbaum, Lisa S. Parker, Charles W. Lidz
2. WHICH Documents, Why? A Guide to Essential Clinical Trial Documentation for Investigators (Clinical trials) by David R. Hutchinson

### CR-552

#### Monitoring of Clinical Investigations

(1 credit)

1. Site management.
2. Role and responsibilities of SMOs.
3. Monitoring; the need & the methods.
4. Liaison with investigators; skills required.
5. Responsibility for Data and Safety Monitoring board.
6. Resolving the Conflict of Interest.

#### **Recommended books:**

1. Data Monitoring Committees in Clinical Trials, A practical Perspective by S. S. Ellenberg, T. R. Fleming, D. L. DeMets
2. Conducting Clinical Research: A Practical Guide for Physicians, Nurses, Study Coordinators, and Investigators by Judy Stone
3. The CRA's Guide to Monitoring Clinical Research by Karen E. Woodin, John C. Schneider, Sara Gambrill, Steve Zisson

### CR-553

#### Emerging Technologies in Clinical Trials

(1 credit)

1. Use of technologies for improvement of clinical trials.
2. Computerized Systems used in clinical trials.
3. Web-based data capture.
4. Electronic data submission.

5. Remote data capture from sites.
6. Use of PDAs for data handling

**Recommended books:**

1. Using Web and Paper Questionnaires for Data-Based Decision Making: From Design to Interpretation of the Results by Susan J. Thomas
2. The Science of Real-Time Data Capture: Self-Reports in Health Research by Arthur Stone, Saul Shiffman, Audie Atienza, Linda Nebeling.

## **CR-554**

### **Quality Control and Quality Assurance in Clinical Trials**

(2 credits)

1. Understanding audit: Audit cycle, identifying key issues, setting standards.
2. **Audit process:** Results and re-audit.
3. Good clinical practice and quality assurance.
4. Quality control versus quality assurance.
5. Quality in/quality out.
6. Role of a clinical quality assurance department.
7. Clinical quality assurance auditor.
8. Source document verification.
9. Types of audit.
10. Inspection by regulatory authority

**Recommended books:**

1. Clinical Trials Audit Preparation: A Guide for Good Clinical Practice (GCP) Inspections by V. M. Madzarevic
2. A Practical Guide to Quality Management in Clinical Trial Research by Graham D. Ogg

## **CR-555**

### **Protocol Writing/Defence Assignment**

(1 credit)

The student is expected to write at least one clinical trial protocol on a hypothetical scenario and defend the protocol with a group of evaluators.

**Recommended books:**

1. Writing Clinical Research Protocols: Ethical Considerations by Evan DeRenzo and Joel Moss

**Courses of Study 2016  
Pharmaceutical Management**





# Pharmaceutical Management

## Semester-I

### PM-501

#### Fundamentals of Management

(3 credits)

1. **Schools of management thought:** Forerunners of Scientific Management; The era of Scientific Management; The human Behaviour School; The social system school; Decision theory school; The mathematical and quantitative school; The system school.
2. **The contingency theory of Management:** Contemporary Management thinkers; Contemporary organizational theories.
3. **Organizations and the need for management:** Why study organisations and management. Efficiency and effectiveness, management, process organisational environments.
4. Social responsibility and ethics.
5. **Planning:** Nature and process, importance, types of plans, strategy, policies, objective planning premises, principles of planning, decision making, making planning effective.
6. **Organising:** Process of organising principles, organizational design and organizational structure; Types of organisational structures.
7. **Downsizing distribution of authority:** Decentralisation, centralisation and making organisations.
8. **Effective Communications process:** Barriers and breakdowns in communications, effective communications.
9. **Controlling:** The system and process of controlling. Control techniques, control of overall performance. Ensuring effective controlling.

#### *Recommended books:*

1. Fundamentals of Management by J. F. Stoner,
2. Fundamentals of Management by Stephen. P. Robbins,
3. Fundamentals of Management by Andrew. J. Dubrin,
4. Fundamentals of Management by Ricky. W. Griffin,
5. Fundamentals of Management by Danay Samson, Richard.L.Daft.

### PM-502

#### Accounting for Management

(3 credits)

1. **Basic accounting:** Concepts and conventions underlying preparation of financial statements; Accounting equations; Accounting Processes and accounting policies; Revenues and costs matching and inventory valuation; Preparation of final accounts; Trading account, profit and loss account, balance sheet. Depreciation accounting; Intangible assets accounting. Understanding published annual reports including fund flow statement. Accounting for price-level changes and human resources. Social and

environmental accounting.

2. **Basic cost concepts:** Cost drivers, how and why costs are classified. Systems of cost determination. Cost analysis for decision making; Marketing and production decisions like deletion or addition of products, optimal use of limited resources, pricing, make or buy, joint product costs etc.
3. **Cost analysis for control:** Standard costing; Variances- materials, labour, overheads, sales and profits, budgeting and control; Budget preparation including master budget and zero-base-budgeting. Contemporary issues in management accounting; Value chain analysis, activity based costing, quality costing, target and life cycle costing.

**Recommended books:**

1. Introduction to Financial Accounting by Charles T. Horngren, Gart L. Sundem, John A. Elliott and Donna R. Philbrick
2. Cost Accounting: A Managerial Emphasis by Charles T. Horngren and S. Datar
3. Financial Statement Analysis by George Foster
4. Core Concepts of Accounting by Robert N. Anthony
5. Management Accounting by S N Maheshwari
6. Financial Accounting by Mukherjee and Hanif
7. Accounting: Text and Cases by Robert N. Anthony
8. Essentials of Cost Accounting by V K Saxena and C D Vashisht
9. Cost Management by V K Saxena and C D Vashisht
10. Cost Accounting: Principles and Practice by B M Lall Nigam
11. Cost Accounting by P C Tulsian
12. Fundamentals of Accounting by N K Agrawal and R K Sharma
13. Fundamentals of Accounting by T P Ghosh
14. Indian Accounting Standards by R.L.Gupta & M.Radhaswamy
15. Financial Accounting A Managerial perspective by Dr. D.Mukhopadhyay

**PM-503**

**Managerial Economics**

(3 credits)

1. **The nature and scope of managerial economics:** Economic theory and managerial economics. Managerial economist's role and responsibilities. The demand theory and analysis. The determinants of demand. Demand elasticities price, income, cross; Using elasticities in managerial decision making.
2. **The theory of consumer choice:** The cardinal utility approach. The indifference curve approach. The revealed preference and the theory of consumer choice under risk.
3. **The production theory and estimation:** The production function. Production with one and two variable inputs. Three stages of production. Economics of state and scope. Estimation of production function. The Cob Douglas and CES function. Use of time-series. The cost theory and estimation. The economic concept of cost. The short and long run cost functions. Theories of cost. Estimation of cost functions.
4. **Market structure and degree of competition:** Perfect competition. Profit maximizing output in the short and long run monopoly. Profit-maximizing price and output in the short

run and long run. Monopolistic competition. Price and output determination in short and long run. Product variation and selling expenses. Behaviour.

5. **Oligopoly:** Characteristics, price rigidity, interdependence. The Cournot Model, Cartels and Collision. Price leadership. The behaviour theory of the firm and managerial theory of the firm.
6. **Price Practices:** Pricing under multiple products, price discrimination. International price discrimination and dumping. Transfer pricing.
7. **The theory of distributio:** Determination of factor prices, rent, wages, interest and profit.

**Recommended books:**

1. Advanced Economics Theory by Ahuja, H.L.
2. Micro Economic Theory and Applications by Browing, E.K. and Browing, J.M.
3. Managerial Economics by Dean. J.
4. Managerial Economics by Duncan, W.R. and Crook, J.N.
5. Modern Micro-Economics by Koutsoyiannis, A.
6. Managerial Economics by Paul, S., Gupta, G. and Mote,V.
7. Managerial Economics by Varshney, R.L. and Maheshwari, K.L.
8. Macro Economics by Shapiro, E.

## PM-504

### Pharmaceutical Marketing

(3 credits)

1. **Marketing tasks and philosophies:** Marketing systems and pharma marketing environment
2. **Consumer market:** Pharmaceutical and buyer behaviour.
- 3.. **Strategic marketing process:** Industrial market, market segmentation, market measurement and forecasting.
- 4.. **Strategic planning in pharma marketing:** Situation analysis, developing marketing objectives; Determining positioning and differential advantage, selecting target markets designing marketing mix for target market.
5. **Product decisions:** Product classification, product life-cycle strategies,
6. Branding, packaging and labeling decisions.
7. **Pricing decisions:** Pricing methods and strategies.
- 8.. **Distribution decisions:** Importance and functions of distribution channels, distribution channel members.
9. **Promotion decisions:** Promotion mix elements,
10. Communication in pharmaceutical industry.

**Recommended books:**

1. Pharmaceutical Marketing by Subba Rao
2. Pharmaceutical Marketing by Dimitris and Dogramatiz

3. Pharmaceutical Marketing by Smith
4. Marketing Management, A South Asian Perspective by Kotlar
5. Marketing Management, Planning, Implementation and Control by Ramaswami and Namakumari.
6. Marketing Management and Administrative Action, Tata McGraw Hill Management Information Systems by Kenneth C. Laudon
7. Information Systems for Modern Management by Robert G. Murdick
8. Fundamentals of Information Systems, Second Edition by Ralph M. Stair and George Walter Reynolds

## PM-505

### Quantitative Techniques and Management Techniques

(3 credits)

1. **Frequency distribution:** Graphical representations; Measures of central tendency (mean, median, mode, quartiles etc.); Measure of dispersion (range, variance, standard deviation). Probability- introduction ideas (probability rules, statistical independence, statistical dependence, joint probability, marginal probability).
  - a) Notion of random variable- expectation.
  - b) Discrete distribution- Binomial, Poisson.
  - c) Continuous distribution- normal, exponential, uniform, joint distribution.
2. **Sampling design:** sampling and non-sampling error, random sampling, systematic sampling, sampling with probability proportions of size, stratified sampling, cluster sampling and multistage sampling. Estimation- point estimation and interval estimation. Hypothesis testing- one sample test, two sample test, z test, x<sup>2</sup> test.
3. **Simple regression and correlation:** Estimation using regression line. Correlation analysis. Introduction to multiple and partial correlation. Time series- variations in time series, trend analysis, cyclical variation, seasonal variation, irregular variation. Index numbers- unweighted aggregates index, weighted aggregates index. Average of relative methods, quantity and value indices.
4. **PERT/CPM:** Phases of project management, work breakdown structure (WBS), network arrow diagram. Measure of activity, Forward and backward pass Computation, representation in tabular form, slack, critical path, probability of meeting the scheduled dates. A critical path for CPM, float, negative float, negative slack, crashing the network.
5. **Basics of linear programming:** Formulation of LPP, graphical method, simplex method, duality; Transportation model, least time transportation assignment model. TPT models- waiting line models, game theory.

#### **Recommended books:**

1. Business Statistics by Weiers
2. A first Course in Business Statistics by McClave
3. Quantitative Methods for Business and Economics by Glyn Burton, George Carroll, Stuart Wal
4. Business Statistics by J.K.Sharma
5. Business Statistics by S. P Gupta
6. Statistics for Management by Kapoor and Levin

7. Statistics for Business & Economics by Anderson
8. Business Statistics by Bhardwaj, R.S.
9. Statistics for Management by Levin & Rubin

## PM-506

### Information Technology and MIS

(3 credits)

1. Introduction to hardware and software.
2. Office automation, business data processing including file organisation, data base management, artificial intelligence, flow charts and data flow diagrams.
3. **End user computing using MS-Office package:** MS Word, MS Excel, MS Power point, word processing including mail merge, transfer, editing, spreadsheet design, graphics, macros.
4. Networking concepts internet, network basics, tools and services on internet, browsing the net. Gopher Eile systems, network menus, electronic mail, address, newsgroup, all USENET, TELLNET for remote login, fundamentals of website design.
5. **Data communication:** Client/server technology, interactive computer graphics, computer viruses, downloading file with FTP, intranet and its business applications using HTML.
6. Functional applications of MIS with particular reference to knowledge management in pharmaceutical.
7. Application of following software in Management:
  - a) Sigma Stat                      b) Excel
  - c) SPSS, SAS                      d) ERP
  - e) SAP

#### **Recommended books:**

1. Management Information Systems by Kenneth C. Laudon
2. Information Systems for Modern Management by Robert G. Murdick
3. Fundamentals of Information Systems, Second Edition by Ralph M. Stair and George Walter Reynolds

## PM-507

### Human Behaviour in Organisation

(2 credits)

1. **Foundations of organisational behaviour:** Understanding behaviour in organisations, OB model.
2. Introduction to Individual.
3. **Motivation:** Needs, contents and processes; Maslow's hierarchy of human needs, Herzberg's two factor theory of motivation, Vroom's expectancy theory.
4. Group processes:
5. **Importance of values:** Types of values, attitudes and consistency (cognitive dissonance theory).

