COURSES OF STUDY

Ph.D.; M.S. (Pharm.); M.Pharm.; M.Tech. (Pharm.);
M.Tech. (Medical Devices);M.Tech. (Biopharmaceuticals);
M.B.A. (Pharm.)

JULY 2023

S.A.S. Nagar

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

Course Structure

Semester I

Semester II

Pharmacy Practice
Clinical Research
Pharmaceutical Technology (Formulations)
Pharmaceutical Technology (Process Chemistry)
Pharmaceutical Technology (Biotechnology)
Medical Devices

Semester III

Clinical Research

Pharmaceutical Management

Semester I
Semester II
Semester III
Semester IV

Ph.D. Courses

Medicinal Chemistry
Natural Products
Pharmaceutical Analysis
Pharmacology & Toxicology
Pharmaceutics
Biotechnology
Pharmacoinformatics
Pharmacy Practice
Pharmaceutical Technology (Process Chemistry)
Pharmaceutical Technology (Biotechnology)

Academic Administration

Prof. Dulal Panda
Director

Prof. Arvind Bansal
Dean

Head/ Incharge of the Departments

Prof. P.V. Bharatam
Medicinal Chemistry

Prof. S.M. Jachak
Natural Products

Prof. I.P. Singh
Pharmaceutical Analysis

Prof. Kulbushan Tikoo
Pharmacology & Toxicology

Prof. A.K. Bansal
Pharmaceutics

Prof. Ipsita Roy
Biotechnology

Dr. Sushma Singh
Pharmaceutical Technology (Biotechnology)

Dr. Joydev Laha
Pharmaceutical Technology (Process Chemistry)

Prof. P. Tiwari
Pharmacy Practice

Prof. Prabha Garg
Pharmacoinformatics

Prof. Anand Sharma
Pharmaceutical Management

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.Tech. (Medical Devices), M.Tech. (Biopharmaceuticals),
M.B.A. (Pharm.) and Ph.D. programmesin 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 Barelli Iuttar 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 immunodiagnostics, 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).

M.Tech.(Medical Devices)

M.Tech. (Biophrmaceuticals)

M.B.A. (Pharm.).

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. 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 regulatns of the Institute.

Fraud/theft/bribery/dishonesty or acting under the influence of outsiders in connection with the

research and studies or property of thenstitute 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 consecutivedays 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 Insttute 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.*

MEDICINAL CHEMISTRY
M.S. (Pharm.)

Course Code	Course Name	Credits
Semester-I		
MC-510	Basics of Drug Action	2
MC-511	Spectral Analysis	2
MC-520	Logic in Organic Synthesis-I	2
MC-530	Green Chemistry and Pharmaceutical R& D	1
NP-510	Separation Techniques	1
PE-510	Pharmaceutical Preformulation - I	1
PT-510	Industrial Process and Scale-up Techniques	1
GE-510	Biostatistics	2
GE-511	Seminar	1
LG-510	General Lab Experience	3
	Total Credits	***16***
Semester-II		
MC-610	Computer Aided Drug Design	2
MC-620	Logic in Organic Synthesis-II	2
MC-630	Structure and Function of Biomolecules	2
MC-640	Organocatalysis and metal-free methods of synthesis	1
MC-650	Stereochemistry and Drug Action and Asymmetic Synthesis	2
MC-660	AI and ML in Drug Design	1
PC-610	Drug Metabolism	1
GE-611	Seminar on research proposal	1
LS-610	General Lab Experience in the Area of Specialization	2
	Total Credits	***14***
Semester-III		
	Project (22 weeks)	
TH-598	Synopsis	5
TH-599	Presentation	3
	Total Credits	***8***
Semester-IV		
TH-698	Thesis	9
TH-699	Defence of Thesis	3
	Total Credits	***12***
	Grand Total (I to IV semesters)	***50***

NATURAL PRODUCTS
M.S. (Pharm.)

Course Code	Course Name	Credits
Semester 1		
NP-510	Separation Techniques	1
NP-520	Natural Products-I	2
MC-510	Basics of Drug Action	2
MC-511	Spectral Analysis	2
PC-540	Chemotherapy of Parasitic and Microbial Infections	1
BT-510	Biotechnology in Pharmaceutical Sciences	1
GE-510	Biostatistics	2
GE-511	Seminar	1
LG-510	General Lab Experience	3
	Total Credits	**15**
Semester-II		
NP-610	Natural Product and Bio-organic Chemistry	2
NP-620	Natural Products-II	2
TM-610	Chemical Standardization of Herbal Drugs	2
NP-640	Structure Elucidation	2
NP-650	Medicinal Plant Biotechnology and Cultivation Propagation	1
MC-650	Stereochemistry and Drug Action	2
PC-611	Pharmacological Screening and Assays	1
GE-611	Seminar	1
LS-610	General Lab Experience in the Area of Specialization	2
	Total Credits	**15**
Semester-III		
	Project (22 weeks)	
TH-598	Synopsis	5
TH-599	Presentation	3
	Total Credits	**8**
Semester-IV		
TH-698	Thesis	9
TH-699	Defence of Thesis	3
	Total Credits	**12**
	Grand Total (I to IV semesters)	**50**

TRADITIONAL MEDICINE
M.S. (Pharm.)

Course Code	Course Name	Credits
Semester 1		
TM-510	Introduction to Traditonal Systems of Medicine	1
TM-520	Ayurvedic Pharmacy	1
NP-510	Separation Techniques	1
NP-520	Natural Products-I	2
TM-530	Pharmacognostical identification of crude drugs	2
TM-540	Industrial perspective of Herbal Drug Products	2
GE-510	Biostatistics	2
GE-511	Seminar	1
LG-510	General Lab Experience	3
	Total Credits	**15**
Semester-II		
TM-610	Chemical Standardization of Herbal Drugs	2
TM-620	Pharmacological Evaluation of Herbal Drugs	2
TM-630	Clinical Aspects of Herbal Drugs	2
TM-640	Herbal Formulations	2
TM-650	Herbal Drugs and its action based on Indian System of Medicine	3
GE-611	Seminar	1
LS-610	General Lab Experience in the Area of Specialization	3
	Total Credits	**15**
Semester-III		
	Project (22 weeks)	
TH-598	Synopsis	5
TH-599	Presentation	3
	Total Credits	**8**
Semester-IV		
TH-698	Thesis	9
TH-699	Defence of Thesis	3
	Total Credits	**12**
Grand Credits (I to IV semesters)		**50**

PHARMACEUTICAL ANALYSIS
M.S. (Pharm.)

Course Code	Course Name	Credits
Semester 1		
PA-510	Topics in Pharmaceutical Analysis	2
MC-511	Spectral Analysis	2
NP-510	Separation Techniques	1
PE-510	Pharmaceutical Preformulation-I	1
PE-530	Pharmaceutical Preformulation-II	1
BT-510	Biotechnology in Pharmaceutical Sciences	1
GE-510	Biostatistics	2
GE-520	Fundamentals of Intellectual Property (IP) and Technology Management	1
GE-511	Seminar	1
LG-510	General Lab Experience	3
	Total Credits	**15**
Semester-II		
PA-610	Pharmacopoeial Methods of Analysis	2
PA-620	Instrumental Techniques for Evaluation of APIs and Drug Products	2
PA-630	Stability Testing	1
PA-640	Quality Control and Quality Assurance	2
NP-640	Structure Elucidation	2
PC-611	Pharmacological Screening and Assays	1
PE-630	Pharmaceutical Product Development-I	1
PE-660	Solid State Pharmaceutics	1
GE-611	Seminar	1
LS-610	General Lab Experience in the Area of specialization	2
	Total Credits	**15**
Semester-III		
	Project (22 weeks)	
TH-598	Synopsis	5
TH-599	Presentation	3
	Total Credits	**8**
Semester-IV		
TH-698	Thesis	9
TH-699	Defence of Thesis	3
	Total Credits	**12**
Grand Credits (I to IV semesters)		**50**

PHARMACOLOGY & TOXICOLOGY
M.S. (Pharm.)

Course Code	Course Name	Credits
Semester 1		
PC-511	Pathophysiology	1
PC-520	General Pharmacology	2
PC-530	Experimental Pharmacology	1
PC-540	Chemotherapy of Parasitic and Microbial Infections	1
NP-510	Separation Techniques	1
PE-520	Biopharmaceutics and Pharmacokinetics	2
BT-510	Biotechnology in Pharmaceutical Sciences	1
GE-510	Biostatistics	2
GE-520	Fundamentals of Intellectual Property (IP) and Technology Management	1
GE-511	Seminar	1
LG-510	General Lab Experience	3
	Total Credits	**16**
Semester-II		
PC-610	Drug Metabolism	1
PC-611	Pharmacological Screening and Assays	1
PC-620	CNS and Respiratory Pharmacology	2
PC-630	Autonomic, CVS, Blood, Renal and GI Pharmacology	2
PC-640	Autocoids, Endocrine- and immuno Pharmacology	1
PC-650	Clinical Pharmacology and Regulatory Toxicology	2
RT-650	Good Laboratory Practices	2
GE-611	Seminar	1
LS-610	General Lab Experience in the Area of Specialization	2
	Total Credits	**14**
Semester-III		
	Project (22 weeks)	
TH-598	Synopsis	5
TH-599	Presentation	3
	Total Credits	**8**
Semester-IV		
TH-698	Thesis	9
TH-699	Defence of Thesis	3
	Total Credits	**12**
Grand Credits (I to IV semesters)		**50**

REGULATORY TOXICOLOGY
M.S. (Pharm.)

Course Code	Course Name	Credits
Semester 1		
RT-540	Principles and Methods in Toxicology	1
RT-550	Introduction to Regulatory Toxicology	2
PC-511	Pathophysiology	1
PC-520	General Pharmacology	2
PC-530	Experimental Pharmacology	1
PE-520	Biopharmaceutics and Pharmacokinetics	2
GE-510	Biostatistics	2
GE-520	Fundamentals of Intellectual Property (IP) and Technology Management	1
GE-511	Seminar	1
LG-510	General Lab Experience	3
	Total Credits	**16**
Semester-II		
RT-630	Molecular Toxicology	2
RT-640	Target Organ Toxicology	2
RT-650	Good Laboratory Practice in Regulatory Toxicology	2
RT-660	Bioethics	1
PC-610	Drug Metabolism	1
PC-611	Pharmacological Screening and Assays	1
PC-650	Clinical Pharmacology and Regulatory Toxicology	2
GE-611	Seminar	1
LS-610	General Lab Experience in the Area of Specialization	2
	Total Credits	**14**
Semester-III		
	Project (22 weeks)	
TH-598	Synopsis	5
TH-599	Presentation	3
	Total Credits	**8**
Semester-IV		
TH-698	Thesis	9
TH-699	Defence of Thesis	3
	Total Credits	**12**
Grand Credits (I to IV semesters)		**50**

PHARMACEUTICS
M.S. (Pharm.)

Course Code	Course Name	Credits
Semester 1		
PE-510	Pharmaceutical Preformulation-I	1
PE-520	Biopharmaceutics and Pharmacokinetics	2
PE-530	Pharmaceutical Preformulation-II	1
PE-540/PT-580	Regulatory Consideration for Pharm Development	1
MC-511	Spectral Analysis	2
NP-510	Separation Techniques	1
BT-510	Biotechnology in Pharmaceutical Sciences	1
GE-510	Biostatistics	2
GE-520	Fundamentals of Intellectual Property (IP) and Technology Management	1
GE-511	Seminar	1
LG-510	General Laboratory Experience	3
	Total Credits	**16**
Semester-II		
PE-620	Drug Delivery I (Controlled Drug Delivery)	2
PE-630	Pharmaceutical Product Development-I	1
PE-640	Pharmaceutical Product Development-II	2
PE-650	Drug Delivery II (Targeted Drug Delivery)	2
PE-660	Solid State Pharmaceutics	1
PA-630	Stability Testing	1
PC-610	Drug Metabolism	1
PC-611	Pharmacological Screening and Assays	1
GE-611	Seminar	1
LS-610	General Lab Experience in the Area of Specialization	2
	Total Credits	**14**
Semester-III		
	Project (22 weeks)	
TH-598	Synopsis	5
TH-599	Presentation	3
	Total Credits	**8**
Semester-IV		
TH-698	Thesis	9
TH-699	Defence of Thesis	3
	Total Credits	**12**
Grand Credits (I to IV semesters)		**50**

BIOTECHNOLOGY
M.S. (Pharm.)

Course Code	Course Name	Credits
Semester 1		
BT-520	Cell Biology	2
BT-530	Microbial Genetics	1
BT-550	Biochemistry	2
PT-520	Microbiology	1
PT-530	Biochemical Engineering Fundamentals	2
MC-511	Spectral Analysis	2
NP-510	Separation Techniques	1
GE-510	Biostatistics	2
GE-511	Seminar	1
LG-510	General Laboratory Experience	3
	Total Credits	**17**
Semester-II		
BT-610	Molecular Biology	2
BT-620	Recombinant DNA Technology	2
BT-630	Immunology and Immunotechnology	2
BT-650	Analysis, Diagnostics and Cell Based Screening	2
BT-660	Sequence Analysis	2
GE-611	Seminar	1
LS-610	General Lab Experience in the Area of Specialization	2
	Total Credits	**13**
Semester-III		
	Project (22 weeks)	
TH-598	Synopsis	5
TH-599	Presentation	3
	Total Credits	**8**
Semester-IV		
TH-698	Thesis	9
TH-699	Defence of Thesis	3
	Total Credits	**12**
Grand Total (I to IV semesters)		**50**

BIOPHARMACEUTICALS
M.Tech.

CourseCode	CourseName	Credits
Semester1		
BM-510	Introduction to Biopharmaceuticals	1
BM-520	Tools of Upstream Processing	1
BM-530	Formulation Strategies and Pharmacokinetics/ Pharmacodynamics of Biologics	1
BM-540	Vaccines and Immunotherapeutics	2
BM-550	Fundamentals of Cell Biology and Microbiology	2
NP-510	SeparationTechniques	1
GE-510	Biostatistics	2
CR-530	IRBs and Ethics in Clinical Trials	1
BM-560	Analytical Tools for Biopharmaceuticals	2
BM-570	Regulatory Affairs and IPR Aspects	1
GE-511	Seminar	1
LG-510	GeneralLaboratoryExperience	3
	TotalCredits	**18**
Semester-II		
BM-610	Gene Therapy	1
BT-620	RecombinantDNATechnology	2
BM-620	Cell-based Therapy and Protein Engineering	2
PT-690	Bioprocess and Downstream Engineering	2
BM-640	Enzymology and Enzyme-based Therapeutics	2
BT-650	Analysis, DiagnosticsandCellBasedScreening	2
BM-670	Artificial Intelligence, Machine Learning and Computational Biopharmaceuticals	1
BM-680	Omics in Drug Discovery	1
GE-611	Seminar	1
LS-610	GeneralLabExperienceintheAreaofSpecialization	2
	TotalCredits	**16**
Semester-III		
	Project(22weeks)	
TH-598	Synopsis	5
TH-599	Presentation	3
	TotalCredits	**8**
Semester-IV		
TH-698	Thesis	5
TH-699	DefenceofThesis	3
	TotalCredits	**8**
GrandTotal (ItoIVsemesters)		**50**

PHARMACOINFORMATICS
M.S. (Pharm.)

Course Code	Course Name	Credits
Semester 1		
PI-510	Introduction to Pharmacoinformatics	1
PI-520	Pharmacoinformatics – C++ Programming	2
PI-550	Pharmacogenomics and Metabolomics	2
MC-510	Basics of Drug Action	2
GE-510	Biostatistics	2
GE-520	Fundamentals of Intellectual Property (IP) and Technology Management	1
GE-511	Seminar	1
LS-510	General Lab experience	3
	Total Credits	**14**
Semester-II		
PI-610	Pharmacoinformatics-Bioinformatics	2
PI-620	Pharmacoinformatics -Chemoinformatics	2
PI-650	Pharmacoinformatics Database Management	1
PI-660	Data Analytics	2`
PI-670	Pharmacoinformatics - Perl Programming	1
PI-680	Pharmacoinformatics – Python Programming	1
MC-610	Drug Design	2
BT-610	Molecular Biology	2
GE-611	Seminar	1
LS-610	General Lab Experience in the Area of Specialization	2
	Total Credits	**16**
Semester-III		
TH-598	Synopsis	5
TH-599	Presentation	3
	Total Credits	**8**
Semester-IV		
TH-698	Thesis	9
TH-699	Defence of Thesis	3
	Total Credits	**12**
Grand Total (I to IV semesters)		**50**

PHARMACY PRACTICE
M.Pharm.

Course Code	Course Name	Credits
Semester 1		
PP-510	Pharmacy Practice-I	1
PP-520	Clinical and Applied Therapeutics-I	3
PP-530	Clinical Pharmacy	1
PE-520	Biopharmaceutics and Pharmacokinetics	2
GE-510	Biostatistics	2
GE-511	Seminar / Presentation	1
LG-511	Clinical Placement	4
LG-512	Computer Applications	2
	Total Credits	**16**
Semester-II		
PP-610	Pharmacy Practice-II	1
PP-611	Pharmacy Practice-III (Community and Rural Pharmacy)	1
PP-620	Clinical and Applied Therapeutics-II	3
PP-630	Evidence Based Medicine and Critical Appraisal	2
PP-631	Clinical Biostatistics	1
GE-611	Seminar / Presentation	1
LG-611	Clinical Placement	5
	Total Credits	**14**
Semester-III		
	Project (22 weeks)	
TH-598	Synopsis	5
TH-599	Presentation	3
	Total Credits	**8**
Semester-IV		
TH-698	Thesis	9
TH-699	Defence of Thesis	3
	Total Credits	**12**
Grand Total (I to IV semesters)		**50**

CLINICAL RESEARCH
M.Pharm.

Course Code	Course Name	Credits
Semester 1		
CR-510	Drug Discovery & Development	2
CR-520	Introduction to Clinical Research	1
CR-530	IRBs and Ethics in Clinical Trials	1
PE-520	Biopharmaceutics and Pharmacokinetics	2
PM-553	National Regulatory Environment	2
GE-510	Biostatistics	2
GE-511	Seminar/Presentations	1
LG-513	Computer Applications	2
	Total Credits	**13**
Semester-II		
CR-610	Bioavailability and Bio-Equivalence Testing	2
CR-620	Clinical Research Management	2
CR-630	Safety in Clinical Trials	1
CR-640	Document for Clinical Trials	2
CR-650	Clinical Data Management	2
CR-660	Medical Writing and Reporting	1
CR-670	Clinical Trials in Special Populations	2
CR-680	Research Designs	2
PC-611	Pharmacological Screening and Assays	1
PE-620	Drug Delivery I (Controlled Drug Delivery)	2
	Total Credits	**17**
Semester-III		
CR-551	Clinical Trials Documentation	3
CR-552	Monitoring of Clinical Investigations	1
CR-553	Emerging Technologies in Clinical Trials	1
CR-554	Quality Control and Quality Assurance in Clinical Trials	2
CR-555	Protocol Writing/Defence Assignment	1
	Total Credits	**8**
Semester-IV		
TH-698	Thesis	9
TH-699	Defence of Thesis	3
	Total Credits	**12**
Grand Total (I to IV semesters)		**50**

PHARMACEUTICAL TECHNOLOGY [FORMULATIONS]
M.Pharm.

Course Code	Course Name	Credits
Semester 1		
PT-580	Regulatory Considerations for Formulation Development	1
MC-511	Spectral Analysis	2
NP-510	Separation Techniques	1
PE-510	Pharmaceutical Preformulation -I	1
PE-520	Biopharmaceutics and Pharmacokinetics	2
PE -530	Pharmaceutical Preformulation - II	1
BT-510	Biotechnology in Pharmaceutical Sciences	1
GE-510	Biostatistics	2
GE-520	Fundamentals of Intellectual Property (IP) and Technology Management	1
GE-511	Seminar	1
LG-510	General Lab Experience	3
	Total Credits	**16**
Semester-II		
PT-620	Pharmaceutical Production Technology	1
PT-660	Formulation Development Concepts as Applied in Industry	2
PT-670	Industrial Pharmaceutical Processing (Scale up and validation)	1
PA -630	Stability Testing	1
PE-620	Drug Delivery I (Controlled Drug Delivery)	2
PE-630	Pharmaceutical Product Development-I	1
PE-650	Drug Delivery II (Targeted drug delivery)	2
PE-660	Solid State Pharmaceutics	1
GE-611	Seminar	1
LS-610	General Lab Experience in the Area of Specialization	2
	Total Credits	**14**
Semester-III		
	Project (22 weeks)	
TH-598	Synopsis	5
TH-599	Presentation	3
	Total Credits	**8**
Semester-IV		
TH-698	Thesis	9
TH-699	Defence of Thesis	3
	Total Credits	**12**
Grand Total (I to IV semesters)		**50**

PHARMACEUTICAL TECHNOLOGY [PROCESS CHEMISTRY]
M.Tech.(Pharm.)