6. Group dynamics and teams.
7. **Leadership:** Trait theories, behavioural theories, Ohio state studies, university of Michigan studies, the managerial grid, contingency theories; Hersey and Blanchard's situational theory and path goal theory.
8. Transactional analysis.
9. **Organisational culture:** What is organisational culture, what does culture do, creating and sustaining culture, how employees learn culture.
10. **Organisational change:** Forces of change, resistance to change, approaches to managing organisational change.
11. **Conflict management:** Transitions in conflict thought, functional Vs dysfunctional conflict, the conflict process.

**Recommended books:**

1. Organizational Behavior by Luthans, F.
2. Organizational Behavior - Human Behavior at Work by Newstrom, J.W. and Davis, K.
3. Understanding Organizational Behaviour by Pareek, U.
4. Organizational Behavior by Robbins, S.P., Judge, T. and Sanghi, S.
5. Organisational Behaviour and Change by Weiss, P.

## **PM-508**

### **IPRs in Pharma Management**

(1 credit)

1. **IPR fundamentals:** IP vs conventional property. Importance/role of IPRs in business management. Introduction to 8 different IP mechanisms, their characteristics, properties and business.
2. **IPRs in strategic business planning:** Business implications and importance of various IP mechanisms, especially patents.
3. **Elements of national and international patent applications:** Forms and formats. Drafting of patent applications; Fee, time schedules and related aspects. International patenting and introduction to PCT. Understanding patent life cycle management.
4. **Patents as sources of technological jumps:** Introduction to technology capture concepts in business development. Making use of technology tools in business globalization. Technology development organizations in India and abroad.
5. **Patent mapping:** Introduction and practical utility in business development.
6. **International treaties-I:** Introduction to TRIPS. Concept behind GATT/TRIPS. Emergence of WTO.
7. **International treaties-II:** DOHA declaration and its significance for Indian pharma industry. Cancun agreement. WIPO and its role in IP promotion at global level.
8. **Development of human IPR resources for business management:** Essential requirements, job profiles. Introduction to MIPC (Germany) and FPLC (USA). Role of AUTM, LESI. Practical tips for enhancing IP related qualifications for management professionals.
9. **Ethics in IP:** Importance and need for training in ethics and values in the context of IPRs.

Case studies.

10. **Case studies:**

- a) Using patents as tools in strategic business planning.
- b) Drafting of technology offers and requests.
- c) Generating an ICC (infringement clearance certificate) and Technology status report) GTSR (Globald)
- d) Practical exercise on patent mapping.

**Recommended books:**

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

**PM-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.

## Semester-II

### PM-601

#### Pharmaceutical Business Environment

(3 credits)

1. **Concept, significance and nature of corporate environment:** Critical elements of various broad environment factors changing dimensions of corporate environment. Emergence of new business houses in India.
2. **Technique of environmental scanning:** Environmental scanning of some industries.
3. **Economic environment of business:** Concept, component (fiscal and monetary policy) and development (pre-globalisation).
4. **Political legal environment of business:** The critical elements of political environment constitution provisions affecting business in India; The preamble, directive principles of state policy and fundamental rights, the economic roles of the government, growth and control of corporate sector in India. Political dimensions of doing business in India, changing dimensions of legal environment in India.
5. **International and technological environment:** Multinational corporation, foreign collaboration and Indian business, non resident Indian and corporate sector, World Bank, IMF policies and India, trade barriers, foreign trade policies, the technological environment in India, policy for research and development, technology and economic development, appropriate technology and problems of technology transfer.
6. Socio cultural environment.

#### **Recommended books:**

1. Business and Government by Francis Cherunilam
2. Business Environment by K Chidambaram and V Alagappan
3. Business Policy and Environment by K Aswathappa
4. Business Environment by F. Cherunilam
5. Business Environment by Raj Aggarwal and Parag Diwan
6. International Business Environment and Management by V K Bhal and S Shiva Ramu
7. Government and Business by N K Sengupta
8. World Trade Organization by Anne Krueger
9. Indian Constitution by D D Basu
10. Constitution of India by P M Bakshi
11. Technology Acquisition and Application: Interpretation of the Indian Experience by A V Desai
12. Technology and Economic Development The Indian Case by Debashish Mallick
13. Multinational Corporations in India by Shiva Ramu
14. Business Laws by N D Kapoor
15. Business Policy and Strategic Management by W F Glueck and Jauch
16. India's Family Owned Business ICFAI Case Study Series
17. Globalisation (The Economist Publication)

18. Economic Reform and Development by Raj Kumar Sen
19. Economic Policy and State Intervention by T N Srinivasan
20. The World is Flat: A brief history of the 21st Century by Thomas L. Friedman
21. Indian Economy by Ruddar Dutt and K P M S Undaram
22. Principles and Practice of Public Enterprise Management by Laxmi Narayan
23. Indian Economy by Bimal Jalan

## PM-602

### Financial Management

(3 credits)

1. **Corporate finance function:** Concept, scope and its relationship with other functional areas. Sources of financial information, financial institutions and markets. Objectives. Function in corporate finance- need, characteristics, classical objective functions, some real world problems, maximizing shareholders wealth. Understanding financial statements ratio analysis, cash flow statement, EVA, reporting on corporate governance. Present value time value of money as basis of financial decision-making, mathematics of finance, spreadsheet modeling in corporate finance. Risk and return concept of risk, relationship between expected return and risk, models for risk and return - CAPM, APT and multi-factor models.
2. **Investment decision making:** Estimating free cash flows, cost of capital decision rules, capital budgeting rules to projects when facing capital rationing constraints. Capital structural planning operating and financial leverage; Capital structure theories and value of firm; Capital structure planning and policy; Cost of capital, capital structure and value of firm.
3. **Financing decision:** Hybrid securities namely convertible and non-convertible debentures, deep discount bonds, warrants, secured premium notes. Asset-based financing leasing, hire purchase. Dividend policy- dividend theories, determination of dividend policy, share buyback, retention of profits, dividend policy studies in India.
4. **Venture capital financing:** Concept, developments in India, process and method of financing, fiscal incentives, debt securitization.
5. **Working capital estimation and management:** Operating cycle concept, managing cash and cash equivalents, managing inventory, managing accounts receivables, managing payables. Working capital financing trade credit, bank finance, commercial paper, factoring, money market structures and recent developments.
6. **Valuation of M & A projects:** Economics of M&A, methods of valuation NAV, PECV, MPS, EPS.
7. **Corporate strategy, financial policy and shareholder value creating:** Link between corporate strategy and financial strategy, implications for capital structure, dividend policy and capital budgeting policy of each corporate strategy.

#### **Recommended books:**

1. Fundamentals of Financial Management by James C. Van Horne and John H. Wachowicz Jr.

2. Financial Management: Theory and Practice by Prasanna Chandra
  3. Principles of Managerial Finance by Lawrence J Gitman
  4. Financial Management by R P Rastogi
  5. Financial Management by Ravi M. Kishore
  6. Financial Management: Principles and Practices by Dr. S N Maheshwari
  7. Financial Management by M Y Khan and P K Jain
  8. Financial Management by I M Pandey
  9. Financial Management by P V Kulkarni
  10. Principles of Corporate Finance by Richard A. Brealey and Stewart C. Myers
  11. Financial Statement Analysis by George Foster
  12. Modern Corporate Finance by Alan C Shapiro and Sheldon D. Balbirer
  13. Creating Value from Mergers and Acquisitions: The Challenges by Sudi Sudarsanam
  14. Understanding and Analyzing Balance Sheets using Excel Worksheet by Ruzbeh J. Bodhanwala
- Journals and Magazines:
15. Vikalpa (IIM, Ahmedabad)
  16. Decision (IIM, Calcutta)
  17. Vision (MDI, Gurgaon)
  18. Chartered Accountant (ICAI, New Delhi)
  19. Management Accountant (ICWAI, now ICAI)
  20. Finance and Development (IMF)
  21. Capital Market
  22. Outlook Business

## PM-603

### Marketing Research

(3 credits)

1. **Introduction:** Nature, scope and importance of marketing research, role of marketing research in decision making; Factors influencing marketing research decisions, marketing information systems, the marketing research process.
2. Problem identification.
3. **Research design:** Exploratory, descriptive and conclusive. Methods of data collection observation, experimentation, survey, desk research method.
4. **Sampling Plan:** Sampling method, sample size, designing of questionnaire.
5. Field investigation.
6. **Data processing:** Editing, coding, classification and tabulation.
7. **Data analysis:** Hypothesis testing.
8. **Application:** Product research, advertising research, market and sales analysis research.

**Recommended books:**

1. Marketing Research by Agrawal, S.
2. Marketing Research by Boyd, Westfall and Stasch
3. Marketing Research, Methodological Foundations by Churchill, G. A.
4. Marketing Research for Managers by Crouch, S.
5. Handbook of Marketing Research by Ferber, R.
6. Research for Marketing Decisions by Green, Tull and Albauni
7. Marketing Research - Measurement and Method by Tull and Hawkins
8. Marketing Research by Aaker
9. Marketing Research by Naresh Malhotra
10. Statistics in Marketing Research by Chuck Chrapani
11. Statistics for Marketing and Consumer Research by Mario Mazzocchi
12. Questionnaire Design by IAN Brace Marketing Research by Malhotra

**PM-604**

**Materials and Operations Management**

(3 credits)

1. **Integrated materials management:** Concept, need, definition, and scope and advantages.
2. **Materials planning:** Need and definition, factors affecting planning, external and internal, purchasing and materials planning, techniques of planning, guidelines of planning.
3. **Materials identification and standardization:** Classification of materials, codification systems, standardization.
4. **Inventory control:** Importance and scope, costs, economic order quantity; Inventory control techniques.
5. **Introduction to production and operations management:** Evolution of Production / operations management; Nature of production/operations management; Production function and its environment, functions of production /operations manager, organization of production function.
6. **Facilities planning:** Product selection and design, service design, process and technology selection, location of manufacturing / service facility, center of gravity and median models, dimensional analysis, Brown and Gibson model.
7. **Layout of manufacturing /service facility:** Product layout, process layout, fixed position and group layout , layout design; Relationship based and load-distance cost matrix, materials handling concepts.
8. **Production planning and control:** Aggregate production planning, materials requirement planning, operations scheduling and production, activity control for mass manufacturing, batch processing and job shop.

**Recommended books:**

1. Operations Research by Kalavathy, S.
2. Operations Research by Kapoor, V.K.
3. Operations Research by Paneerselvam, R.
4. Operations Research: Theory and Applications by Sharma, J.K.
5. Operations Research: An Introduction by Taha, H.A.
6. Operations Management by Bernard Taylor
7. Production and Operations Management by Adam, Ronald and Ebert
8. Production and Operations Management by Aswathappa and Bhat

## PM-605

### Business Communication

3 credits)

1. **Executive communication perspective:** Meaning, importance, elements of the communication model, barriers to communication.
2. **Ethics in business communication:** Ethics, audit, communication in a global market place. Business communication and legal issues, business communication and technology contract.
3. **The case method:** Introduction and brief history. Steps in case analysis, case presentation.
4. **Principles of business communication written:** The Gunning Fog Index. The reasoning process.
5. **Principles of business communications oral:** Making speeches, conducting meetings. Giving dictation.
6. **Types and techniques of business letters:** Basic qualities of business letter. Opening paragraph, closing paragraph.
7. **Mechanics of letter writing:** Specific types of letters, resume, inquiries solicited and unsolicited, answers to inquiry letters, favourable and unfavourable, order, order acknowledgement. Thank you letters, claims, answers to claims, bad news letters, sales letters.
8. Report Writing.

#### **Recommended books:**

1. Business Communication Today by Courtland, B. L. and Thill, J.V.
2. Business Communication: Building Critical Skills by Lochar, K.O. and Maczmarch, S.K., Effective
3. Business Communication by Murphy, H.A; Hilderbrand, W. and Thomas, P.J.,
4. Management Communication: A case Analysis Approach, Pearson Education by O'Rourke, J.S.
5. Handbook for Writers and Editors by Rao, S.S.
6. Basic Communication: Skills for Empowering the Internet Generation by Raymond, L. and Flately, M.

## PM-606

## Human Resource Management

(2 credits)

1. **The field of HRM:** An overview, concept and functions, personnel to HRM.
2. The Personnel organisation: Structure of human resource development and role and responsibilities of the human resource manager.
3. **Personnel policies:** Formulation and essentials of sound personnel policies.
4. **Acquisition of human resources:** Objectives, policies and process, manpower planning, job analysis, job description, job specification, recruitment, selection, induction, placement, promotion and transfer.
5. **Development of human resources:** Determining training needs, training, management development and performance appraisal.
6. **Maintenance of human resources:** Compensation, administrative job evaluation, designing and administering the wage and salary structure.
7. **Separation processes:** Turnover, retirement, layoff and discharge, VRS.
8. Research and the future: Current trends and future implications for HRM.

### *Recommended books:*

1. Human Resource Management by Aswathappa, K.
2. Human Resource Management Theory and Practice by Bratton, J. and Gold, J.
3. Human Resource Management by Dessler, G.
4. Human Resource Management by Flippo, E.
5. Managing Human Resources by Gomez-Mejia, L.
6. Human Resource Management by Ivantsevich, J.
7. Human Resource Management by Kandula, S. R.,

## PM-607

### Supply Chain Management in Pharmaceutical Sector

(3 credits)

1. Concept of supply chain management, scope of SCM in pharma sector,
2. Drivers and obstacles of supply chain.
- 3.. Planning demand and supply in a supply chain.
- 4.. Management of inventories in supply chain.
- 5.. Transportation, network design In supply chain
6. Role of information technology in supply chain.
- 7... Co-ordination in supply chain.
8. Financial factor affecting supply chain.
- 9.. Role of Logistics in supply chain.

**Recommended books:**

1. Supply Chain Management by Chopra
2. Marketing Logistics by Kapoor and Kansal
3. Logistics and Supply Chain Management by Cristopher
4. Strategic Supply Chain Management by Cohen and Rossel
5. Strategic Supply Chain Management by Micheal Hugos

**PT-610**

**Topics Relevant to Drugs and Pharmaceutical Industry**

(1 credit)

1. **Drug and pharmaceutical plants:** Building layout, equipment layout, regulatory requirements for the same.
2. **Safety aspects:** Fire, explosion, toxicity, hazards of some selected organic/ inorganic chemicals and methods to handle them safely.
3. **Disaster planning:** Hazard appraisal and control, “on-sight” and “off-sight” disaster planning.
4. **Corrosion and its prevention:** Corrosion characteristics of selected organic/ inorganic chemicals and compatible materials of construction.
5. **Documentation and regulatory record keeping:** Record keeping as required by different statutory bodies.
6. **Management information systems (MIS):** Information management, need, users, systems.
7. **Pollution and pollution control:** Concept and type of pollution, ecology and ecological balance, pollution and health hazards, gaseous pollution and control, water pollution and control.
8. **Waste Management:** Waste minimization technology used in pharma plants.
9. **Instrumentation and process control:** Fundamentals of automatic control, process measurements -concept of accuracy, sensitivity and precision, measurement and control of temperature, pressure level, density, pH, dissolved oxygen and carbon dioxide.
10. **Use of computers in process control:** Basics and recent computer developments in automation

**Recommended books:**

1. Fire Safety Management by Satish Tandon
2. Pollution Prevention of Chemical Processes by Allen David T.
3. The Treatment and Handling of Wastes by Bradshaw, A.D.
4. Good Pharmaceutical Manufacturing Practice: Rationale and Compliance by Sharp John
5. Management Information Systems by Laudon Kenneth C.
6. Plant Design and Economics for Chemical Engineers by Peters, Max S.

## **PM-611**

### **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.

## Semester-III

### PM-551

#### Project Management

(3 credits)

1. **Overview:** Phases of capital budgeting; Levels of decision making and objectives of capital market and demand analysis: Situational analysis and specification of objectives, collection of secondary information, conduct of market survey, characterization of the market, demand forecasting, market planning.
2. **Technical analysis:** Study of material inputs and utilities, manufacturing process and technology, product mix, plant capacity, location and site, project charts and layouts, work schedule financial analysis: Estimation of cost of project and means of financing, estimates of sales and production, cost of production, working capital requirement and its financing. Estimates of working results, break even point. Project cash hours. Time value of money. Cost of capital appraisal criteria: Net present value. Benefit cost ratio. Internal rate of return, payback period. Accounting rate of return, Investment appraisal in practice.
3. **Analysis of risk:** Types and measure of risk: Single estimation of risk, sensitivity analysis, scenario analysis, Monte Carlo simulation, decision tree analysis, selection of a project, risks analysis in practice.
4. **Financial feasibility analysis:** Preparation of detailed project report, format of application form of all India financial institutions.
5. **Project management:** Forms of project organisation, project planning, project control, human aspects of project management, pre-requisites for successful project implementation.
6. **Social cost benefit analysis (SCBA):** Rationale for SCBA: UNIDO approach to SCBA, Little Mirrless approach to SCBA, SCBA by financial institutions, public sector investment decision making in India.
7. **Environment appraisal of projects:** Types and dimensions of a project, meaning and scope of environment, environmental resources and values, environmental impact assessment and environmental impact statement.
8. **Project financing in India:** Means of finance, issues and policies of financial institutions, SEBI guidelines for financing, plans, structures of financial institution in India, schemes of assistance, term loan procedures, project appraisal by financial institutions.

#### **Recommended books:**

1. Projects: Preparation Appraisal and Implementation by Prasanna Chandra
2. Project Management: Strategic Financial Planning, Evaluation and Control by Bhaunesh M Patel
3. Total Project Management The Indian Context by P K Joy
4. United Nations: Industrial Development Organization's guide to Practical Project Appraisal Social Benefit Cost Analysis in Development Countries
5. Practical Project Management by R G Ghattas
6. Project Management by Harvey Maylor

7. The Balanced Scorecard Measures that Drive Performance by Robert S. Kaplan and D P Norton
8. Why Should anyone be Led by YOU? by Goffee, Rob and Gareth Jones
9. Critical Success Strategies for New Leaders at All Levels: The First 90 Days by Watkins Michael
10. Financial and Managerial Accounting: The Basis for Business Decisions by William J R, Susan F Haka, Mark S Bettner and Robert F. Meigs
11. PM Network of Project Management Institute
12. PMI's Career Track

## **PM-552**

### **Entrepreneurial Development**

(3 credits)

1. **Entrepreneurship:** Need, scope and philosophy.
2. Creativity and entrepreneurship.
3. Entrepreneurial competencies and traits.
4. **Factors affecting entrepreneurial development:** Religious, social, cultural, political, ancestral and demographic.
5. **Entrepreneurship:** A function of innovation.
6. **Entrepreneurship:** The achievement motive in economic growth.
7. **Entrepreneurship:** Theory of social change.
8. **Entrepreneurship:** Family structure, migration and the enterprise entrepreneurship.
9. Intrapreneuring and Entrepreneurship
10. Barriers to entrepreneurship
11. Intrapreneurial grid.
12. Becoming an Intrapreneur
13. Phases in intrapreneurship
14. Major approaches to corporate entre-preneurship.
15. **Entrepreneurship competencies:** Meaning and evaluation.
16. Community and entrepreneurship.
17. Social determinants of entrepreneurial growth
18. Functions of entrepreneur
19. Classification of entrepreneurs.

#### **Recommended books:**

1. Dynamics of Entrepreneurial Development and Management by Vasant Desai
2. Entrepreneurship Development Small Business Enterprises by Poornima Charanthimath

3. Small Scale Industries and Entrepreneurship by Vasant Desai
4. The Theory of Economic Development by Joseph A. Schumpeter
5. Entrepreneurial Development by S S Khanka
6. Business Innovation by Praveen Gupta
7. Launching New Ventures by K. Allen
8. Business Start-Up Kit by Steven D. Strauss

**Journals/Magazines/Newspapers:**

9. The Journal of Entrepreneurship
10. Harvard Business Review
11. California Management Review
12. Economic and Political Weekly
13. Business World
14. Business Today
15. The Economist
16. Franchisee
17. Business Line
18. Business Standard
19. The Economic Times
20. Financial Express

**PM-553**

**National Regulatory Environment**

(2 credits)

1. The Pharmacy Act, 1948.
2. The Drugs and Cosmetics Act, 1940.
3. The Drugs and Magic Remedies (Objectionable Advertisement Act), 1954.
4. DPCO, 1995.
5. Patents Act, 2005/
6. Infant Milk substitutes, feeding bottles (Regulations of production, supply and distribution Act, 1992).
7. Clinical trial application requirement in India.
8. IND, NDA, ANDA application in Indian context.
9. Prevention of Food Adulteration Act.
10. Narcotics Drugs and Psychotropic Substance, 1985.
11. Latest amendments to the Drugs & Cosmetics Act.

**Recommended books:**

1. New Drug Approval Process, edited by Richard A. Guarino
2. The Pharmaceutical Regulatory Process, edited by Ira R. Berry

3. Medical Product Regulatory Affairs, edited by J. J. Tobin and G. Walsh
4. Pharmaceutical Jurisprudence by G K Jani
5. Official websites related to various guidelines - www.ICH.Org
6. Compliance Quality Standards in the Pharmaceutical and Regulated Industries, Siri H. Segalsatd.
7. FDA Regulatory Affairs, edited by Douglas J. Pisano
8. The Pharmaceutical Regulatory Process edited by Ira R. Berry, Marcel Dekker.
9. Effective Drug Regulation, A Multi Country Study by Ms Sauwakon Ratanawijit
10. FDA Guidelines

## PM-554

### International Marketing

(3 credits)

1. **International marketing:** Basis of international trade, theories of international trade, Adam Smith, Ricardo. Difference between domestic and international marketing,
2. EPRG framework. Scanning of international environment: Social, political, legal, economic, cultural environment for overseas markets.
3. **Factors affecting international trade:** Methods of entry, WTO/GATT, regional agreements commodity agreements.
- 4.. **Product:** Identifying new products, international product planning, product design strategy, product elimination, adoption and diffusion of new products, branding strategies.
5. **Pricing strategies:** Methods of pricing, pricing an international product, transfer pricing, exchange rates and its impact on pricing factors affecting international prices.
6. Dumping and anti- dumping regulations.
7. **Distribution strategies:** Direct and indirect channels, factors affecting international channels, international channel management.
8. **Promotion strategy in overseas markets:** Perspectives of international advertising, standardization v/s localization, global media decisions, global advertising regulations, industry self-regulation.
9. Export documentation and procedures.
10. **Foreign trade policy:** EXIM Policy.

#### **Recommended books:**

1. International Marketing Management by Miracle and Albaum
2. Management of International Operations by John Fayerweather
3. Accessing Export Potential by Martin T. Sliiper
4. Manager in the International Economy by R. Vernon
5. International Marketing by Vern Terpstra
6. International Marketing by V. H. Kriplani
7. Export Marketing by B.S. Rathore

8. Export Procedures and Documents by S.C. Jain
9. Global Marketing by Keegan

## **PM-555**

### **Sales Management and Sales Promotion**

(3 credits)

1. **Sales management:** Objectives of sales management, functions and qualities of sales executive.
2. Sales function and its relationship with other marketing function.
3. **Sales organization:** Relationship of sales department (distributors, government and public).
4. Salesmanship and process of selling.
5. **Sales forecasting methods:** Sales budget, sales techniques and quotas.
6. **Sales force management:** Recruitment, selection, training, motivation and compensation of the sales staff. Evaluation and control of sales force.
7. **Sales promotion:** Marketing communication, how it works, barriers to communications.
8. **Sales promotion objectives:** Introduction of sales promotion in pharma sector; Advertising, personal selling, public relations and sales promotion of pharma products with elaboration of sales promotion methods and techniques of target at customer / consumers; Coupons, cash rebates, premiums (gifts), free samples, contests and sweepstakes, point-of purchase displays, product demonstrations, trade shows and exhibitions, advertising specialties, middlemen; Trade shows and exhibitions, point-of-purchase displays, free goods, advertising allowances, contents for sales people, training middlemen's sales forces, product demonstrations, advertising specialties, and sales force; Sales contests, sales training manuals, sales meeting, packets with promotional materials, demonstration model of product and ethical issues.

#### **Recommended books:**

1. Myers: Advertising Management by Aaker
2. Advertising by James and Morris
3. Sales Management, Decisions, Policies and Cases by Cundiff, Still and Govind
4. Sales Programme Management by Benson P. Shapdiro
5. Professional Sales Management by Rolper E. Anderson, Joseph F.Hair, Alex J. Bush
6. Sales Management: Concepts and Cases by Johnson, Kurtz and Scheving
7. Marketing Management by Philip Kotler

## **PM-556**

### **Industrial and Service Marketing**

(3 credits)

1. **Industrial marketing:** Concept and role of industrial marketing, comparison with

consumer marketing, purchasing and industrial marketing.

2. Product decisions in case of industrial products
3. Pricing in case of industrial products,
4. Production and distribution decision with reference to industrial products.
5. **Services:** Service sector and economic growth, service concept characteristics and classification of service, challenges in service marketing.
- 6.. **Marketing mix in services marketing:** Product, price, place, promotion, people, physical evidences and process decisions.
7. Strategic issues in service marketing; Service differentiation and positioning,
8. Managing service quality, productivity in services.
9. **Designing a service strategy:** Marketing of health services - Hospitals and Path labs.
10. **Designing a service strategy:** Consultancy organizations.