Course Code	Course Name	Credits
Semester 1		
PT-510	Industrial Process and Scale-up Techniques	1
PT-560	Synthetic Aspects of Process Chemistry	2
MC-511	Spectral Analysis	2
MC-520	Logic in Organic Synthesis-I	3
NP-510	Separation Techniques	1
GE-510	Biostatistics	2
GE-520	Fundamentals of Intellectual Property (IP) and Technology Management	1
GE-511	Seminar	1
LG-510	General Lab Experience	3
	Total Credits	**16**
Semester-II		
PT-610	Topics Relevant to Drugs and Pharmaceutical Industry	1
PT-630	Synthetic Bulk Drug Technology	2
PT-690	Bioprocess and Downstream Engineering	1
MC-620	Logic in Organic Synthesis-II	3
MC-650	Stereochemistry and Drug Action	2
PA-620	Instrumental Techniques for Evaluation of APIs and Drug Products	2
GE-611	Seminar	1
LS-610	General Laboratory Experience in the Area of Specialization	2
	Total Credits	**14**
Semester-III		
	Project (22 weeks)	
TH-598	Synopsis	5
TH-599	Presentation	3
	Total Credits	**8**
Semester-IV		
TH-698	Thesis	9
TH-699	Defence of Thesis	3
	Total Credits	**12**
Grand Total (I to IV semesters)		**50**

PHARMACEUTICAL TECHNOLOGY [BIOTECHNOLOGY]
M.Tech.(Pharm.)

Course Code	Course Name	Credits
Semester 1		
PT-520	Microbiology	1
PT-530	Biochemical Engineering Fundamentals	2
PT-540	Animal and Plant Cell Technology	1
PT-550	Enzyme and Microbial Technology	1
MC-511	Spectral Analysis	2
NP-510	Separation Techniques	1
GE-510	Biostatistics	2
GE-520	Fundamentals of Intellectual Property (IP) and Technology Management	1
GE-511	Seminar	1
LG-510	General Laboratory Experience	3
	Total Credits	15
Semester-II		
PT-690	Bioprocess and Downstream Engineering	2
PC-610	Drug Metabolism	1
PC-611	Pharmacological Screening and Assays	1
BT-610	Molecular Biology	2
BT-620	Recombinant DNA Technology	2
BT-630	Immunology and Immunotechnology	2
PI-610	Pharmacoinformatics -Bioinformatics	2
GE-611	Seminar	1
LS-610	General Lab Experience in the Area of Specialization	2
	Total Credits	**15**
Semester-III		
	Project (22 weeks)	
TH-598	Synopsis	5
TH-599	Presentation	3
	Total Credits	**8**
Semester-IV		
TH-698	Thesis	9
TH-699	Defence of Thesis	3
	Total Credits	**12**
Grand Total (I to IV semesters)		**50**

MEDICAL DEVICES
M.Tech.(Medical Devices)

Semester – I

Course Code	Course name	Credits
MT-510	Medical Imaging & Processing	2
MT-520	Medical Instrumentation (Diagnostic, Therapeutic & Surgical)	2
MT-530	Physiology of Human Body	2
MT-540	Biostatistics and Data Science	1
MT-550	Computer Applications (CAD & CAM)	1
MT-560	Intellectual Property Rights (IPR) & Ethics	1
MT-570	Biomedical Devices and Systems	1
MT-580	Pharmacopeial Method of Analysis	1
MC-511	Spectral Analysis	2
LS-510	Medical Instrumentation Laboratory	2
LS-520	Pre-clinical Studies Laboratory	1
Total Credits		**16**

Semester – II

Course Code.	Course name	Credits
MT-610	Bioengineering (Neuro, tissue etc.) and Regenerative Devices	2
MT-620	Drug Delivery Engineering	2
MT-630	Advanced Biomaterials	2
MT-640	Biosensor	1
MT-650	Artificial Intelligence in Medical Devices	2
MT-660	Regulatory in Medical Devices	1
PC-611	Pharmacological Screening and Assays	1
MT-680	Biomedical Signal Processing	1
LS-610	Bio and Pharmaco-engineering Laboratory	1
LS-620	AI & Machine Learning Laboratory	1
Total Credits		**14**

Semester – III

Course Code.	Course name	Credits
TH-598	Industry Exposure and/or Professional Training Report	5
TH-599	Research and Thesis Work Presentation	3
	Total Credits	8

Semester – IV

Course Code.	Course name	Credits
TH-698	Industry exposure and/or professional training report	9
TH-699	Research and thesis work presentation	3
MT-910	Seminar	0
MT-920	Communication skills & personality development	0
	Total Credits	12

Grand Total (I to IV Semesters): 50

Non-credit course (Compulsory Audit)

Course Code.	Course name	Credits
MT-910	Seminar	0
MT-920	Communication skills & personality development	0

PHARMACEUTICAL MANAGEMENT
M.B.A.(Pharm.)

Course Code	Course Name	Credits
Semester 1		
PM-501	Fundamentals of Management	3
PM-502	Accounting for Management	3
PM-503	Managerial Economics	3
PM-504	Pharmaceutical Marketing	3
PM-505	Quantitative Techniques and Management	3
PM-506	Information Technology and MIS	3
PM-507	Human Behaviour in Organisation	2
PM-508	IPRs in Pharma Management	1
PM-511	Seminar	1
	Total Credits	**22**
Semester-II		
PM-601	Pharmaceutical Business Environment	3
PM-602	Financial Management	3
PM-603	Marketing Research	3
PM-604	Materials and Operations Management	3
PM-605	Business Communication	3
PM-606	Human Resource Management	2
PM-607	Supply Chain Management in Pharma. Sector	3
PT-610	Topics Relevant to Drugs and Pharmaceutical Industry	1
PM-611	Seminar	1
	Total Credits	**22**
Semester-III		
PM-551	Project Management	3
PM-552	Entrepreneurial Development	3
PM-553	National Regulatory Environment	2
PM-554	International Marketing	3
PM-555	Sales and Sales Promotion	3
PM-556	Industrial and Service Marketing	3
PM-557	Contemporary Issues in Pharmaceutical Marketing	2
PM-558	Fundamentals of R&D Management-I	2
PM-581	Project Summer Training	2
	Total Credits	**23**
Semester-IV		
PM-651	Management Control System	3
PM-652	Strategic Management	3
PM-653	International Regulatory Environment	2
PM-654	Pharmaceutical Product Management	3
PM-655	Pharmaceutical Brand Management	3
PM-656	Consumer Behaviour	2
PM-657	Advertising in Pharmaceutical Sector	3
PM-658	Fundamentals of R&D Management-II	2
PM-680(a)	Major Research Project (Thesis)	9
PM-680(b)	Defence of Thesis	3
	Total Credits	**33**
Grand Total (I-IV semesters)		**100**

Ph.D. Courses

Course Code	Course Name	Credits
Medicinal Chemistry		
Semester-I		
MC-740	Advanced Heterocyclic Chemistry	2
MC-750	Medicinal Chemistry Strategies and Late-Stage Synthesis	2
Semester-II		
MC-810	Principles of Peptide Chemistry	2
MC-830	Advanced Topics in Drug Action and Drug Design	2
Natural Products		
Semester-I		
NP-710	Advanced Separation Techniques for Research	2
NP-720	Natural Product-Based Drugs and Lead Molecules	2
Semester-II		
NP-810	Advanced Structure Elucidation Techniques for Natural Products	2
Pharmaceutical Analysis		
Semester-I		
PA-710	Impurity and Metabolite Profiling	2
Pharmacology and Toxicology		
Semester-I		
PC-750	Mitochondral Pharmacology in Human Diseases	2
Semester-II		
PC-820	Pharmacological Interventions for Ischemic Brain Injury	2
PC-840	Regulatory Toxicology and Drug Safety Evaluation	2
PC-860	Epigenetics and Diseases	2
Pharmaceutics		
Semester-I		
PE-710	Implications of Solid State Properties in Drug Delivery	2
PE-720	Computational Biopharmaceutics and Pharmacokinetics	2
Semester-II		
PE-810	Novel Approaches for Targeted Drug Delivery	2
Biotechnology		
Semester-I		
BT-710	Interfacial Enzymology	2
BT-720	Therapeutic and Diagnostic Approaches in Neglected Tropical Diseases	2
Semester-II		
BT-810	Protein Structure and Stability	2
BT-820	Host-Pathogen Interaction in Infectious Disease	2
Pharmacoinformatics		
Semester-I		
PI-710	Strategies in Lead Optimization	2

Semester-I

PI-810	Artificial Intelligence in Drug Discovery	2

Pharmacy Practice

Semester-I

PP-701	Research Methods-I	2

Semester-II

PP-801	Research Methods-II	2

Pharmaceutical Technology (Formulations)

Semester-I

PT-720	Advances in Formulation and Development	2

Pharmaceutical Technology (Process Chemistry)

Semester-I

PT-710	Technologies for Green Chemistry	2

Semester-II

PT-820	Topics in Organic Process Chemistry	2
PT-830	The Organic Chemistry of Drug Synthesis	2

Pharmaceutical Management

Semester-I

PP-701	Research Methods-I	2
PM-701	Startegic Market Management	2
PM-702	Corporate Restructuring and Valuation	2
PM-703	Corporate Governance and Financial Sustainability	2

Semester-I

PP-801	Research Methods-II	2
PM-801	Contemporary issues in Pharmaceutical Management	2
PM-802	Issues in Global Strategic Management	2
PM-803	Strategy for Entrepreneurship in Pharmaceuticals and allied areas	2
PM-804	Cross-functional issues in Pharmaceutical Management	2

Courses of Study 2023
Semester-I

Medicinal Chemistry

MC-510 : Basics of Drug Action (2 credits)

1. **Structure of drugs**, structure of macro molecules and structures of their complexes. The importance of3D Structure in Drug Action analysis. Electronic structure of drugs – metformin, omeprazole, Isoniazid, etc.Electronic structure of ketenes and its importance in the generation of β-lactams. Conservation of orbitalsymmetry and Diels-Alder reaction. Group theory and Graph theory of drug molecules.
2. **Energy concept** and its importance in drug action. Energy of Drugs. Internal energy vs. thermodynamics.Interaction energy and free energy of drug – macromolecule interactions. Three laws ofthermodynamics and the principles derived from these laws which are of significance to drug action.
3. **Free energy** and Relationship between thermodynamics and statistics. Thermodynamic cycle. Statisticalthermodynamics in predicting the structure of biomolecules and their interaction with drug molecules.Macromolecular vs. micromolecular correlation using thermodynamics and statistical thermodynamics.
4. Inter- and intramolecular interactions. Weak interactions in drug molecules. Covalent, ion-ion, ion-dipole,Hydrogen bonding, C-H hydrogen bonding, dihydrogen bonding, Van der Waals interactions and theassociated energies. Charge transfer interactions, salt bridges, homolytic vs. heterolytic cleavage energies.
5. **Receptors** :Recogition and amplification components of Drug-receptor interactions, Receptor theories anddrug action: Occupancy Theory, Rate Theory, Induced Fit Theory, Macromolecular perturbation theory,Activation-Aggregation theory. Topological and stereochemical consideration.
6. **Enzyme Action** : Enzyme – substrate interactions. Enzyme catalysis. Enzyme kinetics. Mechanismsof enzyme catalysis, Electrostatic catalysis and desolvation. Covalent catalysis, Acid-base catalysis, Strain/ distortion in enzyme catalysis. Coenzyme catalysis.
7. **Enzyme – inhibition** : Enzyme – Inhibitor interactions, drug action through enzyme inhibition. Varieties ofenzyme inhibition – inhibition at substrate binding domain, inhibition at allosteric binding domain, metals asinhibitors. Examples based on PDE4, GSK3, etc. Theories of enzyme inhibition and inactivation.Enzymeactivation of drugs prodrugs.Mechanism based Inhibition (MBI) of cytochromes.
8. **Nucleic Acids** (NA) as targets for drug action. Structure of NA, topology of NA. NA as receptors.NA-interactive agents. Classes of drugs that interact with nucleic acids.Intercalation, NA-alkylation,NA-strand breaking and their importance in drug action.Topoisomerase inhibition via NA binding. DNAcleavage.
9. **Drug likeness concept** :DruLiTo and drug likeness property evaluation.Organic chemistry of Drugmetabolism, drug deactivation and elimination.Organic chemistry of drug toxicity. Enumeration methods,chemical property methods, Lipinski's rules, Weber rules, Ghoshe rules, etc.
10. **Biotrasnformation** and associated drug action: Phase I and Phase II transformations. Concept of hard andsoft drugs. Role of cytochromes in oxidation of drugs. Consequences of drug oxidation reactions.Radical reactions vs. ionic reactions.

Recommended Books:

1. The Organic Chemistry of Drug Design and Drug Action by R.B. Silverman
2. Molecular Mechanism of Drug Action by C.J. Coulson , Taylor & Francis
3. A primer of Drug Action by R.M. Julien, Worth Publishers

4. Drug-Receptor Thermodynamics by R.B. Raffa,Wiley
5. Principles of Drug Action by W.B. Pratt, P. Taylor,Churchill Livingstone
6. Medicinal Chemistry How Drugs Act and Why by A. Gringauz

MC-511 Spectral Analysis (2 credits)

Ultraviolet (UV) and visible spectroscopy:

1. Energy levels and selection rules: Definitions, molecular orbital approach for energy absorption, various modes of transitions.
2. Correlation of structural variation with UV absorption: Factors influencing the position and intensity of absorptions, Inductive and resonance effects, the effect of the ring size, and the influence of stereochemical factors.
3. Predicting UV absorption: Woodward- Fieser, Fieser-Kuhn, and Nelson rules; non-conjugative effect, solvent effect, S-Cis band.

Infrared (IR)spectroscopy:

4. Characteristic regions of the spectrum: Various modes of vibrations, Energy levels
5. Correlation of structure with IR spectra: Influence of substituents, ring size, hydrogen bonding, vibrational coupling, and field effect on frequency.
6. Applications: Determination of stereochemistry. Spectral interpretation with examples.

Nuclear Magnetic Resonance (NMR)spectroscopy:

7. Fundamentals: Physical basis, magnetic nuclei, resonance, relaxation processes, signal-sensitivity. Instrumentation: Continuous-Wave (CW) instrument, Pulsed Fourier Transform (FT) instrument, Functions, Relation with sensitivity, Sampling.
8. 1H NMR, correlation of structure with spectra: Chemical environment and shielding chemical shift and origin of its concept, reference compound, local diamagnetic shielding and magnetic anisotropy, relation with chemical shift, chemical and magnetic non-equivalence, spin-spin splitting, and its origin, Pascal's triangle, coupling constant, mechanism of coupling, integral, NMR solvents and their residual peaks, protons on heteroatoms, quadrupole broadening and decoupling, the effect of conformations and stereochemistryonthespectrum, Karplusrelationship, diastereomeric protons, Heteronuclear coupling to 19F and 31P, virtual coupling, long-range coupling-epi, peri, bay effects. Shift reagents-mechanism of action, spin decoupling, and double resonance. Explanation of spectra of some compounds and drugs.
9. 13C NMR, correlation of structure with spectra: Chemical environment, shielding, and carbon-13 chemical shift, calculation, proton-coupled C13 1 S petra, Proton-decoupled C spectra, Nuclear Overhauser Enhancement (NOE), Problem with integration,Distortionless Enhancement by Polarization Transfer (DEFT), Heteronuclear couplingfor carbon to deuterium, carbon to 19 F, carbon to P. Explanation of spectra of somecompounds and drugs.

Mass spectrometry (MS):

10. Molecular ion and metastable peak, fragmentation patterns, nitrogen and ring rules, McLafferty rearrangement, electron and chemical ionization modes, applications

MC-520 : Logic in Organic Synthesis-I(2 Credits)

1. **Nucleophilic substitution reactions**: Uni- and bimolecular reactions; Nucleophiles and leaving groups; Substrates- steric and electronic effects; Solvent effects;Neighboring group participation; Substitution with rearrangement
2. **Electrophilic substitution reactions**: Aromatic electrophilic substitutions including Friedel-Crafts reactions
3. **Addition reactions**: Reactions of addition to C=C and C=O bonds
4. **Elimination reactions**: Dehydrohalogenation, dehydration; E1, E2 and Syn-elimination mechanism and reactions
5. **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
6. **Umpolung and umpoledsynthons**: Concept, acyl and glycine cation/anion, homoenolate anion, vicinyldicarbo-anion, carbonyl dication equivalence, etc.
7. **Phosphorous ylides and Wittig class of reactions**: Structure and reactivity, stabilized and non-stabilized ylides, Wittig reaction, Wittig-Horner and Horner-Wadsworth-Emmons olefination reactions, Mechanism of these reactions and E/Z selectivity
8. **Sulphur ylides**: Stabilized and non-stabilized ylides; thermodynamically and kinetically controlled reactions with carbonyl compounds, regio- and stereo-selective reactions
9. **Carbene and Nitrene:** Structure, Stability, Preparation, Reactions, Rearrangements, Synthesis of biologically important scaffolds
10. **Synthesis and Drug discovery research:** Synthesis of biologically important various scaffolds using ylide, carbene and other reactions,Synthesis of NP- and drug-skeletons, SAR-enabling synthesis, Drug discovery research.

Recommended Books:

As in previous courses of study, books 1-10.

MC-530 : Green Chemistry and Pharmaceutical R&D (1 Credit)

1. Twelve principles of Green Chemistry – How to practicethem in chemical science research? Not only what to synthesize but also how to synthesize?
2. Green Chemistry Metrics–Environmental impact factor (E-factor), Complete E-factor (cEF),Atom Economy (AE), Reaction Mass Intensity (RMI),Process Mass Intensity (PMI), Effective Mass Yield (EMY), Reaction Mass Efficiency (RME), Carbon Efficiency (CE), Relative Process Greenness (RPG), Global Material Economy (GME),innovationGreenAspiration Level (iGAL) - Features, advantages, and deficiencies.
3. Green Chemistry Perspective of Pharmaceutical industries – Frequently used reactions in R&D; More aspirational reactions; and Solvent theme.

4. Greener reagents – Reagents guides, Various reagents environmentally friendlyalternatives to hazardous and toxic chemicals, Use in various reactions.
5. Greener solvents–Solvent selection guides, ACS GCI Pharmaceutical Roundtable solvent selection tool,ICH guidelines,Select solvents based onmolecular and physicalproperties, EH&Scharacteristics,Water as solvent (On-water, In-water, Water-catalysis)
6. Catalysis–Catalysts in development of greener methods, catalytic reactions over stoichiometric reagent-based reactions.
7. Green chemistry triple win: Planet,People, and Profit; Green reaction methods and technologies.
8. Reduce-Reuse-Recycle philosophy-Concise synthesis, Catalyst reuse, Renewable biomass vs fossil-based feedstocks, basic chemicals from renewable biomass, resource efficiency and waste minimization by design, to replace traditional linear, take–make–use–dispose economies.
9. Green chemistry organic reactionsfrequently used in research.
10. Sustainable synthesis of pharmaceuticals, such as Taxol, beta-lactam antibiotics.

Recommended books:

1. Green Chemstry, Theory and Practice (Oxford Acadmic press) Authors: Paul T. Anastasa and John C. Warner

Green Chemistry and Catalysis (**John Wiley**) **Authors:** Prof. Dr. Roger Arthur Sheldon, Dr. Isabel W. C. E. Arends, Dr. Ulf Hanefeld

2. Handbook of Green Chemistry. Green Processes. Volume 7: Green Synthesis (John Wiley) Authors: Paul T. Anastas(series editor) and Chao-Jun Li (Volume editor)

Handbook of Green Chemistry, Volume 2: Heterogeneous Catalysis (John Wiley)

Authors: Paul T. Anastas (series editor) and Robert Crabtree (volume editor)

3. A Textbook of Green Chemistry (Publisher – Techno World) Authors: Sankar P. Dey, NayimSepay

Handbook of Green Chemistry and Technology (Blackwell) Authors: James H. Clark,

Duncan Macquarrie

11. Sustainable Catalysis: Challenges and Practices for the Pharmaceutical and Fine Chemical Industries (John Wiley) Authors: Peter J. Dunn, K. K. Hii, Michael J. Krische, Michael T. Williams

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

1.

3.

2.