**Recommended books:**

1. Industrial Marketing by Alexander, Cross A Hill
2. Industrial Marketing by Raymond Corey
3. Industrial Marketing by Dodge
4. Services Marketing by S. M. Jha
5. Services Marketing by Ravi Shanker
6. Service Marketing by Lovelock

**PM-557**

**Contemporary Issues in Pharmaceutical Marketing**

(2 credits)

1. Director to consumer.
2. E-detailing
3. Customer relationship management CLV.
4. E-branding
5. Organised retailing
6. Integrated communication.
7. Good marketing practices

**Recommended books:**

1. Marketing Management by Czinkota, M.R. and Kotabe, M.
2. Marketing Management: Text and Cases by Douglas, J., Darymple, J. and Parsons, L.J.
3. Marketing Management: Analysis, Planning, Implementation & Control by Kotler, P.
4. Marketing Management by Michael, J.E., Bruce, J.W. and William, J.S.
5. Basic Marketing by Perreault, W.D. and Jerome, E.M.

## PM-558

### Fundamentals of R&D Management-I

(2 credits)

1. **Pharmaceutical Industry-an introduction:** An introduction to the course and a brief discussion: about the Pharma Industry in the national and global context.
2. **R&D-Understanding the nuances of Research and Development:**  
The meaning of 'Research' and 'Development'-How Research differs from Development  
Role of research in national development and economic progress, financial aspects of national research-outlays/outcomes/challenges.
3. **Management of Research- Funding, Monitoring, Outcome:** Management of Research at national level: Major organizations e.g. DRDO,ICAR,ICMR, CSIR, Univerities and autonomous institutes-1: Management of Research at Global Level(USA and Europe);Major organizations(USA)/Europe-1:Organisation of Research at Regional and Global levels, procedures adopted-1; Linkages and modalities for collaboration and co-ordination-1.
4. **Research policy making:** Research prioritization at National and Global level.
5. **R&D Intellectual Property Rights:** Critical role of IPR's in research management: Meaning and definition of IPRs, types and the mechanism most appropriate for R&D. Usefulness of patents and researchers; Role of propr art search in affecting quality of research; Avoiding duplication, infringement, identification of potential linkages and hot areas of research.
6. **Practical strategies on making R&D benefit society:** Challenges/ mechanisms- Case studies and success stories.
7. **Ethics and values in R&D:** Understanding the elements of ethics and values; Critical importance in R&D-plagiarism and legal remedies.

#### **Recommended books:**

1. Research and Development Management in the Chemical and Pharmaceutical Industry by Peter Bamfield
2. Third Generation R & D by Philip Roussel
3. Fourth Generation R & D by William and Miller
4. Towards Sixth Generation of R & D Management by Denis Nobelius
5. R&D Tactics by H.R. Kaufman
6. Strategic Management of Technology and Innovation by Burgelman and Maidique
7. Practical Process Research & Development by Neal G. Anderson
8. Research and Development Management by Alan Glasser

## Semester-IV

### PM-651

#### Management Control System

(3 credits)

1. **Nature and scope of management control systems:** Basic concepts, boundaries of management control. The management control environment Behaviour in organizations including goals, goal congruence; Informal factors influencing goal congruence; Informal and formal control system; Types of organizations. Functions of the controller.
2. **Management control structure:** Responsibility centers; Revenue centers; Expense centers; Administrative and support centers; Research and development centers; Marketing centers; Profit centers. Transfer pricing objectives, methods, pricing corporate services, administration of transfer prices. Measuring and controlling assets employed structure of the analysis. Measuring assets employed; Economic value added (EVA) vs. return on investment (ROI); Additional considerations in evaluating managers; Evaluating the economic performance of the entity.
3. **Understanding strategies:** Concept of strategy; Corporate level strategies; Business unit strategies. Strategic planning nature, analyzing proposed new programmes; Analyzing ongoing programmes. Strategic planning process. Budget preparation nature, other budgets, budget preparation process; Behavioral aspects, quantitative techniques.
4. **Analyzing Financial Performance:** Variance Analysis. Performance measurement information used in control system performance measurement systems; Interactive control. Management compensation characteristics of incentive compensation plans; Stock options; Phantom shares; Performance shares; Performance criteria and agency theory.
5. **Variations in management control:** Revolution in management control; Emerging management system. Implication on management accounting; Position of management accounting controls for differentiated strategies corporate strategy; Business unit strategy. Modern control methods Just-in-time (JIT); Computer integrated manufacturing; Decision support systems. Total quality management: Core concepts of total quality management quality for profits; Costs of quality; Learning from quality gurus such as Edward Deming, Joseph M. Juran, Kaoru Ishikawa, Philip B. Crosby, William E. Conway, Pitfalls in operationalizing TQM, ISO-9000: Concepts, certifications, methods and certifications. Service organizations and M.C.S.: Service organizations in general, professional service organizations; Financial service organizations; Health care organizations; Nonprofit organizations. Multinational organizations and M.C.S.: Cultural differences; Transfer pricing and exchange rates. Management control of projects.

#### **Recommended books:**

1. Management Control Systems by Robert N Anthony and Vijay Govindarajan
2. Cost Accounting: Planning and Control by Usry and Hammer
3. Cost Accounting: Processing, Evaluating and Using Cost Data by Morse and Roth
4. Cost Accounting A Managerial Emphasis by Charles T. Horngren and Srikant Datar
5. Management Accounting and Behaviour Sciences by Edwin H. Caplan
6. Concepts in Strategic Management and Business Policy by Thomas L. Wheelen and J David Hunger

## PM-652

### Strategic Management

(3 credits)

1. **The conceptual framework of strategy:** Concept and significance in Pharmaceutical Sector, definition,
2. Strategic management process,
3. External and Internal environmental analysis.
4. **Grand strategies:**
  - a) Intensive growth opportunities: Market penetration strategy, market development strategy, product development strategy, diversification strategy.
  - b) Integrative growth strategy: Backward integration, forward integration, horizontal integration.
  - c) Diversification growth strategy: Concentric diversification, horizontal diversification, conglomerate diversification.
5. **Concentration strategy:** Market development, product development, innovation, joint venture, retrenchment / turnaround, divestiture strategy, liquidation, combination strategy.
- 6.. **Choice of strategy:** Factors affecting choice of strategy firms mission, environmental factors, firm's strengths and weaknesses, managerial attitudes towards risk, managerial power relationships.
7. **Implementation of strategies:** Leadership implementation, functional policy implementation, organizational implementation.
8. Evaluation of strategy.
9. **Strategic choice-considering strategic alternatives:** Stability, retrenchment, expansion, combination.

#### **Recommended books:**

1. Business Policy and Strategy Concepts and Readings by McCarthy, Minichiello & Curran
2. Business Policy and Strategic Management Concepts and Application by Gupta, Gollakota and Srinivasan
3. Innovating Organization by Pettigrew & Fenton (eds.)
4. Strategic Management : Building and Sustaining Competitive Advantage by Pitts
5. Strategic Management by Dess and Miller
6. Business policy and Strategic Management by Azhar Kazmi

## PM-653

### International Regulatory Environment

(2 credits)

1. **Concept and historical development of registration of pharma companies and their process over the year:**
  - a) Safety
  - b) Efficacy
  - c) New drug approval.

2. **Types of Registration application:**

- a) NDA
- b) ANDA
- c) DMF
- d) Hybrid NDAs

3. **Information consideration in regulatory filing:**

- a) Preclinical data.
  - b) Clinical data
  - c) Chemistry manufacture and control of data
  - d) Labeling information, environment related issue.
4. Comparative study of US and EU models with respect to NDA/ANDAs.
5. Attempt towards harmonisation of Global regulatory requirements ICH initiatives.
6. Regulatory consideration for bio-tech derived products.

**Recommended books:**

- 1. New Drug Approval Process, edited by Richard A. Guarino
- 2. The Pharmaceutical Regulatory Process, edited by Ira R. Berry, Marcel Dekker
- 3. Medical Product Regulatory Affairs, edited by J. J. Tobin and G. Walsh
- 4. FDA Guidelines
- 5. Effective Drug Regulation, A Multi Country Study, by Sauwakon Ratanawijit  
www.ICH.Org

**PM-654**

**Pharma Product Management**

(3 credits)

- 1. **Introduction to product management:** Definition, role of product management and scope of product management.
- 2. **Product planning and development:** Meaning of product, classification of pharma products, strategic planning for segmenting, targeting and positioning pharma products, product research and need gap analysis and health services. Operational pharma product planning including pharma sales programmes and budgeting, organising and controlling for pharma product management.
- 3. **New product development process and methods:** Type of new pharma products, complete product development process, product innovation, new product adoption and diffusion process, opinion leadership.
- 4. **Pharma product mix strategies:** Product portfolio management strategies, product mix and product line strategies, decisions regarding buying or making new products.
- 5. **Product life cycle strategies:** Domestic pharma product life cycle and international pharma product life cycle; Stages and strategies for each stage. R & D management for new product development.
- 6. **Brand, packaging and other pharma product features:** Pharma branding process and strategies, OTC generic and prescription product branding. Packaging and labeling, legal and social consumer inputs for different kind of packaging and labeling design control of spurious products.
- 7. **Pharma product pricing issues:** Social, economic, legal, ethical issues for pharma

product pricing in India. Pricing methods and techniques. Other factors influencing pharma product pricing.

8. **Pharma product distribution management:** Pharma product channel design, single channel v/s multiple channel strategies, roles and responsibilities of chemists for product promotion and distribution.
9. **Pharma product promotion:** Issues in pharma product promotion, approaches for pharma product promotion, DTC, e-detailing, physician related promotional programmes for increasing acceptance and sales of pharma products.

**Recommended books:**

1. Marketing: Concepts and Strategies by Pride, W.M. and Ferrell, O.C.
2. Marketing Management: Planning by Ramaswamy, V.S. and Namakumari, S. Marketing by Zikmund, A.
3. Innovating Organization, edited by Pettigrew & Fenton
4. Marketing Research - Measurement and Method by Tull and Hawkins
5. Product Policy and Strategy by Luck, D.J.
6. Product Management in India by Majumdar, R.
7. Product Policy, Concepts, Methods and Strategy by Wirid, Yoran R.

## **PM-655**

### **Pharmaceutical Brand Management**

(3 credits)

1. Branding and its potential within the pharmaceutical industry: History, meaning, need, importance,
2. Branding in pharmaceutical industry.
- 3.. Building brand values and brand strategy, timing, patient power,
4. Strategic brand management process.
5. The valuation of pharmaceutical brand: Relevance of brand valuation to the pharmaceutical Industry, The value of a brand, Inter-brand's brand valuation methodology,
- 6.. Role of branding index, assessing brand strength.
- 7.. The role of advertising in branding pharmaceuticals.
8. Brand development process
9. Trade mark and regulatory issues.

**Recommended books:**

1. Strategic Brand Management by Kevin Keller
2. Brand Positioning by Sen Gupta
3. Managing Indian Brands by Ramesh Kumar
4. Brand Failures by Matt Haig

## PM-656

### Consumer Behaviour

(2 credits)

1. **Introduction to the study of consumer behaviour:** Nature, scope and application.
2. **Environmental influences on consumer behaviour:** Cultural, social, personal, family and situation influences, opinion leadership and life style marketing.
3. **Consumer as an individual:** Involvement and motivation, knowledge, attitude, values, personality, learning and life style.
4. **Consumer Behaviour Models:** Consumers economic view, passive view, cognitive view and emotional view. Nicosia Model, Howard Sheth Model, Engel- Blackwell and Miniard Model, Family Decision Making Model.
5. **Consumer decision process:** Pre-purchase process, information processing, purchase processes, consumer decision rules, post-purchase processes; Framework, dissonance, satisfaction / dissatisfaction.
6. **Consumer behaviour and society:** Consumer rights, deceptive advertising and consumer education and consumerism.

#### **Recommended books:**

1. Consumer Behaviour by Long, G. Schiffman & Kanuk, L.L.
2. Consumer Behaviour by Engell and Blackwell
3. Consumer Behaviour by Walters
4. Consumer Behaviour by Holleway, Mattelshaedit and Venkatesan

## PM-657

### Advertising in Pharmaceutical Sector

(3 credits)

1. **Introduction of marketing communication and promotion management:** Nature, scope, importance, role and promotion mix elements.
2. **Nature and scope of advertising:** Changing concepts of advertising, functions and types of advertising, economics and social effects of advertising.
3. **Campaign, planning:** Advertising campaign, campaign planning process:  
(a) Product market analysis      (b) Setting advertising objectives DAGMAR approach  
(c) Advertising budgeting      (d) Creative strategy and information processing  
(e) Media planning and scheduling.
4. **Copy design and development:** Copy, writing, script, story board, copy formats, layouts and illustration.
5. **Advertising control:** Measurement of advertising effectiveness, pre-measurement and post-measurement techniques of advertising research.
6. Advertising agency operations and management
7. **Sales promotion:** Factors affecting sales promotion, type of sales promotion, sales promotion planning.
8. **Direct marketing:** Direct response advertising, tele-marketing, advertising on internet.