Analytical techniques: (75 hours)

a) Spectral analysis workshop (45 hours)

b) Separation Techniques (30 hours)

Computer and application in pharmaceutical sciences (100 hours): Introduction tocomputers, 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.

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 credits)

1. **Separation techniques:** Need for learning 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, eluotropic 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. **Bio-chromatography:** 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
4. Practical HPLC Method Development, 2nd Edition, Lloyd R. Snyder, Joseph J. Kirkland, Joseph L. Glajch
5. Plant Drug Analysis A Thin Layer Chromatography Atlas By Wagner & Bladt

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, green techniques of extraction.
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-parasitic along with screening methods for isolation guidance.
9. Genetically engineered natural products, naturally occurring proteins, biotechnology-derived products.
10. Elucidation of some biosynthetic pathways and impact of molecular biology to control these pathways and by pass the metabolism of the living cell.

Recommended Books:

1. Trease and Evans Pharmacognosy byWilliam CharlesEvans;FifteenthEdition;W.B. SaundersPublisher; 2002.
2. Pharmacognosy & Phytochemistry of Medicinal Plants by Jean Bruneton; Second Edition; Lavoisier Publishing, NJUSA; 1999.
3. Organic ChemistryVol2: 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, 2ndEdition, John Wiley & Sons, Ltd., 2002.

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

1. Analytical techniques (75 hours):

Spectral analysis workshop (45 hours)

Separation Techniques (30 hours)

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.

Pharmacology (25 hours): Animal handling, route of administration of drugs, dose response relationship, acute toxicity, analgesicactivity of a compound, estimation of protein and haematological parameters.

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.

Specialization (50 hours): List of practical for Separation Techniques Course (NP-510)

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

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

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

d) Extraction and isolation of sterols from soya seeds.

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

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 Saptadhatus,
3. Principles
4. of treatment, Prakriti, Panchkarma and Ksharsutra.
5. Pathogenesis and ancient's pathological test: Movement of pulse and finding of
6. different dosha; importance of geriatrics, aphrodisiac and Ayurvedic ethics in present scenario.
7. Importance of Ayurvedic system and its practice in India.
8. Sidhdha and Unani medicine systems and their practice in India.
9. Introduction and importance of different traditional (alternative) systems of medicine such as herbal medicine, Homeopathic medicine, Chinese traditional medicine.
10. Introduction and importance of aroma therapy: African traditional medicine and various other alternative therapies e.g. acupuncture, acupressure.
11. Herbal medicine: Growth, market and need for development.
12. Nutraceuticals and dietary supplements.
13. Home remedies.
14. TKDL, ISM, AYUSH, CCRAS, CCRU, CCRS, CCRH Ayurvedic pharmacopoeia and Ayurvedic formulary.

Recommended Books:

1. Charak 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,
3. Desa, kala, Prakrthi and Ypaya and their utility and application in pharmacy.
4. Concept of Bhesaja examination: Pharmacology and pharmaceutical knowledge according to Ayurveda.
5. Concept of health- Svasthya definition.
6. Dosha, Dhatu, Mala Mulam Hi Shariram: Main components of body.
7. Definition of Dosha and their types, Vayu and Pitta: Importance, definition, type and functions.
8. 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.
9. Study of various pharmaceutical processes used in Ayurveda: This includes extraction of drugs and fermentation of vegetable drugs.
10. Guidelines for Good Manufacturing Practices (GMP) of Ayurvedic and herbal drug materials.
11. Good Laboratory practice (GLP) for Ayurvedic and herbal drug materials.
12. Shelf life of ayurvedic medicine as per notification of AYUSH 2016 and Sharangdhar Samhita
13. Traditional weights and measurement equivalent to metric system

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 Banglore
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;

TM 530 Pharmacognostical identification of crude drugs (2 Credits)

1. General introduction to the importance of Pharmacognosy in herbal drug industry. Factors involved in production of crude drugs. (i) Exogenous (ii) Endogenous factors (iii) Mineral supplements (iv) Nutrients and Pest control and study of pesticides with special importance to natural pesticides.
2. Preparation of herbarium specifications, use of flora and keys of plant identification, Microtomy and advanced histological techniques as applied to pharmacognostical specimen, pharmacognostical drawings and macro and micro photography.
3. DNA finger-printing for establishing authenticity of medicinal plants
4. Quantitative microscopy as applied to drug evaluation and pollen grain analysis, Determination of various diagnostic features of identification of different organs as per different herbal pharmacopoeias.
5. Pharmacognostical identification of crude drugs, some case studies:
    a. *Acorus calamus*
    b. *Aloe barbadensis*
    c. *Andrographis paniculata*
    b. *Azadirachta indica*
    c. *Bacopa monieri*
    d. *Curcuma longa*
    e. *Glycyrrhiza glabra*
    f. *Gymnema sylvestre*
    a. *Justicia adhatoda*
    g. *Mucuna pruriens*
    h. *Phyllanthus amarus*
    i. *Piper nigrum/ longum*
    j. *Psoralea corylifolia*
    k. *Tinospora cordifolia*
    l. *Tribulus terrestris*
    m. *Withania somnifera*
    n. *Zingiber officinalis*
    o. *Coleus forskolii*
    p. *Trigonella foenum-graceum*
    q. *Ocimum sanctum*

6. Skin irritants and sensitizing agents from plant and marine products of medicinal importance.

Suggested Reading:

1. Ayurvedic Pharmacopoeia of India.
2. ICMR Reviews on Indian Medicinal plants.
3. Quality standards of Indian medicinal plants.
4. Cultivation of Medicinal Plants by CK Atal and BM Kapoor.

5. Ayurvedic formulary of India, Govt. of India.
6. Homeopathic Pharmacopoeia.
7. Unani Medical Systems.
8. Indian Medicinal Plants by Kirthikar, Basu.
9. Indian Materia Medica by K.M. Nadkarni.
10. Plant propagation – principle & practices by Hertamann Kester.
11. Pharmacopoeial Standards for Ayurvedic formulations – CCRAS, Delhi.
12. The use of Pharmacological techniques for the evaluation of natural products by BN Chavan and RC Srimal (CDRI).
13. Pharmacognosy : Trease W. C.,Evans G. E. Bailliere & Tindall, London, 14th edition
14. The Wealth of India (Raw M aterials) All Volumes , NISC O M , Delhi.
15. Anonymous (1993) Standardisation of Single Unani Drugs, C C RU M, New Delhi.

TM 540 Industrial perspective of Herbal Drug Products (2 Credits)

1. Herbal Cosmetics Raw materials of herbal origin used in cosmetics, oils, waxes, gums, hydrophilic colloids, perfumes, protective agents, bleaching agents, preservatives, anti-oxidants. Formulation aspects of incorporating herbal extracts in various preparations like skin care creams, deodorants, hair care preparations.
2. Ancient references of formulation regarding cosmetic (angrag), different cosmetic oil, bleaching form and utility in present era.
3. Quality control of finished herbal medicinal products.
4. TRIPS, TQM, ISO-9000, EXIMPatents; Process for Indian patent filing for grant of patent, Patent regime of herbal drugs/ Drug products/ Natural products, Geographical tag, copyright, Patentable subject, prior art search, ever-greening, Patent laws.
5. Nutraceutical and functional foods
6. Licensing regime for various herbal products

Suggested Reading:

1. Ayurvedic Formulary of India, Govt. of India
2. Pharmacognosy: Trease W. C.,Evans G. E. Bailliere & Tindall, London, 14th edition
3. Indian Herbal Pharmacopoeia, Vol. 1 & 2, RRL, IDMA, 1998, 2000.
4. Quality Control of Herbal Drugs by Pulok K. Mukherjee, 1st edition, Business Horizons Pharmaceutical Publishers, New Delhi 2002.
5. Wealth of India, CSIR, New Delhi (Related Volumes).
6. British Herbal Pharmacopoeia, (Vol., 1,2,3) Her Majesty's Services, UK. 10. Various Research Journals on Medicinal Natural products.
7. Pharmaceutical product development 2006, edited by N.K. Jain, CBS publishers and distributors.
8. Good manufacturing practices for pharmaceuticals: A plan for total quality control from manufacturer to customer, 5th edition, revised and expanded by Sidney H. Willig, Marcel and Dekker.
9. CDSO publications and updates of drug and Cosmetics act and rules (Govt. of India). Orange Book, ICH guidelines, Indian Patents Act
10. Kanfer & L. Shargel, "Generic Product Development BE issued" Informa Healthcare.
11. R. A. Guarino, "New Drug Approval Process. The Global challenges". Informa Healthcare.

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

1. Analyticaltechniques:SeparationTechniques (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 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 haematologicalparameters.
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 26 epidermis, trichomes, stomata and arrangements of tissue like palisade cells,vascular bundlesand nature of cell contents.
c) Studyof the bark,root,rhizome andwood byT.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 shallbe used.

II. Qualitative testing of aflotoxin (WHOmethod)(15hours)

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.
    g) 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 ICH Q6 guidelines and understanding of specifications through study of pharmacopoeial monographs on drug substances and products.
3. **Reference standards**: Types (primary, secondary, working and test standards), preparation, containers, labeling, storage and use.
4. **Documentation-STPs, certificate of analysis, laboratory books**: Typical documents used in a GLP.
5. **laboratory including standard test protocols, COA and laboratory notebooks**. Electronic records & signatures (21CFR Part-11 requirement).
6. **Introduction to method development**: Method development concepts, steps involved, intricacies at each step.
7. **Method validation**: Definition and methodology, discussion on each parameter with examples, special considerations in bioanalytical method validation.
8. **Calibration and qualification of equipment**: Difference of definitions, calibration standards, calibration frequency, examples of calibration of pH meter, FTIR, UV spectrophotometer and HPLC. Definition of qualification process involving URS [user requirement specification], DQ, IQ, OQ, CQ and PQ.
9. **Quality risk management in analytical laboratory**: Definition of quality risk management in ICH Q9 guideline. Its importance and application to analytical laboratory with examples.Analytical quality by design.
10. **Impurity profiling**: Types of impurities in drug substances and products. Method development for impurity analysis, techniques, identification and quantitation.
11. **Automation and computer-aided analysis, LIMS**: The concept of autosamplers and high-throughput analysis, computer-controlled instrumentation, and networked laboratory. Peculiarities of laboratory information management systems (LIMS).
12. **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.
13. **Laboratory inspections and audit**: Internal inspection, external audit, concepts, preparing for inspections and audits.

Recommended books(latest available edition):

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. Nineman
6. Handbook of Modern Pharmaceutical Analysis by SatinderAhuja, 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 com- puters, basic unit and functions, H/W and nt, 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 re- sponse 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
   I) Determination of pKa of given sample by spectrophotometric method.

PHARMACOLOGY & TOXICOLOGY

Subject Code	Title	Credits
PC-511	**Pathophysiology**	**1**
	1. Factors influencing the disease conditions such as sex, age, nutritional status, genetic makeup etc. 2. Pathogenesis, symptoms and signs, laboratory findings and complications of a. Central Nervous System: Depression, Schizophrenia, Epilepsy, Parkinson Diseases and Alzheimer disease. b. Cardiovascular System:hypertension, cardiac arrhythmias, MI, CAD, CHF c. Respiratory System: COPD, Bronchial Asthma, d. GIT system: Ulcer, Ulcerative colitis, IBD, hepatitis and cholecystitis. e. Haemostasis and haemopoietic system Anaemia. f. Endocrine System and Thyroid: diabetes mellitus and other endocrine diseases, Pancreatitis, Hypo and hyperthyroidism, UTI h. Rheumatoid arthritis, Gout	
PC-520	**General Pharmacology**	**2**
	1. Concept of receptors as a drug target. 2. GPCR- Classification, structure, drug receptor interaction, G-protein, receptor characterization, receptor theories, agonist, antagonist. 3. Receptor regulation: GPCR desensitization, down regulation, up regulation 4. Regulators of G-protein signalling 5. Ion channels and Ion channel linked receptors and their regulation 6. Nuclear receptors 7. Transmembrane signaling mechanisms 8. Second messenger system 9. Transcription factors 10. Dose response relationship and different types of antagonism 11. Efficacy and Toxicity evaluation using different experimental models, dose-response analysis, margin of safety in pre-clinical development	

	12. Chronopharmacology and Chronotherapeutics	
PC-530	**Experimental Pharmacology**	**1**
	1. Introduction to pharmacological research 2. Common laboratory animals and their physiological parameters, factors affecting the nature and degree of pharmacological responses; Handling and care of different animals; Bleeding and different routes of administration, anaesthetics used in animal research and chemical euthanasia. 3. Animal 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. precautions to be taken in behavioural experiments. 4. Imaging techniques in pharmacological research 5. Drug solution preparations: Storage, concentration expression, common solvents, stabilizing agents, storage conditions, reference standards, False positive and false negative response. 6. *In vitro* experimentation: Advantages and disadvantages, applications of cell culture for drug screening. Aseptic handling, cell counting and cell viability assays. Tissue isolation, tissue fixation, common fixatives, preparation of single cell suspension. 8. Protein and DNA gel electrophoresis: Western, northern, southern blot hybridization and PCR techniques, Flowcytometry 9. Protein purification and identification by two-dimensional gel electrophoresis 10. Artificial Intelligence in drug discovery and development 11. Research ethics and publication ethics	
PC-540	**Chemotherapy of Parasitic and Microbial Infections**	**1**
	1. Introduction to microbial and parasitic disease. 2. General considerations of antimicrobial agents. 3. Infectious diseases in different context; community- acquired infections, emerging infectious diseases, infectious diseases associated with travel 4. Biology, Treatments, Resistance and New drug targets for following diseases a. Bacterial: TB, Pneumonia, UTI b. Viral: HIV, SARS like infections c. Fungal: Candidiasis, Cryptococcosis. Aspergillosis d. Parasitic: Malaria, Amoebiasis, Leishmaniasis	

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 languageand 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):** a. Animal experimentation: 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

   b. Calculations of ED50, pA2, Dose extrapolation, raw data collection, computation, statistics and report preparation.

   c. Blood cell counter.

   c. Histopathological techniques: Gross necropsy, target organs isolation, fixative, preservations, sectioning and staining, Blood Collections from mice and rats and anticoagulants, microscopic techniques

   d. Genotoxic effect of unknown drugs, Effect of cyclophosphamide on neutrophil counts

   e. Behaviour experimentation-demonstration

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.Uses,harmful and beneficial effects
7. Absorption and distribution of toxicants.
8. Human health risk assessment, Environmental and Industrial Impacts
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. **Preclinical to Clinical Interpretation: Dose-calculation and conversion.** 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 languageand 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, glucose andhaematological 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.

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Pharmaceutics

PE-510 Pharmaceutical Preformulation - I

(1 credit)

1. **Preformulationstudies:**Preformulation studies of drug substances, proteins and peptides. Fundamental and derived properties in preformulation profiling. Preformulation work-sheet. Material-sparing approach for preformulation.
2. **Role of pre-formulation in drug discovery:** material properties in lead selection, 'drugability' of new chemical entities, *in silico* and high throughput pre-formulation studies.
3. **Role of preformulation in drug development:** Preformulation as a support for formulation development, identification of 'developmental challenges' during pharmaceutical development, dosage form specific studies.
4. **Salt selection:** Role of salt selection in drug discovery and development, theoretical concepts for selection of counter ions for salt formation, 'pKa rule' for salt formation, decision tree for salt selection, appropriate case studies.
5. **Solubilization:** Solubility and solubilization of non-electrolyte, drug solubilization in surfactant systems, use of co-solvents for development of liquid formulations, solid-state manipulations including use of metastable solid forms like amorphous state.

PE-520 Biopharmaceuticsand 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 Km and Vm. Case studies.
9. **Physiologic pharmacokinetics models: Prediction of the absorption, distribution, metabolism and excretion (ADME) of synthetic and natural chemical substances in humans and other animals. Bottom up and top down approach to define parameter sensitivity analysis (PSA) for drug/formulation development,** 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, byRowland, M. and T. N. Tozer

PE-530 Pharmaceutical Preformulation – I (1 credit)

1. **Complexation:** Metal and organic molecular complexes, inclusion compounds with reference to cyclodextrins, chemical characteristics of inclusion complexes, methods of preparation of cyclodextrin complexes, applications in solubilization / taste masking / enhancement of permeability / enhancement of oral bioavailability, .
2. **Rheology**: Methods for evaluation of viscosity, concept of Viscoelastic, Newtonian/ non-Newtonian flow properties, thixotropy and their applications in development of dosage form, implications of viscosity on performance of liquid dosage forms like suspensions and emulsions, advanced techniques / equipment employed in the rheological characterization of pharmaceutical products.
3. **Micromeritics:** Particle size distribution, evaluation methods including advanced techniques like atomic force microscopy, significance of particle size in different dosage forms including aerosols, parenterals and solid dosage forms.
4. **Dissolution:** Theories of dissolution, Instrinsic dissolution rate, release rates and constants, selection of dissolution media, bio-relevant media, Mechanisms of conventional release and controlled releaseDissolution equipments, Official and non-official apparatus, Hyphenated tests for dissolution and intestinal permeability, Calibration of dissolution apparatus, Dissolution data handling and correction factors, IVIVC, IVRT and IVPT, In vitro bioequivalence

PT-580 / PE-540

Regulatory considerations for Pharmaceutical Development (1 credit)

1. International regulatory trends in pharmaceutical industry; Introduction to Indian regulatory system, definition of new drug.
2. Role of regulatory affairs department in pharmaceutical organization : regulatory audits, interactions with various other departments, single point contact with regulatory agencies.
3. Types of regulatory filings for pharmaceutical products : goals of regulatory registration procedures investigational new drug applications, introduction to various type of regulatory filings.
4. New drug applications : stages involved in NDA, different phrases of clinical trials, purpose of IND, types and categories of IND applications information to be given in IND applications.
5. Chemistry, manufacturing and control (CMC)information in NDA : information related to drug substance like manufacturing process, specifications, description of tests methods. Information related to drug product: description of method of manufacturing, specifications and acceptable limits. Information related to placebo.
6. Hybrid NDA : a difference from NDA, historical background, literature based hybrid NDAs and other sources of information for hybrid NDA, examples of types of products considered under hybrid NDA.
7. Abbreviated New Drug applications (ANDAs) : historical developments leading to creation of ANDA process, Hatch Waxman Act, patent term restoration, criteria for patent term extension, various types of Hatch Waxman Exclusivities, concept of therapeutic equivalence, ANDA review process. Concept of Q1, Q2 and Q3 sameness.
8. Paragraph IV certification ANDAs : different ANDA Patent certification options, Medicare Modernization Act, implications of this act on 30 month stay period and 180 day exclusivity, triggering and forfeiture of 180 day exclusivity, shared exclusivity
9. ANDA with suitability petition: case studies of drug products considered appropriate for filing under suitability petition.
10. Overview of regulatory pathway for Biopharmaceutical products

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.

f) Experiments dealing with preformulation profiling

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

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 /NADP , FAD, lipoic acid, tetrahydrofolate, B_{12}-coenzyme), role of cofactors with specific examples.
5. **Biochemical energetics Part I:** free energy, concept of standard free energy, laws of thermodynamics, exergonic and endergonic reactions.
6. **Biochemical energetics Part II**: energy rich compounds, coupling of reaction, biological oxidation-reduction
7. **Carbohydrate metabolism:** Glycolysis, gluconeogenesis, pentose phosphate pathways (PPP), glycolysis, TCA cycle, glyoxylic acid cycle, regulation of carbohydrate metabolism, electron transport chain and oxidative phosphorylation, disorders of carbohydrate metabolisms.
8. **Lipid metabolism:** Hydrolysis, absorption and transport of lipids, catabolism of lipids, α-, β- and ω- oxidation of fatty acids, ketone bodies formation, biosynthesis of fatty acids, disorders of lipid metabolisms.
9. **Protein metabolism:** Hydrolysis of proteins, pathways of amino acid degradation, urea cycle and formation of uric acid, assimilation of ammonia, biosynthesis of amino acids, inborn error of protein metabolism
10. **Nucleic Acid Metabolism:** Purine and pyrimidine biosynthesis, salvage pathway, degradation of nucleotides, role of ribonucleotide reductase, pharmaceutical importance, disorders of purine and pyrimidine metabolisms.

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 digesion.
   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 autoclaveing and filtration.
Day-2 : Media preparation and cell counting.
Day-3 : Sub cellular fractionation by homoginization, 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 : Lineaweaver-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 chracterization.
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.