9. Public relations and sponsorship marketing, even marketing

**Recommended books:**

1. Advertising Management by Aaker, Myers
2. Advertising by Wright, Warner, Winter and Zeigler
3. Advertising by James and Morris
4. Strategic Marketing, Guide for Developing Sustainable Competitive Advantages, Response Books by M.J. Xavier
5. Strategic Planning Formulation of Corporate Strategy by Ramaswamy and Namakumari
6. Marketing Management by Philip Kotler

## **PM-658**

### **Fundamentals of R&D Management-II**

(2

credits)

1. **Strategic issues in R&D-an introduction:** Introduction to the course and a brief discussion about strategic issues in R&D-project identification and selection; Human resources, infrastructural resources and execution strategies
2. **Research project selection criteria:** Avoiding duplication and infringement appropriate search strategies and inputs for planning.  
Identification of relevance to national and societal needs practical strategies. Industrial problems as a source of project ideas, short-term and long-term perspectives.
3. **Human resources for research projects- building scientific skills and development of human resources for R&D:** Identification of the human skill gap; Monitoring performance, reviewing, development of leadership qualities and managerial skills.
4. **Infrastructural resource optimization:** Strategies to avoid duplication of facilities; Networking and strategic tie-ups/ creation and access of 'infrastructure databases'.
5. **Exploitation of research-invention management and business strategy development for research commercialization:** Understanding and addressing the 'development gaps' in research-reproducibility, scale-up, manufacturing challenges, regulatory aspects, ownership issue, material transfer aspects in case of biotech and pharmaceuticals. Strategies for research commercialization- joint ventures, licensing, transfer of technology (tot) and strategic alliances (MOUs).
6. **R&D management issues:** Interface between R&D, manufacturing and marketing. National perspectives on R&D collaborations with industry.

**Recommended books:**

1. Research and Development Management in the Chemical and Pharmaceutical Industry by Peter Bamfield
2. Third Generation R & D by Philip Roussel
3. Fourth Generation R & D by William and Miller
4. Towards Sixth Generation of R & D Management by Denis Nobelius
5. R&D Tactics by H.R. Kaufman
6. Strategic Management of Technology and Innovation by Burgelman and Maidique
7. Practical Process Research & Development by Neal G. Anderson
8. Research and Development Management by Alan Glasser

**Courses of Study 2016**  
**Ph.D. Courses**

# Medicinal Chemistry

## Semester-I

### MC-710

#### Stereoselective and Stereospecific Synthesis

(2 credits)

1. **General concept:** Differentiation of molecules, group selectivity, topicity and prochirality, substrate and product selectivities.
2. **Chirality:** Topological chirality and modifications of CIP classification of chirality-constitutional properties of CIP system, continuous symmetry measure of chirality, degree of shape chirality.
3. **Chirality and drug action:** Terminologies and definitions, significance of drug stereochemistry on drug action and metabolism.
4. **Fundamentals of chirality generation:** Necessary conditions for stereoselectivity, concept of enantio/diastereo-differentiation, methods of inducing stereoselectivity, strategies for stereoselective synthesis, kinetics and thermodynamics of stereoselective reactions.
5. **Approches for chiral synthesis:** Chiral pool approach, various chiral auxiliaries, self generation of chiral center.
6. **Enantioselective synthesis:** Multiplication of chirality-asymmetric hydrogenation, asymmetric alkylation, enantio/diastereo-selective protonation, asymmetric synthesis using chiral bases, dynamic kinetic resolution-mathematical treatment and implications.
7. **Asymmetric catalysis:** Stereoselective catalytic reduction- homogeneous hydrogenation (chiral ligands, effect of solvent/ pressure/ temperature/ addendum, substrate dependence of enantioselectivity, mechanistic aspects), stereoselective heterogeneous hydrogenation, transfer hydrogenation, hydrosilylation, hydricylation, stereoselective oxidation enantio / diastereoselective epoxydation and dihydroxylation.
8. **Concepts on catalytic asymmetric induction:** Ligand accelerated catalysis; Self replication of chirality- catalytic self-replicating molecules, control of chirality memory, P - stacking effect, selectivity and mechanism of catalytic asymmetric synthesis.
9. **Stereoselective C-C bond formation:** Nucleophilic addition to C=X(X=C, O, S, N), Stereoselective hydroformylation, Pericyclic reaction asymmetric induction in [3+2] and [2+2] cycloaddition, stereoselective carbene addition, chirality transfer in sigmatropic rearrangements. Determination of enantiomeric purity: Various tools, chiral derivatising agents, chiral shift reagents, chiral solvating agents.
10. **Applications:** Chiral auxiliary based and catalytic asymmetric synthesis of natural and unnatural amino acids and other bio-molecules.

### MC-720

#### Synthetic Strategies in the Total Synthesis of Complex Organic Molecules

(2 credits)

1. *Retrosynthetic analysis, disconnections and reliability of reactions, synthons:* Donor and acceptor, functional group interconversions, one group carbon-heteroatom and carbon-carbon disconnections, two group carbon-heteroatom and carbon-carbon

disconnections, chemo-, regio- and stereo- selectivity considerations, natural reactivity and umpolung, 1,3 and 1,5–difunctional compounds.

2. *General synthetic reaction patterns and strategies:* Aliphatic nucleophilic and electrophilic substitutions, aromatic nucleophilic and electrophilic substitutions, addition to carbon–carbon and carbon-heteroatom multiple bonds, eliminations, rearrangements, oxidations and reductions.
3. *Chemistry of protecting groups :* Protection for alcohols, carbonyl groups, carboxylic groups and amino groups.
4. *Applications of synthetic strategies in the total synthesis of selected organic molecules :-*  
(a) Cholesterol      (b) Estrone                      (c) Progesterone                      (d) Reserpine  
(e) Penicillin        (f) Prostaglandin                      (g) Longifolene                      (h) Taxol

## MC-730

### Organometallic and Sustainable Chemistry in the Synthesis of Pharmaceuticals

(2 credits)

1. **Carbon-carbon coupling reactions:** Suzuki, Hiyama, Stille, Negishi, Kumada coupling reactions; Mechanistic aspects of these reactions, comparison in mechanism, relative reactivities of organometallic coupling partners; Palladium and other metal catalysis, controlling parameters; Heck ( $\square$ - and  $\square$ -arylation) and Sonogashira coupling reactions; Palladium- and Coppercatalysis, mechanism; Synthesis of biaryls, multi-substituted alkenes, alkynes, and various scaffolds.
2. **Carbon-heteroatom coupling reactions:** Ullmann, Chan-Lam, and Buchwald-Hartwig reactions. Mechanistic aspects, comparison; Synthesis of various amines, ethers, thioethers, and heterocycles.
3. **Cross-coupling of unactivated arenes:** Direct arene C-H bond arylation; oxidative couplings; two- and multi-fold C-H bond arylations; various approaches and mechanistic aspects; synthesis of biaryls and various scaffolds.
4. Application of coupling reactions (as mentioned in 1-3) in the synthesis of pharmaceutically-relevant compounds; Importance in the drug discovery research.
5. **Metathesis:** Grubbs (first and second generation) and Schrock catalysts, Advantages and disadvantages, Importance of Ru and molybdenum catalysis; Olefin, alkyne, ring closing, ring opening and multiple metathesis; Mechanism of these reactions, aspects of reaction conditions, and structural aspects of reactants.
6. Application of metathesis-reactions in the synthesis of various structural motifs including heterocycles, natural products, and pharmaceuticals; Importance in the drug discovery research.
7. **Green chemistry:** Principles, metrics, perspective of pharmaceutical industries; Green discoveries; greener reactions, catalysis, alternative reaction media, greener technologies; Sustainable synthesis of pharmaceuticals.
8. **Click chemistry:** Click reaction-criteria, water as solvent, various classes of reactions, thermodynamics; Huisgen cycloaddition and its modification, and nucleophilic ring opening of epoxide and aziridine.

9. **Alkyne-azide click chemistry in the drug discovery research:** Synthetic and medicinal chemistry advantageous aspects of the reaction; Combinatorial, structure-based and *In situ* approach of click chemistry in drug discovery research.
10. **Multicomponent reactions (MCR):** Ugi, Passerini, Biginelli, Hantzsch, Mannich, Petasis, Strecker, Kabachnik-Fields reactions, Mechanism of these reactions, Conceptual discovery of MCR, Ugi-deprotection-cyclization (UDC) approach and synthesis of various biologically-relevant scaffolds, multiMCRs in synthesis, Diversity-oriented and convergent synthesis of pharmaceutically-relevant compounds. interface

## Semester-II

### MC-810

#### Principles of Peptide Chemistry

(2 credits)

1. Importance of peptides in drug discovery.
2. **Protection and deprotection:** General aspects, need for protection, minimal versus global protection, protection of amino group by acid and base labile groups, protection of carboxyl group, concept of orthogonal protection in peptide synthesis.
3. Importance of side-chain functional group protection and details of protective groups used for masking individual amino acids, methods used for deprotection.
4. Various methodologies employed for coupling reaction.
5. **Side reactions in peptide synthesis:** Deletion peptides, side reactions initiated by proton abstraction, protonation, over-activation and side reactions of individual amino acids.
6. Segment and sequential strategies for solution phase peptide synthesis with case studies.
7. Principle of Merrifield solid phase peptide synthesis.
8. t-BOC and Fmoc protocols.
9. Various solid supports and linkers, activation procedures, peptide bond formation.
10. **Deprotection and cleavage from resin:** Low and high HF cleavage protocols, formation of free peptides and peptide amides, purification and case studies, Site-specific chemical modifications of peptides.

### MC-820

#### Carbohydrates: Occurrences, Structure, Reactions, Syntheses, Functions and Applications in Present Day Drugs

(2 credits)

1. **Overview:** Introduction; importance of carbohydrates in food & nutrition and biology.
2. **Sources, Structure & Shape:** This will complement course # MC-630 in certain respects. Methods of structure elucidation.
3. **Recognition of carbohydrates by proteins:** Relevance in disease; discussion on the process of infection by microorganisms and possible methods of intervention; specific examples-cholera, flu, etc.
4. **Reactions at the anomeric centre:** Methods of glycosylation; details on the various types of glycosyl donors used; their preparation and methods of activation.

5. **Reactions at centres other than the anomeric centre:** Selective transformations; strategies for selective and global protection & deprotection of carbohydrates and their significance.
6. **Chemical synthesis:** Highlights on the need for synthesis; various approaches adopted for the chemical methods of oligosaccharide synthesis with examples.
7. **Enzymatic & chemo-enzymatic oligosaccharide syntheses:** Scope & limitation; discussion with examples relevant to medicinal chemists.
8. **Solid-phase oligosaccharide synthesis:** Relevance & its importance; different strategies used; applications.
9. **Carbohydrate-based drugs:** Discussion on various drugs (aminoglycoside antibiotics including glycopeptides, enediynes, macrolides, anthracyclines, etc; alkaloid, steroid and terpenoid glycosides; polyphenol glycosides etc.) that contain carbohydrate moiety (moieties) including polysaccharide therapeutics.
10. **Polysaccharide vaccines:** Relevance; discussion on the isolation and modification of bacterial polysaccharides, specifically capsular polysaccharides; protein conjugation.

## MC 830

### Advanced topics in Drug Action and Drug Design

(2 credits)

1. **Molecular basis of drug action:** Receptor specificity and signal transduction, Channel-containing receptors, intracellular receptors, Receptor desensitization, Drug action in cell not mediated through receptors.
2. **Drug metabolism :** Inhibitions, induction, species and sex differences in drug metabolism, age on drug metabolism, CYP 450, Glutathione S-transferases, UDP-Glucuronosyltransferase.
3. **Resistance, Allergy, Tolerance:** Immunologic basis of drug allergy, origin of drug resistance, resistance to the  $\beta$ -lactam antibiotics, resistance via mutation and selection, resistance via gene transfer, resistance via gene amplification, biochemical mechanism of drug resistance, characteristics of tolerance and the dependence, tolerance by indirect mechanisms, cellular tolerance mechanisms, relationship between tolerance and dependence.
4. **Mutagenesis, carcinogenesis, teratogenesis:** DNA target for mutagenetic agents, mechanisms of chemical mutagenesis, types of mutations, biologic consequences of mutation, genetic reversion, mechanisms of chemical carcinogenesis, principal groups of chemical carcinogens, drug metabolizers and carcinogens, principles of teratogenesis.
5. **Lipophilicity and drug action:** Thermodynamics of van der Waals interactions, thermodynamics of hydrophobic interactions, Molecular lipophilicity potential. Physicochemical and biological factors that influence drug permeability by passive diffusion, lipophilicity of metabolites.
6. **Drug-Receptor thermodynamics:** Thermodynamic models of drug-receptor interactions, Effector-receptor interactions. Basics of correlations, relevance to enthalpy-entropy compensation.
7. **Drug action of some agents:** Steroid biosynthesis and action, neurotransmitter action and metabolism, membrane-active agents, hormonal modulators, microtubule action.