Biopharmaceuticals

BM-510

Introduction to Biopharmaceuticals (1 credit)

1. **Introduction**: Drug discovery & development process, current trends in drug development, role of biotechnology, concepts and relevance of biopharmaceuticals, Biopharmaceuticals versus chemopharmaceuticals

2. **Overview of biopharmaceuticals**: Definitions, type of biopharmaceuticals, Biosimilars, Bio-betters, new molecular entity.

3. **Biopharmaceutical applications**: Disease types and therapy, prevention, and diagnosis, trends and perspectives of Biopharmaceutical approvals

4.**Areas in Biopharmaceuticals**: Vaccines, Antibodies, hormones, enzymes, growth factors, Peptide therapeutics, Antisense drugs, Cell and Gene therapy

5. **Biopharmaceutical manufacturing**: Upstream processing, downstream processing, Formulation, impurity characterization

6. **Biopharmaceutical issues**: Poor pharmacokinetics, immunogenicity, approaches for their improvement

7. **Miscellaneous aspects**: Intellectual property,Regulatory perspective, ICH guidelines, Bio-economy

Recommended books:

1. Biopharmaceutical Manufacturing, Volume 1 – IOP science
2. Biopharmaceuticals: Biochemistry and Biotechnology by Gary Walsh, Publisher: Wiley-Blackwell, ISBN-10: 0470843276
3. Review Articles (will be provided by Coordinator)

BM-520
Tools of Upstream Processing (1 credit)

1. **Introduction**: Introduction to upstream process, a pre-fermentation stage of bioprocessing, selection of microbial strains characterized by the ability to synthesize a specific product having desired commercial value

2. **Generation of improved microbial strains**: Improvement of microbial strains by recombination, mutation, cell fusion and gene cloning to maximize the ability of the strain to synthesize desired amounts of the product

3. **Media formulation**: Inoculum media and production media

4. **Microbial growth**: Conditions for growth, phases of microbial growth, age of inoculums, cell mass doubling time, kinetics of microbial growth; Monod's kinetics, metabolic quotient, substrate utilization and product formation; Equations for substrate utilization and product formation.

5. **Reactor design**: Bioreactor design; criteria for bioreactors, Stirred tank; Airlift reactor; Packed bed; surface tissue propagator, Ideal reactor operation; Batch operation of a mixed reactor; membrane bioreactors, continuousandfed-batch bioreactors.

6. **Agitation**: Need of agitation in aerobic fermentation;Effect of agitation;Howagitation helps aeration; Different types of agitational methods; impeller design and relationship with the characteristics of thefluid; flowbehaviour, etc.

7. **Aeration**: Need of aeration in aerobic fermentation; effect of aeration; how aeration helps agitation; different types of aeration methods

8. **Sterilization**: Different methods of sterilization; Kinetics of sterilization; batch and continuous sterilization; advantages and disadvantages

9. **Mass and heat transfer**: Mass and energy balance in microbial processes; Resistance encountered in

fermentationmedium by the oxygen molecule; Role of Dissolved oxygen concentration in the mass transfer; mechanisms of heat transfer; heat transfer between fluids, Calculation of heat transfer coefficients; Heat transfer equipment; Steady state conduction

10. **Scale-up**: Principles and criteria; Different methods of scale up and the detailed analysis with case studies; Instrumentation and controlof bioprocesses

Recommended books:

1. BioprocessEngineering:BasicConcepts by Michael L.Shuler,FikretKarg

2. BioprocessEngineeringPrinciples byPauline M. Doran

3. BiochemicalEngineeringFundamentals by JamesEdwinBailey,David F.Ollis

4. Principles of FermentationTechnologybyPeter F.Stanbury,AllanWhitaker,Stephen J. Hall

5. BiochemicalEngineeringFundamentals by JamesEdwinBailey,David F.Ollis

BM-530	
Formulation Strategies and Pharmacokinetics/ Pharmacodynamics of Biologics	(1 credit)

1.Course introduction & expectations; Bio Process, Bioanalytics & Bioassays

2. Introduction to Formulation Development of Biologics; Biotherapeutics Drug Product

3. Manufacturing and Process Development & Facility Considerations

4. Excipients for Formulation and associated challenges; High concentration protein Formulation

5. Freeze–Thaw Process, Storage and Shipping Considerations, Container Closure, Extractable & Leachable; Lyophilisation: Process Design, Robustness, and Risk Management

6. Novel Drug Delivery System

7. Formulation Case Studies

8. Pharmacokinetics - Routes of administration, Absorption, Distribution, Biotransformation & Elimination

9. Pharmacodynamics - Principles of drug action, Mechanism of drug action, Receptors, Dose-response relationship, Drug efficacy & potency, Therapeutic index, LD 50 & ED 50, Synergism and antagonism, Factors modifying drug action

10. Pharmacokinetic and pharmacodynamics considerations in the development of biotechnology products

11. PK-PD Case studies

12. Clinical Pharmacology, Dosage forms and calculations, Pharmacoeconomics

13. Adverse drug reactions, Pharmacovigilance, Biostatistics, Pharmacogenomics and Personalized Medicine

Recommended reading:

1.Rational Design of Stable Protein Formulations: Theory and Practice by John F. Carpenter and Mark C. Manning

2. Therapeutic Peptides and Proteins: Formulation, Processing, and Delivery Systems by Ajay K. Banga

3. ADME and Translational Pharmacokinetics / Pharmacodynamics of Therapeutic Proteins: Applications in Drug Discovery and Development by Honghui Zhou and Frank-Peter Theil

BM-540

Vaccines and Immunotherapeutics (2 credits)

1.Immune System and its Components: General view on immune system, Innate Immune System, Adaptive Immune System, Cellular and humoral immunology, Cytokines-Chemokines and Immune responses (tolerance, hypersensitivity)

2.Immune-related Diseases and Disorders: Autoimmunity, cancer, viral and microorganism-related diseases and Mendelian disorders

3.Immuno-biotherapeutics: Comprehensive overview of the principles and technology upon which the basis of immune-biotherapeutics are based, peptides, small molecules, antibodies (polyclonal, monoclonal), genes and cells as immunotherapeutic agents

4.Immunomodulation and Immunotherapy: Immunomodulation (Immunostimulation and Immunosuppression), Basic concepts of immunotherapy, Active vs Passive Immunotherapy, Different forms of Immunotherapy and their mechanism of action (Antibody mediated therapy, Cytokine based therapy, Cell based therapy

5. Introduction to Vaccine: (History, scientific basis of vaccination, Prophylactic vs Therapeutic Vaccine, Different vaccines for various diseases, Concept on polyclonal and monoclonal antibody, Anti-idiotype antibodies)

6. Vaccine development/formulation, doses, schedule and delivery system

7. Antibody and Cell-based Memory Response after Vaccinations

8. Safety and Efficacy of Vaccine and Immunotherapeutic Agents

9. Ethics and Integrity in Vaccinology and Immunotherapy Research

10. Scaling and Commercialization of Immunotherapeutics

Recommended books:

1. Kuby Immunology (8th Edition) by Jenni Punt; Sharon A. Stranford; Patricia P. Jones; Judith A. Owen. Macmillan Learning, 2018
2. Roitts Essential Immunology (11th Edition) by Peter J. Delves; Seamus J. Martin; Dennis R. Burton; Ivan M. Roitt, Wiley-Blackwell Scientific Publication, Oxford. 2006
3. Vaccines for Cancer Immunotherapy: An Evidence Based Review on Current Status and Future Perspectives by Nima Rezaei, Mahsa Keshvarz-Fathi, Academic Press

4. Clinical Immunology 2nd Edition, Edited by Angela Hall; Chris Scott; Matthew Buckland, Oxford University Press, Oxford
5. Principles of Biomedical Ethics, 8th Edition by Tom L. Beauchamp; James F. Childress, Oxford University Press, Oxford
6. Relevantreview&researchpapers

BM-550

Fundamentals of Cell Biology and Microbiology (2 credits)

1.**Cells as a unit of life**: Unity and diversity of cells, prokaryotic and eukaryotic cells, evolution of cells, applications of cell biology, model organisms.

2.**Tools and Techniques of Cell Biology**: Histology, staining, Light Microscopy fluorescence, confocal microscopy, TEM and SEM. Fluorescent dyes and GFP tagged proteins in visualization, FACS, cell fractionation, cell culture.

3.**Bacterial and Eukaryotic Cell Structure and Organization**: Bio-membranes, structure, Gram positive and Gram negative bacteria, cilia, flagella, pili, functions of eukaryotic cell organelles i.e. nucleus, ribosomes, ER, Golgi, lysosomes, peroxisomes, cytoskeleton.

4.**Organization of tissues**: Cell-Cell and cell-matrix interactions, cell adhesion molecules, components of the extracellular matrix, cellular junctions. Microbial communities and biofilms.

5.**Cellular Movement & Molecular Motors**: Types of movement, extravasation, role of cytoskeletal proteins in movement. Molecular motors, movement of vesicles, cilia and flagella.

6.**Gene regulation in prokaryotes**: Principles of gene regulation in *E. coli*, Regulation of transcription (operon concept), Translational control, Feedback inhibition, Modes of attenuation.

7.**Viruses**: Introduction, Structure, Classification, Life cycle (Lambda genome as an example), Purification, Quantification.

8.**Microbiological tests and assays, Assays for antibiotics and bacterial endotoxins**.

9.**Yeast**: Model organism, Genetic tool, Types of yeast vectors, Types of selection markers.

10.**Yeast as a protein expression platform**.

Recommended books:

1.Karp's Cell and Molecular Biology (9thEdition)
2. Essential Cell Biology (5thEdition), Bruce Alberts
3. Molecular Cell Biology (9thEdition) by Harvey Lodish, Arnold Berk, Chris A. Kaiser, Monty Krieger, Anthony Bretscher
4. Lewin's Genes (12th edition)
5. Microbiology (11th edition) by Lansing Prescott, John Harley and Donald Klein

BM-560

Analytical Tools for Biopharmaceuticals (2 credits)

1. Isolation and purification of proteins and nucleic acids. Convergence of structure and function.

2. Challenges in characterization of biopharmaceuticals: Post-translational modifications, Microheterogeneity, Size. Quality assurance and quality control.

3. Electrophoretic techniques: Native and denaturing gels (polyacrylamide and agarose), one- and two-dimensional, capillary electrophoresis

4. Chromatographic techniques: Based on size, charge, polarity.

5. Spectrophotometric techniques: Ultra-violet-visible, fluorescence (different formats), circular dichroism, infra-red.

6. Spectroscopic techniques: Nuclear magnetic resonance, X-ray diffraction

7. Binding and stoichiometry studies: Surface plasmon resonance (SPR), isothermal titration calorimetry (ITC), Analytical ultracentrifugation (AUC)

8. Peptide sequencing. Using proteomics for drug discovery.

9. Mass spectrometry: Introduction,instrumentation, high- and low-resolution molecular ions, their recognition,fragmentations and rearrangements. Hyphenated techniques.

10. Tools based on light scattering.

11. Techniques for studying protein-drug interaction and characterization of conjugated proteins.

Recommended books

1.Protein Biotechnology: Isolation, Characterization, and Stabilization by Felix Franks
2. Proteins by Thomas E. Creighton
3. Current Protocols in Protein Science, Wiley (different collections)

BM-570

Regulatory Affairs and IPR Aspects (1 credit)

1.**Introduction to Regulatory Affairs**: Overview of drug development process; Regulatory requirements for biopharmaceutical products; Role of regulatory agencies in the approval process; Clinical trials: phases and regulations in US, India, and Europe; Investigational New Drug (IND) application: filing procedures and requirements; New Drug Application (NDA) and Abbreviated New Drug Application (ANDA): filing procedures and requirements.

2.**Global Regulatory Harmonization**: The impact of global regulatory harmonization on the biopharmaceutical industry; Differences in regulatory requirements across regions; Interaction between Indian and foreign laws during implementation. Global initiatives intended to drive harmonization and development, such as Asian-Pacific Economic Cooperation (APEC), International Council for Harmonization (ICH), The International Pharmaceutical Regulators Programme (IPRP), Pan American Network for Drug Regulatory Harmonization (PANDRH)

3.**Intellectual Property Rights (IPRs)**: Concepts and fundamentals; Economic importance, mechanisms for protection of intellectual property patents, copyrights, trademark; Factors affecting choice of IP protection; Role of IP in pharmaceutical industry; Global ramifications and financial implications.

4.**Trade-Related Aspects of Intellectual Property Rights**: Intellectual property and international trade; Concept behind WTO (World Trade Organisation), WIPO (World Intellectual Property Organisation), TRIPs (Trade Related Intellectual Property Rights); Protection of plant and animal genetic resources; Biological materials; Gene patenting; Biotechnology; IPR issues; Status in India and other developing countries.

5.**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.

6.**Ethical and Legal Issues**: Ethical considerations in drug regulatory affairs and intellectual property rights; Legal issues related to regulatory affairs and intellectual property rights.

7.**Future Trends**: Emerging trends in drug regulatory affairs and intellectual property rights.

Recommended books:

1.New Drug Approval Process, edited by Richard A. Guarino
2.The Pharmaceutical Regulatory Process, edited by Ira R. Berry
3. Law Relating to Intellectual Property by B.L. Wadhera
4.The Patents Act, 1970 (Bare Act with Short Notes) (New Delhi: Universal Law Publishing Company Pvt. Ltd. 2012)
5.Patent Agent Examination by Sheetal Chopra and Akash Taneja
6. Biomedical Research- From Ideation to Publication by G. Jagadeesh and others

LG-510 (BIOTECHNOLOGY)

GeneralLaboratoryExperience15hours/week(3credits)

1. **Analyticaltechniques(75hours):**
   a) Spectralanalysisworkshop(45hours):
   b) Separationtechniques(30hours):
2. **Computerandapplicationinpharmaceuticalsciences(100hours):**Introductiontocomputers,basicunitandfunctions,H/WandS/W,operatingsystems,wordprocessing,spreadsheet,graphicprograms,dbase,windows,statisticalS/WprogramsandpackagesStepsinvolvedinS/Wdevelopment,computerlanguageswithemphasistoFORTRANlanguageandprogramming,handsonexperienceinpharmaceuticalsoftwaresystems.Useofcomputersininformationretrievalsystems.
3. **Biotechnologyforpharmaceuticalsciences(20hours)**
   *Day1:*Preparationforplasmidminiprep.

   *Day2:*Plasmidminiprepandrestrictiondigestion.

   *Day3:*Gelelectrophoresis.andmolecularweightcalculation.

   *Day4:*Discussionofresultandviva.
4. **Biotechnology Specialization(75hours)**

(i) Transformation of cells: Preparation of competent cells; Transformation by heat shock method; Estimation of transformation efficiency; Plasmid purification and analysis by electrophoresis.

(ii) Molecular cloning: Gene amplification by PCR, Quantification of DNA, Ligation, Blue-white screening.

(iii) Monitoring growth kinetics of *E. coli*; Effect of pH, aeration, nutrient source; Determination of wet cell mass.

(iv) Protein expression: Optimization of expression conditions; Expression of protein in soluble fraction and in inclusion bodies.

Pharmacoinformatics

PI-510 IntroductiontoPharmacoinformatics (1credit)

1. Introductionofbioinformatics:Differentsubdomainsofbioinformatics,Applications;Aminoacidandnucleicacidstructure;Properties.
2. Proteinfolding:Concept,Theoreticalandexperimentaltechniquestoidentifythemolecularstructure;Principlesofproteinstructure;Structuralbioinformaticsindrugdiscovery,Metricsystem.
3. Structuralgenomics:Approaches,Structuralgenomicseffort,Proteinstructuralinitiative,structuralgenomicsconsortium,Impactofstructuralgenomics.
4. Introductiontochemoinformatics:Chemoinformaticsanddrugdiscovery,Simulationmethodsandtheirimportance,Representationofmolecules,Visualizationandgenerationof2Dand3Dmolecularstructures;Molecularmodeling,Data analysis,Chemicalinformation.
5. Databasesanditsimportance:2Dand3Ddatabases,Structuralandchemicaldatabases,Implications.
6. Energyofmolecules:Bioactiveconformationofthemolecules,Crystallography,energyminimizedandbioactiveconformation,Conformationalsearchapproaches,Forcefield,Potentialenergysurface,Differentconformations,examples.
7. Ligandbaseddrugdesign:Overview,Similaritymethods,Superimpositionmethods,Pharmacophore,QSARmethods.
8. Structurebasedmethods:Overview,Introductiontomoleculardockingmethods,scoringfunction,synergybetweenligandandstructure-basedmethods.
9. ADME/Tpredictivemethods:Overviewofmethods,insilicoapproachestoADME/Tmodels,pharmaceuticalissues;softwaretoolsinADME/Tprediction,limitationsofinsilicoapproaches.
10. Applications:Applicationofbioinformatics,chemoinformatics,ADME/Tindrugdiscoveryanddevelopment.

Recommendedbooks:

1. MolecularModeling:BasicPrinciplesandApplicationsbyHoltje,Hans-Dieter,Wiley-VCH
2. MolecularModellingforBeginnersbyHinchliffe,AlanJohn,Wiley-VCH
3. Computer-AidedDrugDesignbyPerun,ThomasJ.,B.I.Waverly,Taylor&Francis
4. AnIntroductiontoChemoinformaticsbyLeach,AndrewR,KluwerAcademicPublisher
5. ModernMethodsofDrugDiscoverybyHillisch,Alexander,SpringerBaselAG
6. DrugDiscoveryStrategiesandMethodsbyMakriyannis,Alexandros,Wiley-VCH
7. EvaluationofDrugCandidatesforPreclinicalDevelopment:Pharmacokinetics,Metabolism,Pharmaceutics,andToxicologybyHan,Chao,JohnWiley&Sons

PI-520 Pharmacoinformatics–C++Programming (2credits)

1. ProblemSolving,Introductiontoprogramminglanguages,C++developmentenvironment,programstructureandmainfunction,headerfiles
2. Inputandoutputstatements,comments,datatypes,variabledeclarations,dynamicinitializationsofvariables,scopeofvariables,constants,operatorsandscopeofoperators,statements,blockofcodes
3. Iteration:whileloops,do-whileloops,forloops,nestingofloops
4. Selection:Switchstatement,if-then-elsestatement,terminatingaprogram
5. Functions:Definition,declaration,prototypes,returntype,arguments,inlinefunctions,recursivefunctions,overloadedfunctions
6. Arrays:Dimension,initialization,arraysasargumentstofunctions,strings:arraysofcharacters,stringmanipulation
7. Files:Filestreamobjects,openandclosefiles,inputandoutputfilestreams,stream'sstates,filememberfunctions
8. Pointers:Definingpointervariables,pointersandarrays,pointersasargumentstofunctions,arithmeticandlogicaloperationsonpointers
9. Class:Objects,object-orienteddesign,dataabstraction,classaccessspecifiers,members,inline;staticandfriendfunctions,constructoranddestructor,overloadingconstructor,inheritanceanditstypes,orderofinvocation,virtualinheritance,polymorphism,virtualfunctions,operatoroverloading,andexceptionhandling
10. Datastructures:Arrays,Stacks,Queues,List:LinkList;Two-waylists;Circularlinklist;Insert;Delete;SearchingandSortingofdatainList;Linkedstackandqueues;Graphs:Depthfirstsearch;Breadthfirstsearch,Trees:BinaryTrees;HeightbalanceTree.

Recommendedbooks:

1. ObjectOrientedProgrammingwithC++byBalaguruswamy,McGraw-HillEducation
2. ThinkinginC++byBruceEckel,PrenticeHall
3. TheC++ProgrammingLanguagebyBjarneStroutstrup,Addison-Wesley
4. TheCompleteReferencetoC++byHerbertSchildt,McGraw-HillEducation
5. DataStructureUsingCandC++byA.Tanenbaum,Y.Langsam,M.J.Augenstein,PrenticeHall
6. TheoryandproblemsofDataStructuresbySeymourLipschutz,McGraw-HillEducation
7. DataStructures&ProgramDesign,RobertL.Kruse,PrenticeHall

PI-550 Pharmacogenomics and Metabolomics (2 credits)

1. Multi-omics: Basic introduction to genomics, structural and functional genomics, transcriptomics, proteomics, metabolomics, metagenomics, pharmacogenomics, immunomes and their role in drug discovery,
2. Human Genome Project: History, milestones, background and organization of HGP, how the human genome was mapped, strategies in identifying human disease genes. Genome mapping and Assembly programs (Phred, Phrap, EULER, etc), Genome analysis tools (Mummer, Geneplot, Artemis, BLASt2, MegaBlast)
3. DNA sequencing methods: Manual & automated: Maxam and Gilbert and Sanger method. Chain termination method, Pyrosequencing.Next-Generation Sequencing (NGS): Understanding of NGS and its role in bioinformatics, concepts of DNASeq, RNASeq, ChIPSeq, metagenomics, single cell sequences, data collection, processing, interpretation and quantification of NGS data, tools and software available for NGS data.
4. Biomarker Identification: Definitions, classifications, and characteristics of biomarkers, the importance of biomarkers for modern medicine and bioinformatics analysis of genomic polymorphism, recognizing functional regions in the human genome and interpreting GWAS studies, tools and techniques for identification of biomarker and target validation.
5. Metabolomics: Definition, metabolites and metabolite profiling, metabolomics vs metabonomic, targeted and untargeted metabolomics, pathway and metabolome databases. Pharmacogenomics of Phase I/II/II metabolism: CYP 450 enzyme, CYP inhibition/induction, UGT isoforms, kinetics exhibited by UGTs (inhibition/induction), efflux/influx transporters, drug resistance due to over expression of efflux transporters, substrate/inhibitor selectivity of efflux transporters, IVIVC/ *in silico* modelling, case studies, non CYP metabloism.
6. Reactive metabolites and drug safety: Optimizing drug candidates - Phase I, II and III metabolisms, drug metabolism and disposition profile of drugs, identification of the site of metabolism (SoM), structure metabolism relationships (SMR) and quantum chemical parameters in determining SoM, case studies.
7. PK/PD Modelling: Drug interaction (PK-PD interactions), altered pharmacokinetics, understanding concentration/ response, mechanism-based PK/PD models, simulation for study design including estimation methods and simulation methods, computer-aided simulation for predicting PK/PD
8. Personalized medicine: Concept of personalized medicine, inter individual differences and genetic basis for variability in drug response / metabolism and susceptibility to adverse effects; gene-drug interaction; future of drug therapy. Use of Genomics in drug target identification, drug development and disease diagnosis.
9. Immunoinformatic: Applications in immunoinformatic and computational immunology, epitope prediction, design and evaluation of vaccine design, case studies
10. Multi-omics Applications: Multi-omics approaches in cancer, cancer resistance

Recommendedbooks:

1. Immunoinformatics:BioinformaticsStrategiesforbetterunderstandingofImmuneFunctionVol.254,byGregoryBoc k,JenieGoode,JohnWiley&Sons
2. Immunoinformatics:PredictingImmunogenicityinsilicobyDarresRFlower,HumanaPress
3. ImmunoinformaticsbyShobhaRanganathan,VladimirBrusic,Springer
4. ChemicalGenomicsandProteomicsbyZandersEdwardD.,HumanaPress
5. DrugMetabolisminDrugDesignandDevelopment,editedbyDongluZhang,MingsheZhu,W.GriffithHumphreys,Wi ley
6. EvaluationofDrugCandidatesforPreclinicalDevelopment.Pharmacokinetics,Metabolism,PharmaceuticsandToxic ology,editedbyChaoHan,CharlesB.Davis,BringheWang,Wiley
7. EarlyDrugDevelopment:StrategiesandRoutestoFirst-in-HumanTrials,editedbyMitchellNCayes,Wiley
8. Handbook of Drug Metabolism, edited by Paul Gerard Pearson, Larry C Wienkers, CRC Press

LS-510 GeneralLaboratoryExperiencewithComputerLab. (3credits)

1. Biostatistics(4)
2. ChemOffice(2)
3. MolecularModelling(12)
4. C++Programming(30)
5. Tableau (6)

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. **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.
4. Therapeutic drug monitoring of digoxin, theophylline, phenytoin, phenobarbitone, carbamazepine and gentamicin.
5. **Understanding audit:** Audit cycle, identifying key issues, setting standards; Audit process; Results and re-audit.
6. **Clinical trials and pharmacists' involvement:** Legal and ethical requirements of trials.
7. **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 (4 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 (80 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 trialdesign 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, ScheduleY.

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. Fairclogh

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 reguatory filings development pharmaceutics 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.

PT-560 Synthetic aspects of Process Chemistry (2 credits)

1. Process optimization: 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: Twelve 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. Applications of modern reactions in large-scale synthesis

6. Recent advances in process techniques: Microwave reactions, reagents free synthesis, light mediated 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

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; Cyloaddtition; 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:** Archaebacteria 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: ATextbook 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-qualescence medium; flow behaviour etc.
6. **Sterilization of air and medium:** Different methods of sterilization; Kinetics of sterilization; batch and continuous sterilization; advantages and disadvantages thereof; Calculation of del factor and solving of numerical.
7. **Mass transfer:** Mass and energy balance in microbial processes; Resistance encountered in fermentation medium by the oxygen molecule; Role of Dissolved oxygen concentration in 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 hallow-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, Km and Vmax, 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.
    Enzymes with industrial and diagnostic applications:
    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.

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 Km and Vmax 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 Ñ 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 (KL a) at various aeration rates by Static Gassing out method.
   xii To determine the Mass Transfer Coefficient (KL a) at various mixing rates by Static Gassing out method.
   xiii) To determine the KL a by Sodium Sulphite method.

Medical Devices

MT-510 Medical Imaging & Processing (2 Credits)

1. Medical Imaging

Introduction to Electron Microscopy, X-ray Imaging, Computed Tomography, Ultrasonography, Magnetic Resonance Imaging

2. Image Processing Fundamentals

Structure of the Human Eye, Image Formation in the Eye, Image Sensing and Acquisition, Basic Relationships Between Pixels, Neighbors of a Pixel, Adjacency, Connectivity, Regions, and Boundaries, Distance Measures, Image Operations on a Pixel Basis, Linear and Nonlinear Operations

3. Image Enhancement

Gray Level Transformations, Image Negatives, Log Transformations, Power-Law Transformations, Piecewise-Linear Transformation Functions, Histogram ProcessingHistogram Equalization, Histogram Matching, Enhancement Using Arithmetic/Logic Operations, Spatial domain image Filtering, Image Sharpening, Image Transformations, Biomedical applications

4. Image Restoration

Noise Models, Spatial and Frequency Properties of Noise, Some Important Noise Probability Density Functions, Estimation of Noise Parameters, Image Restoration using Spatial domain Filtering, Mean Filters, Order-Statistics Filters, Adaptive Filters, Biomedical applications

5. Image Segmentation

Point Detection, Line Detection, Edge Detection, Thresholding, Global Thresholding, Adaptive Thresholding, Region-Based Segmentation, Region Growing, Region Splitting and Merging, Biomedical applications

6. Image Compression

Redundancy, Image Compression Models, Elements of Information Theory, Fundamental Coding Theorems, Lossless Compression, Variable-Length Coding, LZW Coding, Lossy Compression, Image Compression Standards

Text Books:

1. R.C. Gonzalez and Wintz Paul, "*Digital Image Processing*", 4th Edition, Addision Wesley, 2018.
2. A.K. Jain, "*Fundamental of Digital Image Processing*", Prentice Hall India Learning Private Limited, 2015.

Reference Books:

1. J.T. Bushberg, J.A. Seibert, E.M. Leidholdt, J.M. Boone, "*The Essential Physics of Medical Imaging*", 3rdEdition, Lippincott Williams & Wilkins, 2012.
2. Rangaraj M. Rangayyan, "*Biomedical Image Analysis*", CRC Press, 2004.

MT-520 Medical Instrumentation (Diagnostic, Therapeutic & Surgical)

(2 Credits)

1. Clinical Laboratory Instruments

UV-Vis Spectrophotometer, Colorimeters, Flame Photometers, Glucometer, Electrophoresis Techniques & apparatus, ELISA reader, RIA units, Auto AnalyzerBiochemical tests Detection and quantification of biochemical parameters, turbidometry.

Blood Gas Analyzers - Pulse-oxymeter, Blood pH measurement, Measurement of blood PCO2 & PO2, Blood cell counters - methods of Cell counting, types of Blood cell counters. Special topics in microscopy in diagnosis.

2. Immuno and Molecular Diagnostics

Introduction, antigen-antibody binding and assays; Immunoassays –types [RIA, ELISA, Chemiluminescent IA, FIA] and specific applications; Immunohistochemistry -principle and techniques. Immunodiagnostics for detection of infectious agents. Overview of Molecular diagnostics. Real Time PCR, principle, instrumentation and application.

3. Cardiovascular and respiratory devices

Cardiac stents, valves, pacemakers, defibrillators and cardioverters. Mechanical ventilator and respiratory drug delivery devices

4. **Ophthalmic and auditory devices**

Contact and ophthalmic lenses. Implantable auditory devices (IADs).

5. **Orthotic, prosthetic and dental devices**

Spinal, hip, upper limb and lower limb orthotic and prosthetic devices. Crowns, bridges and braces.

6. Dialysis devices

Haemodialysis and peritoneal dialysis devices

7. General surgical devices

Gastroscope, colonoscope, laproscope, sigmoidscope, endoscopic retrograde cholangiopancreatography (ERCP).

8. Ophthalmic and thoracic surgical devices

Ophthalmoscope, laryngoscope, bronchoscope, oesophagoscope.

9. Urological surgical devices

Cystoscope, urethroscope, resectoscope, ultrasonic and electronic lithotroptor.

Text Books:

1. Tietz Fundamentals of Clinical Chemistry and Molecular Diagnostics, 8th Edition, Author: Nader Rifai ISBN: 9780323530446

2. Laboratory Instrumentation, 4th Edition by Mary C. Haven, Gregory A. Tetrault, Jerald R. Schenken ISBN: 978-0-471-28572-4

3. Jayanti Tokas, Immunology and Molecular Diagnostics, 2015, ISBN-10 : 9789383828555; ISBN-13 : 978-9383828555

4. John G. Webster, Amit J. Nimunkar. Medical Instrumentation: Application and Design, Wiley, Latest Edition

5. Carr-Brown. Introduction to biomedical equipment technology, 2011, 1 st Edition, Pearson New York

Reference books

1. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics: First South Asia Edition, 1st Edition Authors: Nader Rifai A. Rita Horvath Carl T. Wittwer; Hardcover ISBN: 9788131248973
2. Clinical Chemistry: Principles, Techniques, and Correlations by Michael L. Bishop, Edward P. Fody, Larry E. Schoeff. ISBN-10 : 1451118694; ISBN-13 : 978-1451118698.
3. Lippincott Williams and Wilkins Molecular Diagnostics, 3rd Edition by George P. Patrinos, Wilhelm Ansorge, Phillip B. Danielson Hardcover ISBN: 9780128029718; eBook ISBN: 9780128029886.
4. Academic Press David Wild. The Immunoassay Handbook, 4th Edition: Theory and Applications of Ligand Binding, ELISA and Related Techniques. Hardcover ISBN: 9780080970370;eBook ISBN: 9780080970387. Elsevier Science
5. R S Khandur. Handbook of Biomedical Instruments
6. Albert M. Cook, John G. Webster. Therapeutic Medical Devices. Prentice Hall, Latest Edition
7. Leslie Cromwell, Fred J Weibell and Erich A Pfeiffer. Biomedical Instrumentation, New Delhi 2000

MT-530 Physiology of Human Body (2 Credits)

1. Cell structure and Molecular Biology

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. Nucleic acids – DNA, RNA and Protein. Overview of replication, transcription and translation. **Organization of tissues -** Cell-cell and cellmatrix interactions, cell adhesion molecules, components of the extracellular matrix, cellular junctions and role.

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. Membrane Potentials and Action Potentials

Basic Physics of Membrane Potentials, Measuring the Membrane Potential, Resting Membrane Potential of Nerves, Nerve Action Potential, Roles of other Ions During the Action Potential, Propagation of the Action Potential. Recording Membrane Potentials and Action Potentials.

4. Organization of the Nervous System, Basic Functions of Synapses, and Neurotransmitters

General Design of the Nervous System, Major Levels of Central Nervous System Function, Comparison of the Nervous System with a Computer, Central Nervous System Synapses, Some Special Characteristics of Synaptic Transmission

5. Nerve& Muscle Physiology

Classification of nerve fibres, Nerve conduction, Degeneration and regeneration in nerves, Functional anatomy of skeletal muscle, Neuro-muscular transmission and blockers, Excitation-contraction coupling, Smooth muscle, Mechanisms of muscle contraction.

6. Sensory System :

The Eye Optics of Vision, Physical Principles of Optics, Ophthalmoscope, Neural Function of the Retina, Visual Pathways, Organization and Function of the Visual Cortex, Neuronal Patterns of Stimulation During Analysis of the Visual Image, Fields of Vision; Perimetry, Eye Movements and Their Control, Autonomic Control of Accommodation and Pupillary Aperture, **The Sense of Hearing,** Tympanic Membrane and the Ossicular System, Cochlea, Central Auditory Mechanisms. Sense of Taste and Sense of Smell.

7. Respiratory and Circulatory system

Functional anatomy of respiratory system, Pulmonary ventilation, Alveolar ventilation, Mechanics of respiration, Pulmonary circulation, Principles of gas exchange, Oxygen & carbon-dioxide transport, Regulation of respiration, Artificial respiration. Cardiovascular Physiology - Functional anatomy of the heart, Properties of cardiac muscle,
Cardiac cycle, Heart as a pump, Cardiac output, Generation & conduction of cardiac impulse, Electrocardiogram, Regional circulations.

8. Renal Physiology & Fluid Balance

Body fluid compartments, Water balance; regulation of fluid balance, Urine formation, Regulation of extracellular sodium &osmolarity, Renal mechanisms for the control of blood volume, blood pressure & ionic composition, Regulation of acid-base balance, Renal failure

Text book and Recommended Book

1. Textbook of Medical Physiology by Guyton and Hall, 14th Edition, ISBN-13 : 978-0323597128
2. Guyton & Hall Physiology Review by John E. Hall, 3rd Edition, ISBN-13 : 978-1455770076
3. Lippincott® Illustrated Reviews: Physiology by Robin R. Preston and Thad E. Wilson. 2nd Edition, ISBN/ISSN: 978-1496385826
4. Ganong's Review of Medical Physiology, 26th Edition, ISBN 978-1-260-12240-4
5. Medical Physiology by Walter Boron Emile Boulpaep, 3rd Edition. ISBN: 9780323427968

MT-540 Biostatistics and data science (1 Credit)

1. Statistics

Introduction and its role and uses, Collection, Organization, Graphics and pictorial representation of data, Measures of central tendencies and dispersion, Coefficient of variation

2. Probability

Basic concepts, Common probability distributions and probability distributions related to normal distribution

3. Sampling

Simple random and other sampling procedures, Distribution of sample mean and proportion

4. Estimation and Hypothesis testing

Point and interval estimation including fiducial limits, Concepts of hypothesis testing

and types of errors, Student-t and Chi square tests, Sample size and Power.

5. Experimental design and analysis of variance

Completely randomized, randomized blocks, Latin square and factorial designs, Post- hoc procedures

6. Correlation and regression

Graphical presentation of two continuous variables, Pearson's product moment correlation coefficient, its statistical significance, Multiple and partial correlations, Linear regression, Regression line, coefficient of determination, interval estimation and hypothesis testing for population slope, Introduction to multiple linear regression model, Probit and logit transformations

7. Non-parametric tests

Sign, Mann Whitney U, Wilcoxon matched pair, Kruskal wallis and Friedman two way ANOVA tests, Spearman rank correlation

8. Statistical techniques in pharmaceutics and medical devices

Experimental design in clinical trials, Parallel and Crossover designs, Statistical test for bioequivalence, Dose response studies, Statistical quality control.

Reading material

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

MC-511 Spectral Analysis (2 Credits)

1. Ultra Violet (UV), visible and fluorescence 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.

e) Theory and Instrumentation, Factors affecting fluorescence, the relation between the intensity of fluorescence and concentration, measurement of fluorescence, Quenchers and Application.

2. Infrared (IR)spectroscopy

a) Characteristic regions of the spectrum: Various modes of vibrations, Energy levels

b) Correlation of structure with IR spectra: Influence of substituents, ring size, hydrogen bonding, vibrational coupling and field effect on frequency.

c) Applications: Determination of stereochemistry. Spectral interpretation with examples.

3. Nuclear Magnetic Resonance (NMR)spectroscopy:

a) Fundamentals: Physical basis, magnetic nuclei, resonance, relaxation processes, signal-sensitivity.
b) Instrumentation: Continuous-Wave (CW) instrument, Pulsed Fourier Transform (FT) instrument, Functions, Relation with sensitivity, Sampling.
c) 1H NMR, correlation of structure with spectra: Chemical environment and shielding, chemical shift and origin of its concept, reference compound, local diamagnetic shielding and magnetic anisotropy, relation with chemical shift, chemical and magnetic non-equivalence, spin-spin splitting and its origin, Pascal's triangle, coupling constant, mechanism of coupling, integral, NMR solvents and their residual peaks, protons on heteroatoms, quadrupole broadening and decoupling, effect of conformations and stereochemistry on the spectrum, Karplus relationship, diastereomeric protons, Heteronuclear coupling to F and 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) 13C NMR correlation of structure with spectra: Chemical environment, shielding and carbon-13 chemical shift, calculation, proton-coupled C Spectra, Proton-decoupled C spectra, Nuclear Overhauser Enhancement (NOE), Problem with integration, Distortion less Enhancement by Polarization Transfer (DEFT), Heteronuclear coupling for carbon to deuterium, carbon to F, carbon to 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, Different ionizations modes: EI, CI, FAB, ESI, APCI, APPI MALDI and other techniques, applications.

Text Books

1. Pavia DL, Lampman GM, Kriz GS, Vyvyan JA. Introduction to spectroscopy. 2008. Cengage Learning ISBN-10 : 8131529169, ISBN-13 : 978-8131529164
2. Dyer JR. Applications of absorption spectroscopy of organic compounds. 1978. Prentice Hall, Mumbai, India, ISBN-10 : 8120302524, ISBN-13 : 978-8120302525
3. Jürgen H. Gross. Mass Spectrometry: A Textbook. 2nd edition, 2011**.** ISBN-10 3-540-40739-1, Springer-Verlag Berlin Heidelberg, Germany ISBN-13 978-3-540-40739-3

Reference books

1. Neil E. Jacobsen,NMR Spectroscopy explained, 2007**,** John Wiley & Sons, Inc., Hoboken, New Jersey. ISBN 978-0-471-73096-5
2. Jack Cazes, Ewing’s Analytical Instrumentation Handbook. 2005. Marcel Dekker, Madison Avenue, New York, U.S.A. ISBN-10 : 1482218674, ISBN-13 : 978-1482218671
3. Spectrometric Identification of Organic Compounds by Robert M. Silverstein, Francis X. Webster & David J. Kiemie

MT-550 Computer Application (CAD & CAM) (1 Credit)

Introduction and components of Computer aided design (CAD)/Computer aided manufacturing (CAM); 3D Modeling and Viewing: Modeling operations and strategies; Modeling Aids and Tools; Mass and Geometric Properties; Assembly Modeling: Bottom-up, top-down assembly approaches, Mating conditions, subassemblies, assembly analysis (Motion study); Engineering Drawing: Drawing structures, Angle of projections, Annotations, Tolerances, Manufacturing information; Product Data Exchange; Computer Aided Process Planning (CAPP): Significance, Architecture of a CAPP systems, CAPP approaches; Part Programing: Data exchange, Machine tool, Programming steps, Toolpath Planning, 2D and multi-axis, Post processing the Data; CAD/CAM Programming: Macros, CAD/CAM API functions; Introduction to CAE; Structural analysis, Thermal analysis.

S. No.	Module
1	Introduction and components of Computer aided design (CAD)/Computer aided manufacturing (CAM); Product life Cycle, Scope, GUI and Menu of a CAD/CAM software
2	3D Modeling and Viewing; Modeling entities & features, Modeling operations and strategies
3	Modeling Aids and Tools; Entity selection, transformation, measurement, color, material
4	Mass and Geometric Properties; Area, Volume, Centroid, inertia, etc.
5	Assembly Modeling; Bottom-up, top-down assembly approaches, Mating conditions, subassemblies, assembly analysis (Motion study)
6	Engineering Drawing; Drawing structures, Angle of projections, Annotations, Tolerances, Manufacturing information
7	Product Data Exchange; IGES, STEP, ACIS & DXF, STL
8	Computer Aided Process Planning (CAPP); Significance, Architecture of a CAPP systems, CAPP approaches
9	Part Programing; Data exchange, Machine tool, Programming

	steps, Toolpath Planning; 2D and multi-axis, Post processing the Data
10	CAD/CAM Programming; Macros, CAD/CAM API functions
11	Introduction to CAE; Structural analysis, Thermal analysis

MT-560 Intellectual Property Rights (IPR) & Ethics (1 Credit)

1. Intellectual property

Concepts and fundamentals; Concepts regarding intellectual property (IP), intellectual property protection (IPP) and intellectual property rights (IPR); Economic importance, mechanisms for protection of intellectual property patents, copyrights, trademark; Factors effecting choice of IP protection; Penalities for violation; Role of IP in pharmaceutical industry; Global ramifications and financial implications.