8. **Case study 1:** PfDHFR-Thymedylate synthase, mechanism of protein synthesis, action of anti-folates, selective prevention of protein synthesis in *plasmodium falciparum*, enzyme action associated with dihydrofolate reduction.
9. **Case study 2:** Mechanism based inhibition, carbene reactive metabolites, epoxide reactive metabolites, nitroso reactive metabolites, S-oxidation vs epoxidation in thiophene.
10. **Case study 3:** Drug action of agents acting at Glycogen Synthase Kinase (GSK), seven different methods of lead action on GSK3, drug design strategies for anti-diabetic drugs acting at GSK3.

# Natural Products

## Semester-I

### NP-710

#### Advanced Separation Techniques for Research

(2 credits)

1. **High performance liquid chromatography (HPLC):** Basic principles of separation, Resolution, minimum resolution, resolution as a function of solvent strength, selectivity and plate number, strategies to improve resolution, sample size effect on resolution, systematic approach to method development.
2. **Sample preparation:** Preliminary processing, Sample pre-treatment for liquid samples, solid-phase (SPE) and liquid-liquid extractions, membrane filters for particle - and sterile filtration, sample pre-treatment for solid samples, column switching, derivatization.
3. **HPLC sorbents:** Column chemistry, reverse phase and normal phase sorbents, Type A/Type B silicas, retention and stability of bonded phases, column specifications, chiral stationary phases, sterically protected bonded phases, bifunctional bonded phases, high density and pH stable columns, aqueous stable columns, multi-mode columns, characterization of RP columns (Tanaka parameters), selection of right stationary phase, column specifications, column problems and remedies.
4. **HPLC method development for neutral samples:** Retention and selectivity in RP and NP chromatography, optimizing separation in RP and NP chromatography, solvent-strength, solvent-type and column-type effects on retention and selectivity in NP and RP chromatography, non-aqueous reverse phase chromatography.
5. **HPLC of ionic samples:** Acidic and basic samples, retention on reverse phase, optimizing reverse phase separation of ionic samples, ion-pair chromatography, basis of retention and selectivity, ion exchange chromatography.
6. **Gradient elution:** Applications, gradient elution in routine analysis, gradient elution for method development, developing gradient separation.
7. **Semi-preparative and preparative HPLC systems:** Analytical vs preparative HPLC, method development and scale-up calculations, practical aspects, prep HPLC columns.
8. **Biochromatography:** Size exclusion chromatography, affinity chromatography, chiral chromatography, Fast Protein Liquid Chromatography, (FPLC).
9. **Hyphenated techniques:** Basic principles and applications of LC-MS, LC-NMR, and supercritical fluid chromatography.
10. **TLC/HPTLC:** Selection of TLC/HPTLC plates and sorbents, sample preparation, sample clean up, application of sample, selection of mobile phase (AMD), development (separation), factors influencing HPTLC separation, detection/visualization, instrumentation, densitometric scanners, selection of suitable wavelengths for scanning, in-situ scanning. Preparative TLC, dual-phase TLC, reverse phase TLC, flexibility and efficiency, quantification of results, documentation, purity profile of drug substances, validation of analytical parameters, comparative evaluation of HPTLC and HPLC. TLC and reversed-TLC of unknown commercial herbal products and drugs, detection and classification of components, qualitative and quantitative estimation of active constituents, analysis of herbal drug mixtures, electroplanar chromatography/electrophoresis.

## NP-720

### Natural Product-based Drugs and Lead Molecules

(2 credits)

1. **Discovery and development of drugs from natural products (NPs):** Plant-derived NPs, Microbial NPs, Marine NPs, Animal-derived NPs, Macromolecule-derived NPs; Challenges and opportunities in Natural Product-based drug discovery and development: Few challenges that come across natural product (NP)-based drug discovery programs include, isolation and characterization of bioactive compounds from natural product extracts are labour intensive and time consuming; difficulty in the scale-up for extensive drug profiling; lack of dereplication strategies in natural-product extract libraries, incompatibility of extracts in HTS-bioassays. Opportunities include, chemical diversity with structural complexity and biological potency associated with NPs, NPs are main source of pharmacophores and possess drug-like properties, many natural product resources are unexplored so far, NP researches led to the discovery of novel mechanism of actions and they are excellent 'biochemical tools'.
2. **Epothilones as novel microtubule inhibitors for anti-cancer drug development:** Mechanism of action, epothilone analogues and SAR study, pharmacophore modelling and epothilone leads under clinical development.
3. **Vancomycin and other glycopeptide antibiotics:** Classification of glycopeptide antibiotics, mechanism of action, synthesis, structural modifications and SAR study.
4. **Discodermolide, a potent microtubule inhibitor obtained from a marine sponge:** Chemistry, synthesis of analogues, SAR study and clinical status.
5. **Huperzine A:** A drug for the treatment of Alzheimer's disease: Pharmacological activity, design and synthesis of HA analogues, SAR study, clinical trial status of HA and analogues.
6. **Curcumin, an exciting NP lead molecule for development of anti-cancer drug:** Chemistry, biological activity, design and synthesis of analogues, SAR study, and clinical status of curcumin and lead molecules derived from curcumin.
7. **Forskolin:** A labdane diterpenoid isolated from Indian herb *Coleus forskohlii* is a potent adenylate cyclase activator developed for the treatment of cardiomyopathy, glaucoma and asthma. Chemistry, synthesis of analogues and SAR study.
8. **Flavopiridol:** A novel flavonoid analogue designed on a natural product rohitukine. Chemistry, synthesis, SAR study and clinical status.
9. **Artemisinin:** A novel anti-malarial drug discovered from Traditional Chinese Medicine (TCM). Chemistry, design and synthesis of analogues, SAR study, Artemisinin as a scaffold for the development of novel trioxane and tetraoxane anti-malarials agents.
10. **Triterpenoid compounds viz. lupeol, oleanolic-, ursolic- and betulinic acid derived from plants as leads for drug development:** Chemistry, design of semi-synthetic and synthetic analogues of these triterpene compounds, SAR study, clinical trial status of leads derived from oleanolic-, ursolic- and betulinic acid.

## Semester-II

### NP-810

#### Advanced Structure Elucidation Techniques for Natural Products (2 credits)

1. **<sup>1</sup>H-NMR:** Magnetic properties of nuclei, interpretation and use of chemical shift and coupling constant, first and second order spectra, signs and mechanisms of coupling constants, long range coupling, quantitation, experiments for simplification of complex spectra and their interpretations.
2. **<sup>13</sup>C-NMR spectroscopy:** Basic principles, APT, DEPT & SEPT techniques, applications in structure elucidation of natural products with examples from mono-, sesqui-, di- and pentacyclic triterpenes and saponins.
3. **Two dimensional homonuclear NMR techniques:** Basic principles, definitions and explanation of COSY experiments, importance of COSY in structure elucidation of natural products, 1H-1H-COSY, DQF-COSY, 13C-13C correlations INADEQUATE, NOESY and ROESY techniques and their use in structure elucidation of natural products.
4. **Two dimensional heteronuclear NMR techniques:** Heteronuclear 1H-13C-COSY, heteronuclear single quantum coherence (HSQC), heteronuclear multiple quantum coherence (HMQC), heteronuclear multiple bond correlations (HMBC), and TOCSY.
5. **Mass spectrometry:** Development of APCI, ESI, FAB, MS<sub>n</sub>, HRMS techniques for the structure elucidation of natural products with examples, LC interfaces with applications, introduction and applications of MALDI.
6. **Optical and chiroptical techniques:** CD and ORD, Circular birefringence and circular dichroism, optical rotatory dispersion and circular dichroism, and cotton effect.
7. **Infra red spectroscopy:** Group frequencies, factors affecting group frequencies, structural analysis by IR, stereoisomerism by IR.
8. **Stereochemistry:** Absolute and relative stereochemistry by spectral and chemical methods Coupling constants, Mosher method, Marfey method, exciton chirality, NOE, NOESY etc.
9. **Computer assisted structure elucidation:** Use of computer methods for prediction of chemical shifts and structures.
10. Structure elucidation (structure and stereochemistry) of selected natural products by combined use of above methods. Introduction and applications of MALDI.

# Pharmaceutical Analysis

## Semester-I

### PA-710

#### Impurity and Metabolite Profiling

(2 credits)

1. **Introduction:** Basics of impurity and metabolite profiling.
2. **Impurity profiling:** Practical approach
3. **Metabolite identification:** In-vitro / in-vivo approaches and sample preparation.
4. Regulatory perspectives.
5. **Basics of Instrumentation techniques:** HPLC, LC-MS, LC-NMR, LC-IR and metabolite identification using radioligand techniques.
6. **Case studies:** Impurity profiling, isolation and characterization.
7. **Case studies:** Metabolite profiling, isolation and characterization.

# Pharmacology and Toxicology

## Semester-II

### PC-810

#### Application of Biotechnology in Parasitic Disease Research (2 credits)

1. **Biotechnology and parasitic disease research - an introduction:** Role of genetic engineering in parasitic disease research, study of parasites and recombinant DNA technology, immuno technology and parasitology. Molecular biology of malaria parasites, leishmania donovani and entamoeba histolytica.
2. **General techniques:** Cultivation and cloning of plasmodium falciparum, leishmania donovani and entamoeba histolytica. Preparation of malaria parasites from experimental animals. Isolation of different stages of malaria parasites and synchronization; Identification, counting, cryopreservation and recultivation of parasites.
3. **Cellular and molecular basis of the pathogenesis of parasitic diseases:** Mechanisms of Ph.D. Courses pathogenesis in malaria-general considerations; Mechanism(s) of erythrocyte invasion, immune evasion, antigenic variation and cytoadherence in malaria; Mechanisms of the survival and growth of leishmania donovani in macrophages and, mechanisms of virulence in entamoeba histolytica. Role of cytokines in the pathogenesis of malaria, leishmaniasis and amoebiasis. Mechanisms of protective immunity in malaria and leishmaniasis. Conventional and DNA vaccine development against malaria. In vitro correlates of protective immunity in vivo in parasitic diseases.
4. **Recombinant DNA technology in parasitic disease research:** Strategies for the use of rDNA technologies in the study of parasite antigens; Application of rDNA technology in the identification and exploitation of new drug targets in parasites; Biotherapy of parasitic diseases, detection and analysis of cytokine mRNA in cells and tissues using RT-PCR; Development of DNA probe based diagnostic tools for parasites; Construction of cDNA libraries and genomic DNA cloning and other related genetic engineering techniques.
5. **Hybridoma technology and analysis of proteins:** Basic principles of somatic cell hybridization; Production of monoclonal antibodies; Detection and characterization of monoclonal antibodies using immunofluorescence assay and ELISA; Applications of hybridoma technology in parasitic disease research; Metabolic and surface labeling of parasite antigens and SDS-PAGE and two-dimensional analysis of parasite antigens.

### PC-820

#### Pharmacological Interventions for Ischemic Brain Injury (2 credits)

1. Pathophysiology of ischemic brain injury, clinical manifestations and laboratory evaluation.
2. Excitotoxicity of ischemic brain injury: Glutamate excitotoxicity, excitatory amino acid (EAA) receptors EAA antagonists. Problems with EAA antagonists.
3. Oxidative stress in ischemic brain injury: FRs measurement and potential of free radical scavengers in brain injury, nitric oxide in ischemic brain injury.
4. Potential neuroprotective approaches for ischemic brain injury: Calpain inhibitors, PARP inhibitors, MAP kinase inhibitors, apoptosis inhibitors etc.

5. Animal models for focal and global ischemia. Neuronal culture and brain slices for testing neuroprotective drugs.

## PC-830

### Parasitology/Microbiology, Community and Pharmacy

(2 credits)

1. **Parasitic, microbial and viral infections, community and pharmacy:** The general perceptions, linkages and relevances; Basic principles of epidemiology; Epidemiology of infectious/tropical diseases; Community related issues involved in the epidemiological studies; Community participation in epidemiological studies; Role of epidemiological studies on disease treatment, control and prevention.
2. **Emerging and re-emerging infections:** Role of vectors and population migration; Impact of travel on the transmission patterns of infectious diseases; Mapping and managing of the drug-resistant pathogens.
3. **Biomedical and biocultural definitions of parasitic and microbial diseases:** The perceptions of community; Community or selected schools participation/involvement in the control and treatment of infectious diseases; Role of NGOs and media; Modern and traditional medicines for the treatment of tropical diseases.
4. **Mothers definition of malaria:** Mothers beliefs and behaviours in relation to malaria in children; Home management of childhood malaria, diarrhoea and respiratory infections; The decision-making dynamics in treatment seeking behaviours, antimalarials available in retail outlets and home; Impact of parasitic and microbial diseases on the education of children.
5. **Women and tropical diseases:** Introduction; Women's participation in the treatment and management of infectious diseases; The relationship between gender and tropical diseases: Risk factors of infection, social costs and access to care, knowledge and resources; Assessment of women's need as related to infectious diseases, their involvement in the identification of their own needs, setting their own goals and targets; Training of women to train themselves.
6. **Mass chemo and immunoprophylaxis against tropical diseases:** Evaluation of their impact and the understanding of the cost-effectiveness.
7. **Determination of disease burden, the disability-adjusted life years, and the understanding of the economical aspects of tropical diseases:** Details of studies the social and economic burden of malaria and tuberculosis.

## PC-840

### Regulatory Toxicology and Drug Safety Evaluation

(2 credits)

1. **Concept and development of regulatory toxicity testing models:** Bio assays and end-points: Human pharmaceutical products; Exposure characterization; Routes of exposure; ADME profiles.
2. **Stages of drug development:** Drug laws, FDA, OECD, ICH, Schedule Y; Design of pre-clinical toxicity studies and clinical development, clinical risk/benefit analysis. Safety

evaluation of medical devices and bio materials. Good Laboratory Practices (GLP), issues and implementation.

3. **Different methods in toxicity testing:** Dose determination, response characterization, NOAEL.
4. **MTD and threshold limitations:** Hormesis, lower dose extrapolation, in vitro and in vivo correlation, animal to human extrapolation; Flow chart.
5. **Mechanism of toxicity: Evaluation across different models:** Target organs, cell death, necrosis, apoptosis, oxidative stress, chromosome and DNA damage.
6. **Acute and chronic toxicity, genetic toxicity:** Types of genetic toxicity testing; Principles of detection; Genotoxicity of marketed drugs, test batteries, Salmonella test, micronucleus test, chromosome aberration test, Comet assay, New-bio assays.
7. **Reproductive toxicity:** Germ cell toxicant, effect on gonads, F1 generation study. Neonatal toxicity; Transplacental mutagenesis and carcinogenesis.
8. **Carcinogenicity, carcinogen identification:** Carcinogenesis process, drug induced carcinogenicity, lifetime carcinogenicity bio assays, neonatal mouse models; Short and medium term bio assays, limitations and impacts.
9. **Regulations, discovery-development gap:** Risk characterization; Management and Communication.
10. Future of regulatory toxicology in drug safety evaluation.

## PC-850

### Cellular and Molecular Parasitology

(2 credits)

1. **Ultrastructure of parasites/microbes/viruses:** Plasmodium, leishmania, entamoeba, mycobacterium, candida, HIV, hepatitis B virus; Basic principles related to structure and function of the cell membranes; Biology of the cell membranes of plasmodium, leishmania and entamoeba; Cell wall of mycobacterium tuberculosis and its unique features; Structure of HIV.
2. **Disease processes and the definition of pathogenesis:** Modern concepts of the pathogenetic mechanisms with special reference to the underlying genetic basis; Mechanisms of virulence; Acute-phase response and proinflammatory mechanisms during infections; Mechanisms of mimicry; Cerebral malaria (CM) and mechanisms of sequestration; Experimental models of CM; Hematopoiesis and anaemia in malaria; Genetic factors that determine the susceptibility and resistance to malaria. *E. histolytica*: Mechanisms of encystation and excystation; Macrophage-mycobacteria interaction, and the mechanisms of latency during *M. tuberculosis* infection.
3. **Bioimmunotherapy of infectious diseases and the development of protein drugs:** Brief introduction to carbohydrate, protein, lipid and nucleic metabolism in parasitic infections (plasmodium, leishmania and *M. tuberculosis*); Studies on some known potential drug targets in plasmodium, leishmania, *M. tuberculosis* and HIV. genes and antigens/proteins of plasmodium, leishmania, *M. tuberculosis* in the development of vaccines and drugs.

4. **Drug-resistance:** The definition; Drug-resistance in parasites and microbes; General mechanisms of drug-resistance; Detailed studies on mechanisms of resistance of (1) Plasmodium to chloroquine, artemisinin derivatives and pyrimethamine; (2) M. tuberculosis to isoniazid, rifampicin, pyrazinamide, ethambutol and streptomycin; Reversal of drug-resistance; Experimental selection of drug-resistant strains of Plasmodium berghei (in vivo) and P. falciparum (in vitro); Role of cloning in experimental selection of drug-resistant strains.
5. **Basic principles of vaccinology:** Conventional (whole cell live, killed and attenuated), sub-unit and molecular vaccines. nucleic acid vaccines; Prime-boost vaccination; Adjuvants and the mechanisms of their action; Experimental models of vaccination against malaria and tuberculosis; Latest knowledge in the human vaccine development against malaria, leishmania, tuberculosis and HIV.
6. **Fundamentals of the immunodiagnosis with special reference to torpical diseases; Immunodiagnosis:** Approaches, practices and research needs; Impact of immunodiagnosis on the disease control. Various serological tests (ELISA, IFA, IHA etc.); Studies on presently used diagnostic kits for malaria, tuberculosis and HIV; Molecular diagnosis: Weaknesses and strengths.

## PC-860

### Epigenetics and Diseases

(2 credits)

1. Toxicogenomics, pharmecogenomics, pharmecogenetics and personalized medicine.
2. **Proteomics in Drug Discovery:** Two dimension gel electrophoresis; in-gel digestion etc.
3. **Microarray technology:** Hybridization and types of arrays, tilling array, protein arrays.
4. **Chromatin structure and functions:** The Nucleosome, euchromatin & heterochromatin, regulation and alteration of chromatin higher order structure.
5. **Chromatin Immunoprecipitation:** Chip on chip technology.
6. **Epigenomics, Histone modifications:** Acetylation, methylation, phosphortylation, Ubiquitination, ribosylation etc.
7. Role of histone modifications in diseases in diabetes.
8. Role of histone modifications in cancer.
9. Neurodegenerative diseases.
10. The use of chromatin immunoprecipitation assays in genome-wide analysis of histone modifications.

## Pharmaceutics

### Semester-I

#### PE-710

#### Implications of Solid State Properties in Drug Delivery

(2 credits)

{Pre-requisite to course PE-660}

1. **Barriers to Drug Delivery:** Aqueous solubility, permeability, first pass metabolism.
2. **Solid State Properties and Biopharmaceutics:** Implications of molecular level and particle level solid state properties on aqueous solubility, permeability, first pass metabolism.
3. **Molecular level of Solid State and Drug Delivery:**
  - a) Polymorphs- thermodynamic properties, solubility advantage.
  - b) Co-crystals- crystal engineering aspects, synthons exploited in pharmaceuticals, phase behavior, solubility behavior.
  - c) Amorphous phase- thermodynamic and kinetic properties, physical stability, solubility advantage, challenges in use of amorphous phase, stabilization strategies and surface behavior of amorphous form.
4. **Particle level of solid state and drug delivery:**
  - a) Particle size reduction to micron and nano size- Nanocrystals, polymeric nano-crystalline solid dispersions, small molecule assisted nano-crystalline solid dispersions.
  - b) Crystal habit- surface anisotropy and its impact on dissolution behavior.

### Semester-II

#### PE-810

#### Novel Approaches for Targeted Drug Delivery

(2 credits)

1. **Principles of drug targeting and molecular basis of targeted drug delivery:** Receptor mediated endocytosis; Different levels of targeting-first order, second order and third order targeting; Different types of targeting-active and passive targeting.
2. **Disease based targeting approaches:** Novel approaches to target diseases and disorders such as cancer and infectious diseases, exploitation of disease environment for the targeted delivery of therapeutics.
3. **Organ based targeting:** Novel strategies for CNS, pulmonary, liver, and colon targeting.
4. **Cell/Organelles based targeting:** Mitochondria, Nuclear targeting, lymphatics/M cells, liver parenchymal cells/macrophages, hepatocytes and bone marrow cells.
5. **Physico-chemical approaches of targeting:** Stimuli responsive: Magnetically, thermal and pH assisted drug delivery systems, Chemical drug delivery (prodrugs), Lipid-drug/Polymer-drug conjugates.
6. **Carrier based approach for targeted drug delivery:** Functionalized liposomes,

polymeric and lipid nanoparticles, liquid crystalline nanoparticles, polymeric micelles, functionalized carbon nanotubes and inorganic nanoparticles.

7. **Gene Delivery:** Barriers to gene delivery, novel approaches based on viral and non viral vectors for site specific gene delivery, their advantages and limitations, siRNA delivery.
8. **Advanced characterization techniques for nanocarriers:** Nanoscale characterization techniques, Biophysical characterization of nanoparticles and In vivo imaging techniques- Fluorescence Gamma scintigraphy, X rays.
9. **Miscellaneous Topics:** Emerging roles of Emulsomes, transferosomes, ethosomes, bilosomes, virosomes etc. for drug/ macromolecule delivery.
10. **Nanotoxicology and regulatory issues:** Toxicity and regulatory hurdles of nanocarriers, Nanotoxicity in lungs

# Biotechnology

## Semester-I

### BT-710

#### Interfacial Enzymology

(2 credits)

1. **Enzymology:** fundamental, enzyme kinetics, enzyme inhibition and inhibitors, example of enzymatic reactions, regulation of enzyme.
2. **Biophysics of enzyme:** *lipid interaction:* structural features of membrane lipids, critical micellar concentration, cooperativity of micellization, liposomes, lipoprotein particles.
3. **Membrane properties modulating structure-function of enzymes:** Properties of lipid bilayer phases, effect of sterols on aggregates of lipids, membrane fluidity.
4. **Interfacial and non-interfacial enzymes:** issues of interfacial and non-interfacial enzymology, interfacial enzymes of lipid metabolism, phospholipase A<sub>2</sub>, interface phenomenon.
5. **Interfacial Activation:** Enzyme versus substrate model, interfacial processivity, interfacial catalytic turnover, Scooting and Hopping model, interfacial allostery, inhibition and Inhibitors.
6. **Methods to study interface and interfacial enzymes:** IR spectroscopy, Attenuated total reflection Fourier transform infra-red (ATR-FTIR) spectroscopy, IRE, sample preparation, use of fluorescent substrate and indicators
7. **Determination of protein secondary structure:** dynamic and orientation in lipid-protein mixture, methods for ATR-FTIR spectra evaluation.
8. **Lipoproteins:** Lipoproteins, different types, major components, apolipoproteins, reverse cholesterol transport.
9. **Lipoproteins associated enzymes:** Various enzymes associated with lipoproteins, their role in physiology and pathology.
10. **Screening of enzyme inhibitors:** various methods available to screen enzyme inhibitors.

### BT-720

#### Therapeutic and Diagnostic approaches in Neglected Tropical Diseases

(2 credits)

1. **Application of biotechnology in drug discovery:** Introduction, identification of sources for isolating the gene that encodes the target proteins, engineer expression system for target protein.
2. **Protein expression systems:** Optimization of cell expression system to maximize production of target proteins; application of TAP tagging in protein protein interaction and drug discovery.
3. **Identification of potential vaccine candidates:** Basic concepts of vaccines, types of vaccines, techniques for identification of potential vaccine candidates, conventional vaccinology vs. reverse vaccinology.
4. **Genomics:** Key role of genomics in modern vaccine and drug design for emerging infectious diseases. Genomics and diagnosis of infectious diseases.
5. **Biomarkers in infectious diseases:** Introduction to biomarkers, classification of

biomarkers, types of biomarkers-genes, proteins, RNA, biomarkers of infectious diseases, technologies for identification of biomarkers-PCR, Combined PCR-Elisa and other non PCR methods.

6. **Monoclonal antibodies as therapeutic targets:** Antibody structure and function, antibody classes and biological actions, monoclonal antibody and infectious diseases.
7. **Epitope mapping:** Epitope mapping and its application in vaccines and protein therapeutics, advantages of monoclonal antibodies over existing chemotherapy.
8. **Immunogenicity and immunotoxicity of Biopharmaceuticals:** Biotech derived products-cytokines, plasminogen, growth factors, monoclonal antibodies and fusion proteins, preclinical and clinical levels of biopharmaceuticals, rules for regulation of synthesis and testing of biopharmaceuticals.
9. **RNA silencing technologies in drug discovery and target validation:** Silencing of genes inducible and reversible RNAi mediated knockdown, antisense oligonucleotides, mechanism of action of antisense oligonucleotides, antisense oligonucleotides for neglected tropical diseases, RNAi as an anti-infectious agent.
10. **Generation of mutant strains for functional analysis of essential genes:** Gene knock out and knock in by double displacement and overexpression strategies.