2. Trade related aspects of intellectual property rights

Intellectual property and international trade; Concept behind WTO (World Trade Organisation), WIPO (World Intellectual Property Organisation) GATT (General Agreement on Tariff and Trade), TRIPs (Trade Related Intellectual Property Rights),TRIMS(Trade Related Investment Measures) and GATS(General Agreement on Trade in Services); Protection of plant and animal genetic resources; Biological materials; Gene patenting; Biotechnology / NIPER 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 / nondisclosures, 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-Beme convention, WIPO copyright treaty (WCT), WIPO performance and Phonogram Treaty (WPPT); Protection for computer data bases, multi media works; Trade marks legislation and registration system in India-an introduction, meaning of trademark criteria for eligibility; filling application for trademark registration; Trade secrets-scope modalities and protection; Case studies-drug related patents 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. The Patents Act, 1970 (Bare Act with Short Notes) (New Delhi: Universal Law Publishing Company Pvt. Ltd. 2012)
3. Patent Agent Examination by Sheetal Chopra and Akash Taneja
4. Making Innovation Happen- A simple and Effective Guide to Turning Ideas into Reality by Michael Morgan
5. Making Breakthrough Innovation Happen by Porus Munshi

6. 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
7. How to Write and Publish a Scientific Paper by Rober A Day
8. Concise Law Dictionary-with Legal Maxims, Latin Terms and Words and Phrases by Justice Y.V. Chandrachud
9. Biomedical Research- From Ideation to Publication by G. Jagadeesh and others

MT-570 Elective 1; Biomedical Devices and Systems (1 Credit)

Introduction: Biomedical engineering design, engineering approaches to clinical challenges, clinical problems requiring implants/devices for solution; Materials for biomedical implants and devices; Implantable devices and systems: Vascular and cardiovascular devices, pacemakers, heart valves, stents, synthetic grafts, orthopedic implants, intraocular lens implants, cochlear implants; Wearable devices: Assistive devices for the blind, foetal movement, finger movement, gait analyzer, ventricular assist devices, energy harvesting; Implantable neural prostheses and nerve stimulation: Brain, visual prosthesis, cochlear implants, spinal cord stimulation, cardiology system, artificial limbs; Minimally invasive devices and techniques: Instrumentation for Laparoscopic Surgery, Ocular Surgery; Imaging and image-guided techniques: endoscopy, medical ultrasound devices, medical X-ray imaging, imaging-aided design of personalized devices and assistive reproduction technology; Rehabilitation Engineering: Deafness, blindness, passive and active Orthoses and Prostheses.
Reading material
1. Andrés D. Lantada. Handbook on Advanced Design and Manufacturing Technologies for Biomedical Devices. Springer London 2013
2. Aimé Lay-Ekuakille and Subhas C. Mukhopadhyay, Wearable and Autonomous Biomedical Devices and Systems for Smart Environment. Springer-Verlag Berlin, 2010
3. David D. Zhou and Elias Greenbaum. Implantable Neural Prostheses 1. Devices and Applications. Springer, London, 2009
4. Gail D. Baura. Medical Device Technologies: A Systems Based Overview Using Engineering Standards Academic Press, Oxford, UK 2012
5. Paul H. King, Richard C. Fries. Design of Biomedical Devices and Systems. CRC press, Boca Raton, 2009
6. James Moore and George Zouridakis. Biomedical Technology and Devices Hand Book. CRC press, Washington DC, 2004
7. Martin Culjat, Rahul Singh, Hua Lee. Medical Devices: Surgical and Image-Guided Technologies, John Wiley & Sons, Inc New Jersey, 2013
8. ASM Handbook Volume 23, Materials for Medical Devices

9. Joseph D. Bronzino, Donald R. Peterson. Medical Devices and Human Engineering, CRC Press, New York, 2015
10. Frank E. Johnson, Katherine S. Virgo, The Bionic Human: Health Promotion for People with Implanted Prosthetic Devices, Humana Press Inc., New Jersey, 2006

MT-580 Elective 2; Pharmacopoeial Methods of Analysis (1 credit)

1. ICH Q4 Pharmacopoeial harmonization process: Current Status.
2. Study of different parts of various pharmacopoeias.
3. Critical comparative analysis of the following tests in IP, BP/EP and USP:
4. Limit tests: Tests for arsenic, lead, chloride, sulfate, and heavy metals.
5. Microbiological tests and assays: Antimicrobial (preservative) effectiveness testing, microbial limit tests, sterility test, vitamins assay (zone of exhibition), antibiotics assays, bacterial endotoxin test,
6. Leachables and extractables.

Reference books:

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

LS-510 Medical Instrumentation Laboratory (2 Credits)

1. Hands on experiment on different Medical Devices and Evaluation

LS-520 Pre-clinical Studies Laboratory (1 Credit)

2. Animal handling and its anatomy
3. Hands on experiment on mammalian cell lines
4. *In-vitro* Biocompatibility studies
5. *In-vivo* Biocompatibility studies
6. Hands on experiment on Electrocardiogram (ECG)
7. Hands on experiment on *in-vivo* imaging (anatomical, functional and molecular imaging)
8. Acquisition and analysis of florescence imaging

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

Recommended books:

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

GE-520

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

1. **Intellectual property:** Concepts and fundamentals; Concepts regarding intellectual property (IP), intellectual property protection (IPP) and intellectual property rights (IPR); Economic importance, mechanisms for protection of intellectual property-patents, copyrights, trademark; Factors effecting choice of IP protection; Penalities for violation; Role of IP in pharmaceutical industry; Global ramifications and financial implications.
2. **Trade related aspects of intellectual property rights:** Intellectual property and international trade; Concept behind WTO (World Trade Organisation), WIPO (World Intellectual Property Organisation) GATT (General Agreement on Tariff and Trade), TRIPs (Trade Related Intellectual Property Rights), TRIMS (Trade Related Investment Measures) and GATS (General Agreement on Trade in Services); Protection of plant and animal gentic

resources; Biological materials; Gene patenting; Biotechnology / drug related IPR issues; Status in India and other developing countries; Case studies and examples; TRIPS issues on herbal drugs.

3. **Nuts and bolts of patenting, copyright and trademark protection criteria for patentability, types of patents; Indian Patent Act, 1970; WTO and modifications under TRIPS:** Filing of a patent application; Precautions before patenting-disclosures / non-disclosures, publication-article / thesis; Prior art search-published patents, internet search patent sites, specialized services-search requests, costs; Patent application-forms and guidelines, fee structure, time frames, jurisdiction aspects; Types of patent applications- provisional, non provisional, PCT and convention patent applications; International patenting-requirement procedures and costs; Financial assistance for patenting- introduction to schemes by NRDC and TIFAC; Publication of patents-gazette of India, status in Europe and US; Patent annuity; Patent attomeys technical aspects, criteria for selection, addresses, fee, rights and responsibilities of a patentee; Practical aspects regarding maintaining of a PATENT FILE; Patent infrigment- meaning, scope, litigation, case studies and examples; Patenting by research students, lecturers and scientists-University / organisational rules in India and abroad; Thesis research paper publication, credit sharing by workers, financial incentives; Useful information sources for patents related information-internet sites, brouchers, periodicals, CD roms; Significance of copyright protection for researchers; Indian Copyright Law and digital technologies-Beme convention, WIPO copyright treaty (WCT), WIPO performance and Phonogram Treaty (WPPT); Protection for computer data bases, multi media works; Trade marks legislation and registration system in India-an introduction, meaning of trademark criteria for eligibility; filling application for trademark registration; Trade secrets-scope modalities and protection; Case studies-drug related patents infringments.

4. **Technology development / transfer / commercialisation related aspects:** Technology development-meaning; Drug related technology development; Toxicological studies, bioequivalence (BU), clinical trials-phase-I, phase-II and phase-III; Approved bodies and agencies; Scale-up, semi-commercialisation and commercialisation-practical aspects and problems; Significance of transfer of technology (TOT), bottlenecks; Managing technology transfer-guidelines for research students, scientists and related personnal;

   TOT agencies in India-APCTD, NRDC, TIFAC, BCIL, TBSE/SIDBI; TOT related documentation-confidentiality agreements, licensing, MOUs, legal issues; Compulsary licensing excess to medicine issues; DOHA declaration, POST WTO product patent regime from 2005; Challenges for Indian pharmaceutical industry in the context of globalisation of IP; Drug registration and licensing issues-national and global; Drug master file submissions, SOPS; Related registration and marketing issues; Case studies-antiretroviral drugs and others.

5. **Funding sources for commercialization of technology:** Preparation of a project report, financial appraisal, business models; GOI schemes and incentives; NRDC, TePP, HGT, TDB schemes. PATSER; Venture capitalists, banks. Incubator concept-Case studies with respect to IIT, CCMB, IMTECH, NIPER. Documentation and related aspects.

6. **Ethics and values in IP:** IP and ethics-positive and negative aspects of IPP; Societal responsibility; Avoiding unethical practices; Echo-responsibility-economic, social and environmental benifits of modern biotechnology; Voluntary adoption of pollution control strategies.

Recommended books:

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

GE-511

Seminar (1 credit)

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

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

Courses of Study 2023
Semester-II

Medicinal Chemistry

MC-610— Computer Aided Drug Design (2 CREDITS)

1. **Structure Activity Relationshipsin drug design**: Qualitative versus quantitative approaches- advantages and disadvantages. Random Screening, Nonrandom 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.
2. **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.
3. **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. The importance of biological data in the correct form; 2D – QSAR; 3D-QSAR – Examples CoMFA and CoMSIA.
4. **Molecular docking** Rigid docking, flexible docking, manual docking. Advantages and disadvantages of Flex-X, Flex-S, Autodock and Dock softwares, with successful examples.
5. **Molecular dynamics,** Monte Carlo simulations and Molecular dynamics in performing conformational search, MMGBSA, MMPBSA, comparison with FEP methods. The importance of time and entropy in molecular dynamics. Residuewise energy estimation, $\Delta\Delta G$ value estimation. Thermodynamic cycle.
6. **Pharmacophore concept**, Pharmacophore mapping, methods of conformational search used in pharmacophore mapping. Comparison between the popular pharmacophore methods like Catalyst/HipHop, DiscoTech, GASP, etc. with practical examples.
7. **Electronic Structure methods.** Quantum chemical methods – semi-empirical and ab initio methods. Schrodinger wave equation, postulates, electronic structure analysis of drugs, partial atomic charges, electrophilicity index and its relation to toxicity.
8. **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 aqueoussolvation calculations for the design of ligands. Conformational interconversion, transition-state determination and their role in designing rigid analogs.
9. **De Novo drug design** techniques and associated virtual screening and comparison to molecular docking.
10. **Informatics methods in drug design** :Bioinformatics, cheminformatics, genomics, proteomics, chemogenomics, Pharmainformatics. ADME databases, chemical biochemical and pharmaceutical databases – drug design techniques using these databases

Reference Books:

1. Molecular Modelling – A. R. Leach
2. Organic Chemistry of Drug Design and Drug Action – R.B. Silverman
3. Practical Applications of computer aided drug design – P.S. Charifson

4. Molecular modeling in Drug Design – C. Cohen
5. Chemical Applications of Molecular modeling – J. Goodman
6. Pharmacophore mapping – O.F. Guner
7. Drug Discovery and Development – P. Rama Rao

MC-620 : Logic in Organic Synthesis-II(2 credits)

Medicinal Chemist's reactions-toolbox

1. Amide bond formation reactions**,** Suzuki couplings to produce biaryl derivatives, *N*H and *O*H–derivatizations (various alkylations and arylations),
2. Functional group interconversions, Functional group additions (halogenation, hydroxylation, amination, sulfonation),
3. Ester condensations, Oxidations and Reductions (various reagents-based methods).

Organometallic chemistry

4. Organometallic M-C ionic/covalent character, nucleophilicity/basicity, organolithium and organomagnesium compounds (Grignard reagents), preparation, structure, Organo-lithum/magnesim as base and nucleophile, planning a Grignard synthesis, restrictions on use.
5. Organocopper compounds : organocuprates (Gilman reagents), reactions including 1,4-addition
6. Transition-metal-catalyzed C–C bond forming coupling reactions: Organo-metallics (Pd, Ni, B, Sn, Zn, Si, Mg, etc)- Name reactions; Suzuki, Negishi, Stille, Hiyama, Kumada, Heck, Sonogashira, Mechanism, Chemistry features, Conceptual variant reactions.
7. Transition-metal-catalyzed C–C and C–heteroatom bond forming coupling reactions: Ullmann-type, Chan-Lam, Buchwald-Hartwig coupling reactions
8. Synthesis of various scaffolds, natural products, and bioactive compounds.

Heterocycles synthesis:

9. Indole synthesis – Fischer indole reaction, Larockindole synthesis; Synthesis of quinolines-some of approaches- Skraup reaction, Doebner–Miller reaction, Friedländer reaction, Combes reaction; Povarov reaction approach; Isoquinoline synthesis - Pictet-Spengler reaction; Pyridine synthesis- Hantzsch approach, Pyrrole synthesis- Knorr reaction, Synthesis of dihydropyrimidin-2(1H)-ones- Biginelli reaction
10. Synthesis of N-heterocyclic scaffolds frequently present in drugs

Recommended books:

As mentioned in previous course of study; list 1-10.

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

1. **Methodsforthedeterminationof the structureofbiomolecules:** Biological crystallography-crystals-generation, macromolecular structure determination.Identification of the active site,electron density maps; Differences in the small molecule and biomoleculescrystallography.
2. **Spectrofluorimetry**- basic principles of fluorescence, the intensity of fluorescence, fluorescent group, the sensitivity of fluorescence to the environment and biological applications; Optical activity measurements.
3. **Optical methods:** Basic principles of fluorescence, intensity, fluorescent group, the sensitivity of fluorescence to the environment, and biological applications. Optical activity measurements, ORD/CD applications to Nucleic acids and proteins.
4. **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.
5. **Properties of amino acids and peptide bond:** End group determination of peptides, sequencing of peptides using various chemical and analytical techniques; Aptechniqueswith case studies like LHRH and TRH peptides.
6. **Protein structure building block to quaternary structure of proteins:** Ramachandran plots; Peptidomimetics; Protein-ligand interactions; Multiple binding modes.
7. Structure of lipoproteins and glycoproteins in relation to their function.
8. **Carbohydrates and lipids:** Structure, synthesis, physicochemical properties, and their biological function.
9. **Detailed structure of nucleic acids and protein-nucleic acid interactions:** Nucleic acid and small molecule interactions; DNA damage and repair.
10. **Structure and function of biomolecules pertaining to different therapeutic areas:** Cancer- tubulin-role in cell proliferation, various binding sites, the chemistry and biology of tubulin inhibitors; farnesyltransferase- 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.

Recommended books:

1. Physical Biochemistry: Applications to Biochemistry and Molecular Biology by David Freifelder
2. Methods in Modern biophysics, by B. Nolting
3. Introduction to Biophysical Methods in Protein and Nucleic Acid Research, by J.A. Glasel
4. Monosaccharides. Their Chemistry and Their Roles in Natural Products
5. Essentials of Glycobiology by Varki
6. Carbohydrates by Osborn
7. Modern Methods in Carbohydrate Synthesis by Khan and O'Neill
8. Organic Synthesis with Carbohydrates by Boons and Hale
9. Enzymes in Synthetic Organic Chemistry by Wong and Whitesides
10. Methods in Modern Biophysics by B. Nolting
11. Introduction to Biophysical Methods in Protein and Nucleic Acid Research by J.A. Glasel.

MC-640 Organocatalysis and metal-free methods of synthesis (2 credits)

Organocatalysis

1. Introduction: Importance of asymmetric synthesis and concept of organocatalysis; chiral induction-factors controlling facial selectivity; chiral reagents/catalysts, auxiliaries, enzymes, and antibodies; kinetic resolution.
2. Category of organocatalysis: Lewis base, Lewis acid, Bronsted base, Brosted acid catalysis.
3. Case studies and examples on the use of iminium and enamine catalysis in different organic transformations (aldol reaction, cross-aldol, Mannich reaction, Micheal addition, various α-functionalization of carbonyl compounds, MBH-reaction, cycloadditions, etc.).
4. Carbocation-catalyzed reactions; N-heterocyclic carbene (NHC) catalyzed transformations; Organo SOMO catalysis.
5. Concept on organophotoredox catalysis.
6. Applications in the synthesis of natural products and drug molecules.

Metal-free methods in organic transformation

7. Introduction and the general importance of metal-free methods.
8. Tandem multicomponent reactions, rearrangements, and isomerization reactions;
9. Ugi and Passerini reaction and applications.
10. Various strain-release-driven reactions and strategic applications in organic synthesis and medicinal chemistry

Books/literature:

1. Asymmetric Organocatalysis: New Strategies, Catalysts, and Opportunities, 2 Volumes. Lukasz Albrecht (Editor), Anna Albrecht (Editor), Luca Dell'Amico (Editor); ISBN: 978-3-527-34907-4.
2. Organocatalysis. First Edition, 2007. M. T. Reetz, B. List, S. Jaroch, H. Weinmann. ISBN: 978-3-540-73494-9. Springer

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MC-650 :Stereochemistry in Drug Actionand Asymmetric synthesis (2 credits)

1. **Molecular isomerism:** Molecular motion, time scales, and energy; Conformation of open chain and saturated cyclic systems.
2. **Chirality and molecular symmetry:** Nomenclature and representations; Macromolecular stereochemistry; Dynamic stereochemistry.
3. **Group theoretical interpretation of chirality group:** Laws of group theory, symmetry elements, and operations, classification of symmetry operation into groups, chiral and achiral point groups, determination of molecular structures into symmetry point groups, platonic solids, desymmetrization.
4. **Conformational analysis:**
   a) Definitions: Internal coordinates, the distinction between conformation and configuration.

b) Conformational analysis of cyclic compounds: carbocycles and heterocycles, bi- and tri-cyclic compounds.
c) Conformational analysis of acyclic compounds: potential energy diagrams of various acyclic systems, Gauch effect, generalized anomeric effect.

5. **Assignment of configuration:** Various projectional formulae, molecular with the 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 a 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.
9. **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.
10. Examples of asymmetric synthesis of various natural products and drugs.

Recommendedbooks:

1. StereoChemistryof OrganicCompoundsbyErnestL. Eliel,SamuekH.Wilen, LewisN. Mander
2. StereoChemistryofCarbonCompoundsbyErnestL.Eliel
3. ChemicalApplicationofGroupTheorybyF.AlbertCotton
4. Relevantresearcharticlesas suggestedtimetotimeduringtheprogress of classroomteaching.

MC 660 : AI and ML in Drug Discovery (1 credit)

1. Logic, mathematics of logic, set theory, development of PROLOG and LISP. Applications in Drug Design.
2. Introduction to the use of artificial intelligence (AI) and machine learning (ML) in drug discovery. Basic concepts for AI / ML, commonly used methods for tabular data and different types of neural networks. The importance of data for modeling in medicinal chemistry, drug metabolism, drug delivery.
3. AI in ligand-based methods, virtual screening, prediction of properties based on chemical structure, structure-based methods, image-based methods, de novo drug design and network / graph-based methods.
4. ANN, CNN, RNN, DNN, etc. neural network methods in drug discovery. Predictions and interpreting the results, steps for training and validation of AI / ML models. AI with quantum chemical accuracy in drug discovery.
5. Generative artificial intelligence (GAI) in drug discovery. Explainable artificial intelligence (XAI) in drug discovery. Transparency, justification, informativeness, uncertainty prediction.
6. Genetic algorithms in molecular docking and QSAR, QSTR. AI and ML in de novo design.
7. Knowledge based methods and expert systems in medicinal chemistry. AI in bioinformatics for macromolecular target prediction.

8. Naive Bayesian, Random Forest, Support vector machines – classification methods in pharmaceutical sciences including clinical trials and pharmacovigilance. Feature analysis using K-nearest neighbor approach.
9. AI and ML in toxicological research, toxicophore identification, toxic metabolite identification.
10. AI and ML in synthesis planning. Rule based methods, transformer models, reaction similarity methods, Bayesian probability schemes. Attempts of ANN, DNN in synthesis planning.