## Semester-II

### BT-810

#### Protein Structure and Stability

(2 credits)

1. **Protein structure:** Diversity, Taxonomy, Higher levels of organization, Post-translational modifications.
2. **Analytical chromatographic methods:** Chromatography of peptides and high molecular weight proteins.
3. **Spectroscopic techniques for protein structure analysis.**
4. **Strategies for sequence determination:** Enzymatic and chemical.
5. **Forces responsible for protein structure and stability:** Thermodynamics.
6. **Kinetics of protein folding:** Two-state and multistate kinetics, Transition states and intermediates.
7. **Protein folding in the cell:** Lessons learnt
8. **Stability of proteins:** Kosmotropes and chaotropes. Denaturation and renaturation of proteins.
9. **Protein stabilization:** Theories
10. **Stabilization of proteins:** Role of additives.

### BT-820

#### Host-Pathogen Interaction in Infectious Disease

(2 credits)

1. **Introduction Infectious Disease and relevance:** Causative agents, bacterial and viral diseases, Pandemics.
2. **Tuberculosis:** *Mycobacterium tuberculosis*- a global epidemic, reasons for resurgence, drug resistance and emergence of new diseases.

3. **Fundamentals of the process of Infection:** Basic concepts of Immunology & Cell Biology, Intercellular pathogens; extracellular pathogens.
4. **Survival strategies of *Mycobacterium tuberculosis*:** Cell wall, phagocytosis, virulence factors, secretion systems in *M.tb* and other pathogens and their importance.
5. **Immunity and Resistance:** Host-pathogen interaction, Invasion, adhesion, cell signalling and trafficking, manipulating host resources, extracellular matrix and cytoskeleton, fibrinolytic pathway.
6. **Iron metabolism:** Iron and copper, iron metabolism, iron uptake and transport mechanisms in host and pathogen, role in infection, essential requirement of iron in tuberculosis.
7. **Multifunctional proteins:** Concept of multifunctionality, role in pathogenesis, interplay and regulation of these proteins during infection.
8. **In vivo and in vitro techniques:** Cell culture models, fluorescent proteins, rDNA techniques, lentiviral and retroviral vectors, microscopy, FACS analysis, animal models.
9. **Intervention Strategies:** Drugs and their limitation, targeted delivery of drugs, utilizing cell and pathogen biology to design new drugs, newer approaches for drug discovery.
10. **Vaccines:** Types of vaccines, Future perspectives.

# Pharmacoinformatics

## Semester-I

### PI-710

#### Strategies in Lead Optimization

(2 credits)

1. **Introduction:** Overview of strategies; Lead optimization; Drug discovery cycle; Success story of captopril.
2. **Denovo ligand design:** Overview; Active site analysis method; Whole molecule method; Connection methods; Genetic algorithm for ligand building; Limitations; Software.
3. **Structure based drug design:** Introduction; Bioactive conformation; Ligand anchoring; Desolvation effect; Entropic effect; Role of water; Analog design; Data base searching; De novo design; Success stories.
4. **Iterative Protein crystallographic analysis:** Introduction; Experimental approaches; Role of crystallography in drug design; Conformation and biological ac. Advantages and limitations of crystallography; Applications; Case studies.
5. **Docking and Scoring:** Molecular recognition. Methods, algorithms, conformational ensemble, molecular determinants for binding, scoring functions, solvation effect. In silico tools, flexible docking, Applications, case studies.
6. **Small molecular crystallography:** Introduction, direct and indirect design, CSD, bioactive conformation, polar and non-polar molecules, crystal packing and ligand protein interaction. Data base mining, CHO hydrogen bonding, applications.
7. **Peptidomimetics:** Introduction, types of peptidomimetics, conformational restriction, template mimetics, peptide bond isosteres, transition state nalogos, rational drug design. Case studies.
8. **ADMET and Duggability:** Property based drug design, absorption, distribution, metabolism, excretion and physico chemical properties. Descriptors, bioisosterism, prodrug and soft drug approaches.
9. **Metabolism by Cytochromes:** Introductions, significance of cytochrome P450s, substrates and inhibitors, predicting cytochrome P450 metabolism; Ligand based and structure based models for cytochrome P450. Case studies.
10. **Human Ether-a-ggRelated Gene K+ Challen (HERG):** Introduction, cardiac arrhythmias, SAR around HERG, in silico approaches. Examples.

### PI-720

#### Computational Bio-pharmaceutics and Pharmacokinetics

(2 credits)

1. **Preclinical proof-of-concept:** Definition, traditional drug development chain, problems in drug development, economical pressures in drug development, new development chain-exploratory Vs confirmatory.
2. **Absorption:** Introduction, rate limiting steps to oral drug absorption, portal bioavailability, predictive drug absorption models, strategies to improve bioavailability.

3. **Permeability:** Permeability predictions, models of intestinal drug permeability, drug transporter modelling, case study of P-gp and PEPT1.
4. **Distribution:** Plasma protein binding, free drug fraction, free drug hypothesis.
5. **Metabolism:** Integration of nonclinical and clinical data, polymorphism of phase I, II, III metabolising enzymes and relevance to pharmacokinetics and pharmacodynamics.
6. **Physicochemical properties:** Introduction, theories of prediction (local Vs Global models), Log P, pKa, Log D, solubility, Peff.
7. **Physiologically based pharmacokinetics and pharmacodynamic modelling:** Definition, modelling methodology, extrapolation across doses, routes of exposure and species, application to risk assessment, limitations, pharmacodynamic studies of drug-drug interactions, PK/PD modeling.
8. **QSAR studies on drug transporters involved in toxicology:** Introduction, the problem of multispecificity, QSAR approaches to design inhibitors of p-glycoprotein (ABCB1), other ABC transporters-ABCG2, ABCC1 and ABCC2, ABCB11), predicting substrate properties, the antitarget concept.
9. **Computational modelling of receptor mediated toxicity:** Introduction, receptors involved in toxicity of environmental chemicals (estrogen, androgen, thyroid, aryl hydrocarbon), receptors involved in drug metabolism and drug-drug interactions (pregnane X receptor/ steroid and xenobiotic receptor) constitutive androstane receptor, glucocorticoid receptor, clinical drug drug interaction studies.
10. **Computational methods for prediction of solid-state:** Energetics of molecules in crystals- coulombic interactions, polarisation, dispersions, repulsions. Ab initio method to calculate the structure of the molecule, determination of single crystal structure, the molecular model, intermolecular forces and the search procedure (Cambridge Crystallographic Database).

# Pharmacy Practice

## Semester-I

### PP-710

#### Research Methods-I

(2 credits)

1. **Introduction to research methodology:** Meaning and objectives of research; Types of research; Approaches to research; Research methods versus methodology; Research Process; Criteria of good research; Common problems encountered in research; Quantitative and qualitative research methods.
2. **Defining the research problems:** Selecting a problem; Necessity of defining the problem. Research design; Meaning and features of research design; Concepts related to research design; Basic principles of experimental designs; Developing a research plan;
3. **Methods of data collection:** Primary data collection methods, use of questionnaires; Secondary data collection; Selection of appropriate method of data collection; Interviewing and principles of good interview.
4. **Processing & analysis of data:** Processing operations; Elements of analysis; Measures of asymmetry; relationships, associations; Summary chart concerning analysis data collection.
5. **Fundamentals of sampling:** Need for sampling; Sampling distributions, central limit theorem; Sampling theory; Sandler's A-test; Standard error; Estimating population proportion; Sample size and its distribution; Determination of sample size based on various basis.
6. **Interpretation of results:** Meaning of interpretation; Techniques of interpretation; Scientific writing and report preparation; Fundamentals of scientific writing; Steps in report preparation; Layout of reports; Types of reports; Precautions in writing research report.
7. **Questionnaire and survey techniques:** Analysis of qualitative data; Interview and focus groups.
8. Principles of validity and reliability.
9. Ethics committees.
10. Patient consent and confidentiality.

## Semester-II

### PP-810

#### Research Methods-II

(2 credits)

1. Theoretical perspectives and models in survey research.
2. **Qualitative interviews:** Focus groups.
3. **Triangulation:** Comparing methods.
4. **Evaluation of pharmaceutical services:** Objectives, design, framework, methods and measures.
5. National surveys pertaining to healthcare assessment.

# Pharmaceutical Technology (Process Chemistry)

## Semester-I

PT-710

Technologies for Green Chemistry

(2 credits)

1. **Introduction:** Importance and principles of green chemistry, green chemistry metrics, Environmental factor (E-factor), process mass intensity (PMI), examples of greener route to chemical reactions.
2. **Reaction media for green chemistry:** Solvent less condition, working without organic solvents, reactions in water, reactions using ionic liquids.
3. **Catalysis in green chemistry:** Design, development and implementation of efficient catalysts, asymmetric organo-catalysis, Green chemistry and catalysis, ionic liquid catalysis in green chemistry, photo-redox organo-catalysis.
4. **Biocatalysis:** Use of enzymes in organic reaction, kinetic and dynamic resolution, applications of biocatalysis in developing green chemistry
5. **Sustainable development:** Materials for sustainable economy, atom economy and sustainability, chemistry of longer wear.
6. **Environmental concern:** Pollution prevention, chemistry of recycling, avoid of toxic chemicals (illustrated by phosgene), waste minimization, specific examples of safer reaction.
7. **Applications of green chemistry in manufacturing drugs:** HIV integrase inhibitor-Raltegravir, Process development of Glucokinase activator, Environmentally benign synthesis of Sildenafil citrate, Process Development of Rizatriptan.
8. **Green chemistry approaches for application in pharmaceutical industry:** Amide bond formation, oxidation, reduction, halogenations, Baylis-Hillmann reaction.
9. How do the fine chemical, pharmaceutical, and related industries approach green chemistry and sustainability?
10. **Recent examples of green chemistry articles of interest to the pharmaceutical industry:** C-H activation, green fluorination, continuous processing and process intensification

## Semester-II

PT 820

Topics in Organic Process Chemistry

(2 credits)

1. **Organic reactions:** Mechanisms and stereo-chemical aspects of the common reactions used in process development and scale up synthesis.
2. **Heterocyclic chemistry:** Its role in drug synthesis, importance and synthesis of drugs containing heterocycles.
3. **Aromatic heterocycles:** Three- four-five and six membered heterocycles and benzofusedheterocycles -synthesis and reactions.
4. **Non-aromatic heterocycles:** Small ring heterocycle such as azirdines, oxiranes, thiranes, azetidines, oxetanes and thietanes- synthesis and reactions.
5. **Organic reactions in aqueous media:** Water as a green solvent and its use in process

research and development and scale-up synthesis.

6. **Selected reactions in water:** Nucleophilic substitution displacements and C-C bond formation reactions in aqueous media.
7. **Process chemistry:** Approaches to process R&D, route selection, solvent selection, optimization and troubleshooting.
8. **Process chemistry in pharmaceutical industry:** Importance, need and role of it in pharma industry.
9. **Case studies of process R&D:** Involving process development of leading drugs such as sutent, sitgaliptin, sildenafil and emerging trends in process R&D.
10. **Innovations in process R&D:** Examples and case studies from literature- review of OPRD journal.

# Pharmaceutical Technology (Biotechnology)

## Semester-II

### PT-810

#### **Biotransformation and stereoselective biocatalysis of pharmaceutically important compounds** (2 credits)

1. **Introduction of biotransformation:** Advantages and disadvantages over chemical catalysis; different types of biocatalysis: microbial, enzymatic and immobilized system of biocatalysis; current industrial biocatalysis.
2. **Common enzymes used in biocatalysis:** Biocatalysis with lipase and amidase / aminopeptidase.
3. **Enzymes used in biocatalysis:** Biocatalysis with acylase and hydantoinase.
4. **Enzymes used in biocatalysis:** Biocatalysis with lyases and oxido-reductase.
5. **Enzymes used in biocatalysis:** Biocatalysis with nitrilase and epoxide hydrolase.
6. **Enzymes used in biocatalysis:** Biocatalysis with hydroxylase, aldolases and decarboxylase.
7. **Biocatalysis of pharmaceutically important compounds:** Stereoselective biocatalysis for the synthesis of some chiral pharmaceutical intermediates, such as synthesis of ACE inhibitors; definition, mode of action of inhibitors.
8. **Biocatalysis of pharmaceutically important compounds:** Recent developments, synthesis of anti-cholesterol drugs by biocatalytic routes, calcium channel blocking drugs, potassium channel openers.
9. **Biocatalysis of pharmaceutically important compounds:** Biocatalytic production of enantiomerically pure antiarrhythmic compounds, anti-psychotic compounds, anti-infective drugs.
10. **Biocatalysis of pharmaceutically important compounds:** Biocatalytic production of enantiomerically pure anti-inflammatory drugs, antiviral agents; prostaglandin synthesis.