Recommended books:

1. ARTIFICIAL INTELLIGENCE IN DRUG DISCOVERYby Nathan Brown (Editor) Royal Society of Chemistry.
2. Deep Learning for the Life Sciences: Applying Deep Learning to Genomics, Microscopy, Drug Discovery, and More (Greyscale Indian Edition) by BharathRamsundar (Author), Peter Eastman (Author), Vijay Pande (Author), Patrick Walters (Author)Shroff/O'Reilly; First edition (5 May 2019)

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

Synthesis of a drug that includes 4 to 5 reaction steps; Isolation of each productby 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 biomedicinals and marine toxins from bacteria, microalgae, rhodophyta, chlorophyta, porifera, ascidians, corals, nudibranchs, biosynthesis of marine natural products.
2. Recent developments in natural product chemistry of plant andmicrobial sources.
3. Carbohydrates: Mono, di, oligo- and polysaccharides, separation & isolation, purification, structure determination, linkage stereochemistry, biological activity.
4. Glycoproteins, lipoproteins and glycopeptideslipids; 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 theoryof 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
7. Tetrahedron, Bioorganic & Medicinal Chemistry; and few research articles published on semisynthesis 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 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:
4. (a) anticancer, (b) anti-diabetic, (c) anti-haemmoroids, (d) anti-viral, (e) bronchial asthma, (f) cardiovascular, (g) hepatoprotective, (h) sedative/tranquilizer, (i) urinary stone (j) laxative etc.
5. Terrestrial and marine based bioactive leads, synthesis of some bio-active natural products and their analogues.
6. Plantibodies (immunoglobins) from plants.
7. Edible dyes, plant sweeteners, perfumery and cosmetic agents.
8. Bioactivity: Activity versus toxicity, rapid screening methods, correlation between enzyme
9. inhibition and pharmacological activity, general screening of enzyme inhibitors.
10. Radio-ligand receptor binding assays (adrenoreceptors, opiate, benzodiazepine, ion channels, 5 HT, dopamine, adenosine, muscarinic, histamine, ATPase, GABA), cytotoxicity tests; bioassay-guided fractionations.
11. Dietary anti-oxidants in disease prevention.
12. Dereplication techniques and scale up studies 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, A L 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-640

Structure Elucidation (2 credits)

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

Recommended books:

1. Spectroscopy by Pavia, Lampman, Kriz, Vyvyan
2. Spectrometric Identification of Organic Compounds by RM Silverstein
3. OrganicSpectroscopy byWilliam Kemp 4. Spectral Data for StructureElucidation

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 tran- scription 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.Good Agriculture and collection practises (GACP) and organic farming for Medicinal and Aromatic plants (MAP's)
6. Tissue culture techniques: Micro-propagation of medicinal and aromatic plants, sec- ondarymetabolism in tissue culture, germplasm storage, methods of cell immobilization, Brassinosteroids as plant growth regulators
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.
11. Techniques to enhance secondary metabolites
12. Techniques for conservation and sustainable utilization of MAP's
13. Threatened and endangered species of medicinal plants

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 byR. M.Twyman
4. Ecology-Principles andApplications by J. L. Chapman and M. J. Reiss
5. Instant Notes in Ecology by Aulay Mackenzie, Andy S Ball, Sonia R, Virdee
6. Gene byLewin

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 triterpenses and rearrangement studies of sterols.
3. Separation of polar compounds using ion exchange and gel filtration chromatography.

4. Preparation of 16-DPAfrom 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. Standardization of Herbal Drugs: Need for standardization, issues related to herbal medicines, safety of herbal medicines, substitution and misidentification, toxicity, efficacy, standardization, and documentation and Regulatory aspects 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 flavonoids, 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, Stability testing of herbal drugs.
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.
11. Preparation of Drug Master File for herbal formulations with examples.
12. Regulatory aspects and quality control: Regulatory requirements of herbal drugs, registration and licensing requirements.

Recommended books:

1. WHOGuidelines on QualityControl of MedicinalPlants

2. AyurvedicPharmacopoeias of India
3. VariousResearchPublications
4. Traditional Herbal Medicine research Methods by WJH Liu(ISBN 9780470149362)

TM-620

Pharmacological Evaluation of Herbal Drugs (2 credits)

1. Principles of drug evaluation: Methods, types and Importance of drug evaluation; general know – how of laboratory animals, dose fixation and general aspects.
2. Methods of drug screening: Importance and study of in vitro and in vivo methods.
3. Therapeutic categories of botanical drugs: Different therapeutic category of botanical drugs; pharmacological activities of these drugs and their correlation.
4. Bio-assay Methods: Different in vitro and in vivo bioassays for evaluation of pharmacological activity of botanical/herbal drugs.
5. Pharmacodynamics of herbal medicines: Combined effects of pharmacodynamics on the efficacy of herbal drugs.
6. Herbal-drug and food-drug interactions
7. Safety aspects and adverse reactions of herbal medicines.
8. 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. Major Challenges: Scientific understanding of herbal medicines; complications such as multi-constituent product and multi-target actions.
2. Evidence of clinical research: Critical analysis on published data on clinical research of herbal drugs.
3. Clinical trial protocol development: Different Phases of clinical trial, their importance; responsibilities of investigators and sponsor. Parallel and cross over design of clinical trial; Placebo in clinical trials, sample size
4. Design and objectives: Design and broad objectives of clinical trials for herbal drugs, type and laying of protocol for clinical trial.
5. Limitations of clinical trials of herbal drugs.
6. Data comparison: Comparison of clinical study data of pharmaceuticals versus herbal drugs and their linkages.
7. Epidemiological studies: pharmacological and epidemiological studies carried on herbal drugs.
8. Adverse reaction and pharmacovigilance: 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. GMPand GLPas per guideline ofAYUSH,Ministry of Helath andFamilyWelfare,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. Different problems encountered in herbal formulations and their remedy.
5. Setting of Standard Operating procedures (SOPs) for each step of herbal formulations with emphasis on reproducibility.
6. SOPS: 3-4 Examples from herbal products.
7. Stability testing of herbal drugs.
8. NDDS and Application of NDDS for herbal drugs and their bioactives
9. Phytosomes, liposomes and microemulsions (SMEDDs and SNEDDs), nanoparticulate drug delivery system.
10. Preparation of Drug Master File (DMF) for herbal formulations with examples.
11. Regulatory aspects and quality control: Regulatory requirements for herbal drugs, registration and licensing requirements.

Recommendedbooks:

1. Review and research articles published on herbal formulations in the Journals, Fitoterapia, Phytomedicine, International Journal of Pharmaceutics, European Journal of Pharmaceutics and Biopharmaceutics,AAPSPharmaSciTech-USAand Indian Journal ofPharmaceuticalSciences.
2. Herbal Drugs IndustrybyR.D. Chaudhary

TM-650

Herbal Drugs and its action based on Indian System of Medicine (3 credits)

1. Dravyaguna: Seven basic concepts- Dravya (Drug), Guna (Property), Rasa (Taste indication based on chemical composition), Vipaka (Metabolic properties), Virya (Potency or Dynamic properties), Prabhava (special action due to Specific properties) and Karma of Dravya (Action of Drugs). Their co-relation with modern terminologies with examples
2. Dravya: Definition, and importance, Panchbhautic constitution, Attribute of Drug (Aushadhatva based on Sushruta) and Nighantus; Their co-relation with modern terminologies with examples
3. Drug classification based on Ayurveda: (Karya, Karan, bheda, Chetana, Bheda,Yoni bheda Panchmahabhuta, Nomenclature and synonyms of Drugs, Plant Collection period as per ancient text; Their co-relation with modern terminologies with examples
4. Guna: characteristics, types, examples of Gurvadiguna and Vishishta Guna, Rasa Vikalpa.
5. Rasa: Definition, characteristics, and numbers of Rasa, different opinions regarding Rasa, Panchbhautatva of rasa and its evolution; Difference between Rasa and Uprasa.
6. Vipaka: Characteristics, Analysis of general principle and opinions of different Acharya.
7. Virya: Characteristics and nature of Virya, Analysis of general principle and opinions of different Acharya, properties and functions of Virya.
8. Prabhava: Characteristics, its functions with examples.
9. Karma (Actions): Characteristics, types and modality of Karma from ancient and modern perspectives. Explanation of the following ancient terminologies of Karma- Sthambhan-Grahi, Agnisadan, Sransana, Anulomana, Deepam-Pachan, Vidahi, Bhedan, Pramathi Rechana,Vishtambhi, Madakari, Shaman -Samshodhan based on Bhavprakash.
10. Properties, actions different class of dravya: Trin Panchmool, Madhyam Panchmool, Kantak Panchmool, Rasayan and vajikaran dravyas, Vidarigandhadi, Aaragvadhadi, and Pippalayadi, Gana (group of drugs) as per Sushruta

Suggested reading:

1. Acharya Priyavrat Sharma. Dravyagun Vigyan. Part I, (Basic principles of drug) 15th edition. Chaukhambha Bharati Academy, Varanasi.
2. Sushrut Samhita
3. Charak Samhita
4. Bhav Prakash Nighantu

LS-610

General LaboratoryExperience - 15 hours/week (2 credits)

1. Standaridization 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 (FixedOilContent)
   h) Determination of Moisture Content(Losson 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 Microrganisms

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 ofKshar-sutra.

Preparation of one ayurvedic formulation from the following sections Solid: Churna, Vati, Satva, Kshar, Guggulu, Lauh, Tablet Semi Solid: Awaleha or Pak, Ointment, Toothpaste (Paste) Liquid: Kwatha, Asava-Arishta, Taila, Syrup

Pharmaceutical Analysis

PA-610

Pharmacopeial Methods ofAnalysis (2 Credits)

1. **Detailing of ICH Q3 and correlation with Pharmacopeia.**

2**. Detailing of ICH Q4.**

a) Pharmacopeial Harmonization.

b) Evaluation and recommendation of Pharmacopeial texts for use in the ICH regions.

3. **Critical comparative analysis of the following tests in IP, BP/EP and USP.**

4. **Pharmacopoeia General notices, amendments in different pharmacopoeia and their usage**

5. **Physical tests**: Viscosity, melting point, boiling point/range, water content and water analysis including Karl Fischer titration, loss on drying, loss on ignition, iodine value, peroxide value, acid value, optical rotation, pH, specific gravity, osmolality/osmolarity, refractive index, MVTR, etc.

6**. CDSCO guideline for phytopharmaceutical, Ayurvedic Pharmacopoeia of India**.

7.**Impurities**: Tests for epianhydrotetracycline and epi tetracycline (USP), elemental impurities, residual solvents, etc.

8. **Microbiological tests and assays**: Antimicrobial (preservative) effectiveness testing, microbial limit tests, sterility test, vitamins assay (zone of exhibition), antibiotics assays, bacterial endotoxin test.

9. **Testing of packaging materials – equipment used, extractable and leachable.**

10. **Basic in dope testing and case studies.**

Recommended books:

1. The Indian Pharmacopoeia, Indian Pharmacopoeia Commission, Ghaziabad.

2. The British Pharmacopoeia, Stationary Office British Pharmacopoeia Commission, London.

3. The United States Pharmacopeia-National Formulary, Board of Trustees, Rockville.

4. TheEuropeanPharmacopoeia,DirectorateforQuality of Medicinesof theCouncil ofEurope.

PA-620

Modern Instrumental Techniques for Evaluation of APIs and Drug Products(2 Credits)

1. **Non-destructive analysis and pharmaceutical visualization**: Principle, instrumentation, qualitative and quantitative applications (including PAT and/or visualization) for the following equipment: FT-NIR, ATR, FT-Raman, X-Ray Diffraction (XRD), Time-of-Flight Secondary Ion Mass Spectrometry. CD and fluorescence spectroscopy.
2. **Thermal techniques**: 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, pharmaceutical applications. TGA: Principle, instrumentation, factors affecting results, pharmaceutical applications.
3. **Particle sizing**: Static & dynamic laser light scattering, Working Principle, Selection between Powder and Suspension Methods.
4. **Analysis of trace components**: Techniques employed for the qualitative and quantitative evaluation of impurities, degradation products, drug-drug and drug-excipient interaction products, metabolites, elemental impurities, residual solvents, etc.
5. **LC-MS**: Variety of mass systems available, their essential differences, strategy for qualitative and quantitative analysis of trace components, specific case studies.
6. **LC-NMR**: Nature of interfaces, qualitative and quantitative applications.
7. **Other Hyphenated Systems**: Utility for the same purpose of GC-MS, CE-MS, SFC-MS, CE-NMR, LC-FT-IR, ICP-MS, GC-HS, IR-MS etc.
8. **Microscopic Allied techniques**:Applications of Advanced Microscopic Techniques Optical Microscopy, Scanning Electron Microscopy (SEM), Transmission Electron Microscopy (TEM) – Basic Principles and Applications to API and Drug product characterization.
9. **Case Studies & Troubleshooting**

Recommended books(latest available edition):

1. Principles of Instrumental Analysis by Dougla A. Skoog, F. James Holler, Timothy A.
2. Nieman
3. Instrumental Method of Analysis by Hobart H. Willard, Lynne L. Merrit, John A. Dean, Frank A. Settle
4. Fundamentals of Fourier Transform Infrared Spectroscopy by Brian C. Smith
5. Modern Raman Spectroscopy: A Practical Approach by Ewen Smith, Geoffery Dent
6. Chemical Analysis: Modern Instrumental Methods and Techniques by FranscisRouessac and AnnickRouessac
7. Handbook of Pharmaceutical Analysis by Lena Ohannesian, Antony J. Streeter
8. HPLC for Pharmaceutical Scientists, Edited by Yuri Kazakevich and Rosario LoBrutto
9. Introduction to Thermal Analysis Techniques and Applications by Michael E. Brown
10. Modern Methods of Particle Size Analysis, Edited by Howard G. Barth
11. 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. **Drug stability testing guidelines**: International, Regional, and National drug stability guidelines.
3. **WHO vs. ICH drug stability testing guidelines**: Comparison of different aspects in WHO guideline, and critical comparison with ICH parent guideline Q1A(R2).
4. **Specific discussion on following ICH guidelines**: Q1B, Q1C, Q1D, Q1E and Q5C.
5. **Additional topics**:
   Stress testing and stability-indicating method development: Role, regulatory aspects, protocols/approaches, practical considerations.
   Stability testing of phytopharmaceuticals and herbal products: Regulatory requirements. **Stability test equipment**: Types of stability chambers (walk-in, stand-alone), design considerations, qualification, and other critical issues.
   Stability testing for Shipping & Distribution: Stability testing during transport, Transportation validation studies.
   Approaches to increase stability.
6. **Case studies w.r.t. Drugs, Biologics and Herbals.**

Recommendedbooks:

1. ICH (www.ich.org) and WHO (www.who.int) guidelines
2. Pharmaceutical Stress Testing (Predicting Drug Degradation) by Steven Baertschi
a. and Karen Alsante
3. Drug Stability (Principles and Practices) by S. James, Jens ThurØCarstensen

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

PA-640

Quality Control and Quality Assurance (2 Credits)

1. **Good manufacturing practices [Schedule M] and Good laboratory practices [Schedule L-I]**: Their applications to the pharmaceutical industry.
2. **Basic principles and concepts of quality management**: Quality control, quality assurance, quality auditing, ISO system, electronic quality management system (eQMS).
3. **Control of raw & packaging material and labelling, sampling, testing, release and distribution of finished products and retesting.**
4. **Document control**: Preparation, review, approval, issuance, storage and retrieval (e.g., master manufacturing and packaging records, site master file, etc.), electronic document management system (e-DMS).
5. **Standard operating procedures in process quality control**: SOP on SOPs, change control procedure, annual product review/product quality review, handling of deviations & non-conformity, corrective & preventive actions (CAPA), handling of laboratory incidents and OOS test results.
6. **Qualification of facility and utilities**: Concepts of facility validation, qualification of HVAC and water systems.
7. **Process validation, product change over, basic requirements of cleaning and its validation**
8. **Technology transfer from R&D to manufacturing, including product life-cycle approach**.
9. **Handling of market complaints, recalls and returned goods**.
10. **Quality risk management in production area, data integrity management**.
11. **Advances in Process analytical technology (PAT) and other control strategies for QbD**.

Recommended books(latest available edition):

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

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

Practicals in lab:

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

Practicals in CIL:

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

Pharmacology & Toxicology		
PC-610	**Drug Metabolism**	**1**
	1. Biotransformation of drugs. 2. Enzymes responsible for bio-transformations, microsomal an 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 of 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**
	1. Role of pharmacology in drug discovery 2. General principles of pharmacological screening. 3. Animal ethics, regulations for conducting animal experimentation, 3 R's concept, alternatives to animal experimentations, Organs-on-chips 4. Pharmacological screening models 6. Correlations between various animal models and human situations. 7. Correlation between in-vitro and in-vivo screens. 8. Metabolic stability studies, CYP enzyme inhibition studies and CaCo-2 cell permeability assay, Single cell gel electrophoresis assay (COMET) assay. 9. Zebrafish model to screen pharmaceutical molecules. 10. Biochemical assays. 11. Introduction to cell culture, role of genomic and proteomic techniques in the process of target identification in drug discovery, MALdiTof., microarray. 12. High throughput screening and high content screening, Humanized and transgenic animal model for drug screening. 13. Pharmacogenomics and Personalized medicine	
PC-620	**CNS and Respiratory Pharmacology**	**2**
	1. CNS drug discovery and challenges. 2. Neurotransmitters: dopamine, 5-HT, excitatory	

	amino acids, GABA, glycine, cannabinoids, melatonin etc; Neurotransmitters receptors, their agonist and antagonists 3. Neuromodulators, neuromediators and transporters 4. Peptides as mediators: Substance P, neuropeptide Y, somatostatin, cholecystokinin, neurotensin, enkephalin, Orexin, CGRP etc 5. Pharmacology of antianxiety drugs, antidepressants, antipsychotic drugs and psychomotor stimulants. 6. Pharmacology of antiepileptics. 7. Pharmacology of antimigraine drugs 8. Pharmacology of local anaestheics, general anaesthetics, sedatives and hypnotics, centrally acting muscle relaxants. 9. Pharmacology of narcotic analgesics, Drug dependence and withdrawal responses 10. Pharmacology of drugs used in neurodegenerative disorders such as Parkinson's disease, Alzheimer's disease, Huntington's disease, Multiple sclerosis 11. Drugs for stroke 12. Pharmacology of nerve growth factors 13. CNS disease models for evaluation of effects of NCEs 14. Gene therapy and cell based therapy for CNS disorders 15. Pharmacology of bronchodilators, pharmacology of anti-inflammatory agents used in asthma& COPD and cough suppressants. Experimental models for Asthma/COPD for evaluation of effects of NCEs	
PC-630	**Autonomic, CVS, Blood, Renal and GI Pharmacology**	**2**
	1. Autonomic Pharmacology A. Introduction to Autonomic Pharmacology: Chemical transmission of in the ANS (cholinergic and adrenergic) B. Pharmacology of muscarinic cholinergic receptor agonists and antagonists. anticholiestrase agents, C.. Pharmacology of sympathomimetic drugs. D. Ganglionic stimulants and blocking agents, neuromuscular blocking agents **2. Cardiovascular Pharmacology** A. Introduction to CVS Pharmacology: CVS drug discovery and challenges B. Antihypertensives drugs and newer targets for hypertension C. Antianginal drugs and newer targets for MI 8. Drugs for Heart failure and antiarrhythmic drugs. D. Pharmacology of Lipid lowering and antiobesity agents **3. Blood**	

	A. Factors necessary for erythropoiesis: Homopoietic growth factors. Mechanism of blood clotting, hematopoietic agents, Oral anticoagulants: Factors increase/decrease the efficacy of oral anticoagulants, Heparin, B. Platelet adhesion and activation: Antiplatelet agents, thrombolytic agents and antifibrinolytic agents and hemostatic agents, integrins as therapeutic agents. New oral anticoagulants (NOACs) **4. Renal Pharmacology** A. Renal Pharmacology: Diuretics, vasopressin **5. GI Pharmacology** A. Pharmacology of GI drugs: Drugs for peptic ulcer, emetics, antiemetics, drug regulating GI motility B.. GI disease models for evaluation of effects of NCEs C. Gut microbiota and its role in diseases, Prebiotics and probiotics	
PC-640	**Autacoids, Endocrine- and Immuno- Pharmacology**	**1**
	1. Introduction to autacoids 2. Pharmacology of histamine: Histamine receptors, histamine agonists and antagonists 3. Pharmacology of bradykinin: Bradykinin receptors, bradykinin agonists and antagonists 4. Pharmacology of eicosanoids: COX inhibitors 5. Pain and inflammatory models for screening 6. Adenohypophyseal hormones and related substances. 7. Thyroid and antithyroid drugs. 8. Insulin and oral hypoglycemic agents, Endocrine pancreas. 9. Adrenocortical hormones: adrenocortical steroids and inhibitors of the synthesis. 10. Agents affecting the calcification, 11. Sex hormones and their inhibitors, contraceptives 12. Introduction to immunopharmacology, immunomodulators, immunostimulants and immunosupperssants, Cancer Chemotherapy	
PC-650	**Clinical Pharmacology and Regulatory Toxicology**	**2**
	1. Introduction to clinical pharmacology 2. Investigational new drug (IND) application, clinical trials, new drug application (NDA) requirements;	

	Regulatory agencies 3. Pharmacovigilance, 4. GCP Guidelines and GLP Guidelines 5. Individualization of drug therapy: Personalized medicine 6. Preclinical testing strategy; Vis-à-vis envisaged clinical studies; Experimental clarification of possible human risk; Technical details of experiments; Flow chart for development of preclinical testing. 7. Single dose and repeat dose toxicity studies: Factors influencing such studies such as species, sex, route, dose level; Data evaluation and regulatory requirements. 8. Reproductive toxicology assessment of male reproductive toxicity: Spermatogenesis; Risk assessment in male reproductive toxicity; Female reproductive toxicology; Oocyte toxicity. 9. Mutagenicity: Mechanisms of mutagenesis, germ cell mutations, somatic cell mutation; Tests systems in vitro, test for gene mutation in bacteria, chromosome damage, in vivo micronucleus tests in rodent, metaphase analysis. 10. Carcinogenicity: Principles of carcinogenicity, dose-setting for carcinogenesis bio assay, transplacental carcinogenesis; Cocarcinogenisis/tumor promotion. 11. Preclinical toxicological requirements for biological and biotechnological products: Safety analysis; problems specific to recombinant products secondary pharmacology. 12. Safety Pharmacology - ICH S7 and S7B guidelines 13. Safety pharmacological studies for pharmaceuticals 14. Safety pharmacological studies for biological products	

RT 650	**Good Laboratory Practices**	**2**
	RT 650 (PC 660 course replaced with RT 650) **Good Laboratory Practices** 1. Introduction to GLP, International Overview, OECD, WHO and FDA 2. Quality control and Quality Assurance. 3. SOP writing and implementation: GLP Establishment. 4. Study plans: Study protocols, Test Item Controller, Veterinarian and Sponsor 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.	
LS 610	**GeneralLabExperienceintheAreaofSpecialization**	**2**
	1. SDS PAGE, western blotting experiment, DNA Gel Electrophoreses experiment, 2. MTT and LDH assay, 3. Gene expression study, PCR/RTPCR 4. Demonstration of Nerve conduction velocity measurement and nerve blood flow measurement 5. Behavioural Experiments for evaluating pain (Hyperalgesia and allodynia) 6. Antibacterial assay MIC calculation 7. Mitochondria isolation and Assays	

SEMESTER-II

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:** Excitory 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,Autophagy,Ferroptosis significance in toxicity evaluation.
8. **Toxicogeneomics 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, coment 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-640Target Organ Toxicology (2 credits)

1. Haematotoxicity: Hematopoiesis,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. Endocrine disruptors: Emphasis on neurotoxic, genotoxic and carcinogenic agent
8. Targets of toxic drugs: Toxicity of chemotherapeutic drugs, antibiotics, antiviral agents.
9. Toxicity of drugs used for chronic treatment: Drug pollutant interactions.
10. Historical control data: Importance in generation of quality data, back ground lesions,

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. Introduction toGLP, International Overview, OECD, WHO and FDA
2. Quality control and Quality Assurance.
3. SOP writing and implementation: GLP Establishment.
4. Study plans: Study protocols, Test Item Controller, Veterinarian and Sponsor
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.Need for scientific research
3. Market requirements.Disease and iNoovative research needs
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 prepara

Semester II

Pharmaceutics

PE-620

Drug Delivery Part – I Controlled Drug Delivery(2 credits)

1. **Influence of drug properties and routes of drug administration on design of sustained and controlled release systems:** Rationale for controlled drug delivery, physico-chemical properties and biological factors influencing the design and performance of sustained/controlled release products
2. **Polymeric materials in controlled drug delivery:** Polymer classification, physical and chemical characterization techniques of biomaterials, biocompatibility testing of biomaterials and their pharmaceutical/biomedical applications in tissue engineering.
3. **Biopharmaceutic and pharmacokinetic aspects of peroral Controlled Drug Delivery Systems:** Strategies and design, factors affecting controlled release drug delivery system, 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.
4. **Peroral controlled release delivery:** Design and fabrication of oral systems, dissolution controlled release, diffusion and dissolution controlled release, Ion-exchange resins, pH-independent formulations, osmotically controlled release, altered density formulations, Case studies
5. **Parenteral drug delivery:** Major routes of parenteral administration; selection, design and development, biopharmaceutics of sustained/controlled release parenteral drugs products, polymer microspheres and their biocompatibility and dispersed DDS.
6. **Transdermal / skin drug delivery system:** Principles of skin permeation, factors affecting percutaneous absorption of drug, sorption promoters, absorption enhancement by energy input- Iontophoresis, sonophoresis and electroporation, pharmacokinetics of skin permeation, design, development and evaluation of transdermal patches, overview of microneedles in transdermal drug delivery.
7. **Implantable Therapeutics Systems** - Historical background; Advantages, disadvantage and applications; Types of implantable therapeutic systems including self-regulated and implantable pump systems; non-biodegradable and biodegradable polymers used for implantable systems, Tissue and blood compatibility testing.
8. **Proteins / peptides drug delivery systems:** Enzyme, epithelial/endothelial barriers, pharmacokinetics, different routes of delivery, practical considerations.
9. **Controlled Ocular Drug Delivery Systems: Ocular route of drug delivery, Ocusert systems, Ophthalmic Punctal plugs**
10. **Regulatory approval pathways involved in controlled release formulations:** New Drug Application and abbreviated new drug applications.

- **11. Role of controlled release in veterinary formulations**: Background and present scenario, formulation considerations, major hurdles and challenges, future prospects

12. Product specific guidelines related to above topics

PE-630

Pharmaceutical Product Development - I (1 Credit)

1. **Development of dosage forms:** Four stage development including preformulation, prototype development, scale up studies and commercialization.
2. **Design of materials and product specifications:** Creation and optimization of material and product specifications. In-process, product release and regulatory specifications.
3. **Quality by design (QbD):** Fundamentals of pharmaceutical quality by design, identification of critical quality attributes, critical material attributes, critical process parameters and quality risk management.
4. **Methods of optimization –** OVAT and Design of experiments (DOE).Experimental designs, screening designs, factorial designs, composite designs, mixture designs, response surface methodology. Applications of systematic optimization techniques.
5. **Process analytical technology (PAT)** and other control strategies for QbD.
6. **Pharmaceutical Packaging:** Pack types for different dosage forms, packaging materials like glass and plastic, selection of proper material, labelling, preformulation screening of package components; barrier, child resistance and temper evident packaging systems; regulatory perspectives.
7. **Testing of packaging materials** – equipment used, extractable and leachable. QC tests for packaging materials
8. **Documentation protocols:** Forms and maintenance of records in product development department including clinical batches.
9. **Case studies or regulatory guidelines** related to above topics shall be discussed after each topic.

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. Implications of quantitative selection of each excipient in product development.
2. **Drug-excipient interaction**: Drug-excipient interaction and incompatibilities like physical, chemical, pharmaceutical and therapeutic, analytical techniques to characterize drug-excipient incompatibility.
3. **Improved tablet production:** Advances in materials, material handling, granulation equipments and granulation technologies; process automation. Processing problems in tablet and troubleshooting.
4. **Tablet coating:** Advances equipment for coating, sugar coating, film coating, advanced coating technologies, Wurster process, aqueous based film coating, solvent free coating, coating defects.
5. **Specialized tablets:** Formulation and evaluation of effervescent, orodispersible and chewable tablets.
6. **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.

7. **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.
8. **Drug Nano-crystals**: Generation – 'top down approach, 'bottoms up approach' and 'mixed approaches', stabilization of nano-crystals and their applications.
9. **Inhalation Products:** Nebulizers, Inhalers – Metered Dose Inhalers (MDI) and Dry Powder Inhalers (DPIs) : Formulation aspects, types of excipients / propellants, devices used and stability aspects. Evaluation of Inhalable products

. 3D Printing: Introduction and Classification of Additive Manufacturing (AM) technologies, Advantages, AM versus Pharmaceutical Conventional manufacturing processes. AM for Oral solid dosage forms,Stability, Safety, Efficacy, Scalability of AM technology, Regulatory challenges, Cost-effectiveness..

PE-650

Drug Delivery Part II - Targeted Drug Delivery and Novel Carrier Systems

(2 Credits)

1. **Fundamentals of targeted drug delivery:** Need of targeted drug delivery, ligand receptor interaction, levels of targeting, active and passive targeting, EPR effects, receptor mediated endocytosis, multifunctional approach in targeted drug delivery.
2. **Chemical drug delivery systems:** Prodrug concept for drug design, drug targeting and antibody directed enzyme prodrug therapy (ADEPT), soft drug design, Lipid-drug/ polymer-drug conjugate.
3. **Targeted brain delivery:** Overview of brain, specific targets for brain delivery, Nasal to brain delivery, types and key elements: Ideal carrier system and approach with case studies depicting utility in various brain diseases.
4. **Targeted Tumor Delivery:** Structural features of tumor vasculature, levels of tumor targeting, tumor ligands for targeted drug delivery, biopharmaceutical characteristics of delivery systems for tumor specific delivery.
5. **Colloidal drug delivery systems:** Preparation and characterization, biopharmaceutical considerations, evaluation and applications in drug delivery of the following delivery vectors:
   a) Liposomes and niosomes
   b) Solid lipid nanoparticles and nanostructured lipid carriers
   c) Polymeric nanoparticles – Biodegradable polymers, synthetic and natural polymers
   d) Carbon nanotubes
6. **Overview of Specialized drug delivery systems:** Transfersomes,ethosomes, Layersomes, Bilosomes, Emulsomes, Virosomes, Cubosomes, Aquasomes, Pharmacosomes. Dendrimers, nanoemulsion, self emulsifying drug delivery systems, Polymeric micelles and Resealed Erythrocytes
7. **Stimuli responsive drug delivery systems:** Magnetically, thermal and pH-assisted drug delivery systems.
8. **Miscellaneous targeting approaches:** Fundamentals of gene delivery,Overview of colon, liver, macrophage, mitochondrial and M cells targeting.

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, enatiotropy / monotropy, concept of transition temperature, Burger and Ramberger rule.
4. **Crystallization process**: Molecular aggregation events in crystallization, energetic of crystallization, enthalpy entropy balance, types of nucleation, Ostwald's step rule, experimental protocols for polymorph screening.
5. **Implications of polymorphism in pharmaceutical development**: Regulatory concerns related to polymorphism, introduction to latest regulatory position on polymorphism.
6. **Amorphous state**: Definition, long range order versus short range order, disorder in the amorphous state, concept of glass transition temperature (Tg), thermodynamic necessity for Tg, entropy crisis.
7. **Role of amorphous state in drug delivery**: Solubility advantage, spring parachute effect during solubility studies, physical instability of the amorphous form, techniques for stabilization of amorphous form, amorphous solid dispersions.
8. **Co-crystals**: Introduction, synthons used for formation of co-crystals and applications in drug delivery
9. **Particulate level properties**: Crystal habit, generation of different crystal habits, implications of crystal habit on product performance and processing.
10. **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 different nano drug delivery systems, , formulation development and evaluation, Hands on training on spray drying, freeze drying, hot melt extrusion, DSC, permeability testing.

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:** Lymphoidcells,Tcells, Bcells, 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 surfacemarkers, 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. **Naturalkiller 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 antibodiesa 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 MTYT assay, assay for apoptosis, cell-line derived assays, whole animal assays, etc.

4. **Principles, methods and applications of immuno-diagnostics:** Principles and methods of some clinically used diagnostic immunoassays, e.g., homogeneous immunoassays, fluorescence, chemiluminescence and bioluminescence enzyme immunoassays, immunoblot, immunoaffinity, immunoprecipitation, biotinylation, immunosensors.
5. **Principles, methods and applications of DNA-based diagnostics:** DNA probe based diagnostics, sample preparation, hybridization, separation, detection, PCR-RFLP in paternity and forensic cases SNP detection MALDI and DHPLC.
6. **Diagnostics:** Cancer diagnostics, human retroviral diseases specially AIDS. Role of enzymes in diagnostics.
7. **High-throughput screening:** Requirements and parameters, Advantages and disadvantages of biochemical and cellular assays; miniaturization and automation.
8. **Cell-based screening assays:** Advantages over in vitro assays. Different formats: radioactive, luminescence, fluorescence, etc. Assays compatible with cell membranes: GTPγS, 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, β-arrestin, receptor internalization, reporter gene assays; orphan GPCRs; desensitization and internalization.

Recommended books:

1. The Immnoassay 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 α-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.

BM-610 Gene Therapy (1 credit)

1. **Overview of Gene Therapy**: Historical perspective, introduction, basic concepts, Somatic and germ line genetherapy.

2.**Gene Editing and targeting:** Gene replacement and gene addition. Transductional and Transcriptional targeting. Transduction of antisense constructs, Intracellular antibodies, RNA interference;Gene editing by engineered nucleases: Zinc finger nucleases (ZFN), Transcription activator like effector nucleases (TALENs), Cas nucleases of CRISPR Cas 9 system.

3. **Molecular Basis of Gene Therapy:** Gene Therapy Vectors, Vector Considerations, Vector Design and Preparation, Gene Therapy Challenges, Viral vectors for gene therapy, Non-viral gene transfer, liposomes.

4.***In vivo* Gene Therapy**: Indications in *in vivo* gene therapy, viral vectors: adenovirus, retrovirus, adeno-associated virus, non-viral vectors, delivery systems, challenges.

5.***Ex vivo* Gene Therapy**: Indications in *ex vivo* gene therapy, Chimeric Antigen receptor (CAR) T-cell Therapy, Vectors, Conditioning, Insertional Oncogenesis, Adrenoleukodystrophy.

6. **Gene Therapy in Cancer**:Specific aspects of cancer gene therapy, Proliferation-dependent vectors; Combined therapy, RNA-DNA chimera, Criglar-Najjar syndrome I.

7. **Gene Therapy of Inherited Diseases**:Severe combined immunodeficiency syndrome (SCID), Cystic fibrosis, Duchenne muscular dystrophy, Inherited coagulopathies, Tyrosinemia.

8. **Gene Therapy of Acquired Diseases**:Infectious diseases, Ocular disorders, ischemic diseases

9.**Regulatory and Ethical Considerations**: Safety issues at preclinical and clinical stage, Regulatory laws, Ethical issues, FDA and other guidelines.

10.**Recent Advancements in Gene Therapy and Future Prospects**: Gene therapy products, Commercially available products

Recommended books:

1. Friedman T. 1999. The Development of Human Gene Therapy. Cold Spring Harbor,NY: Cold Spring Harbor Lab. Press.
2. Knipe DM, Howley PM, eds. 2001. Fields Virology. Philadelphia, PA: Lippincott Williams & Wilkins.

3. Hackett NR, Crystal RG. 2000. Adenovirus vectors for gene therapy. In Gene Therapy, ed. NS Templeton, DD Lasic, pp.17-39. New York: Marcel Dekker

BT620 Recombinant DNA Technology (2 credits)

1. **Basic TechniquesinGeneAnalysis:**Purificationandanalysisofnucleicacids, Isolation ofDNAandRNA,plasmidpurification, agarose, polyacrylamideandpulsefieldgelelectrophoresis,southern,northernandwesternblotting.

2. **DNAModifyingEnzymes:**TypeI,IIandIIIrestrictionenzymes,reverse transcriptases,ligases,polymerases,kinasesandphosphatases.

3. **PCR & Mutagenesis:** PCR enzymes, primer design, RT-PCR, Real time PCR, cDNAsynthesis,applicationsofPCR,randomandsitedirectedmutagenesis,primerextensionmutagenesis,strandselectionmutagenesis,cassettemutagenesis,PCRbasedmutagenesis,QuikChangemutagenesis.

4. **Vectors:** Cloning, and expression vectors, Plasmids, selectable markers, blue-whiteselection,phage,yeastvectorsandYACs.Tagsforpurificationandvisualization,bacterialtransformation,manualandautomatedsequencing.

5. **PlantBiotechnology:** *Agrobacteriumtumefaciens*,vectors,nuclear,chloroplasttransformation,pestresistance,delayoffruitripening,antibodygenerationinplants,ediblevaccines.EthicsofrDNA products.

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

7. **Viralvectors:**Adenovirus,adeno-associatedvirus,baculovirus,herpesvirus,retrovirus-basedexpressionsystems.

8. **Genetargeting:**Randomandspecific,*Cre/loxP*system,knock-outmice.

9. **Transgenicanimals:**Principle,nucleartransferfromsomaticcells,stemcells,testsforpluripotency,mouse,frog,Drosophila.

10. **Protein 'pharm'ing:** Design of second generation therapeutic molecules, examples ofengineeredproteinsoftherapeuticpotential,toolsforproteinengineering,library-basedselectionmethods.

11. **Genetherapy:**Somaticcellgenetransfer,autologousandnon-autologous*ex*vivogenetherapy,prospectsandlimitations.

12. **Nucleicacidtherapeutics:**Antisensetechnology,siRNA,trans-splicing,ribozymes,aptamers,casestudies,advantagesandchallenges.

Recommendedbooks:

1. PrinciplesofGeneManipulationandGenomics(7th edition)bySandyPrimroseandRichardTwyman,Wiley-Blackwell

2. AnalysisofGenesandGenomesbyRichardJReece,JohnWilley&Sons
3. MolecularBiotechnology:PrinciplesandApplicationsofRecombinantDNA(4th edition)byBernardR.Glick,JackJ.PasternakandCherylL.Patten.ASMPress
4. Relevantreview&researchpapers

BM-620 Cell-based Therapy and Protein Engineering (2 credits)

1. *Introduction to cell-based therapy****: Basic cellular biology, Cell culture and maintenance in aseptic conditions, cell processing and handling techniques, Cryopreservation and cell analysis***

2. *Diseases pertinent to cell-based therapy****: Autoimmune diseases, cancer, neurological disorders including spinal cord injury and other diseases***

4. *Adoptive Cell Therapy****: Blood transfusion and Stem cell therapy. Chimeric antigen Receptor-T (CART)-Therapy, Tumor Infiltrating Lymphocyte (TIL) therapy, Dendritic Cell (DC) based therapy, Natural Killer (NK) cell therapy***

5.Risk, advantage and future of cell-based therapy.

6. Limitations of naturally occurring proteins. Difference between optimal and maximal function.

7. Structural modification of proteins. Random and site-directed mutagenesis. Fitness of mutants.

8. Exploiting promiscuity to generate enzymes of industrial importance.

9. Tools of directed evolution of proteins. Computational tools of protein design.

10. Conjugation chemistry and stabilization of proteins.

Recommended reading

1. Hand book of Stem Cell Therapy, Edited by Khawaja H Haider, Springer Nature

2. Cell Therapy: Current Status and Future Direction, Edited by Dwaine F. Emerich and Gorka Orive, Humana Press

3. Protein Engineering: Principles and Practice by Jeffrey L. Cleland and Charles S. Craik

4. Bioconjugate Techniques (3rd edition) by Greg T. Hermanson

5. Protein Engineering: Tools and Applications by Huimin Zhao, Sang Yup Lee, Jens Nielsen, Gregory Stephanopoulos

6. Related reviews and research papers

BM-640 Enzymology and Enzyme-based Therapeutics (2 credits)

1. **Introduction to enzymes**: Classification of enzymes, concept of active site and enzyme substrate complex; mechanisms of action and principles of catalysis, enzyme specificity.

2. **Coenzymes and cofactors**: Coenzymes, cofactors, mechanism ofaction of coenzymes, role of cofactors in catalysis.

3. **Enzyme Regulation**: Regulation of enzymes, effect of parameters on enzyme activity, allosteric enzymes, isoenzymes, covalent modification, multi-enzyme complex.

4. **Enzyme kinetics**: Enzyme kinetics, Michaelis–Menten equation, kinetic parameters, turnover number; enzyme inhibitors, types of inhibition, substrate inhibition.

5.**Mechanism of catalysis:** Covalent catalysis, catalysis by proximity and orientation, acid-base catalysis and metal ion catalysis.

6. **Enzyme purification and enzyme assays**: Various methods for isolation of proteins, enzyme assays

7. **Improving properties of therapeutic enzymes**: Limitations therapeutic enzymes - poor pharmacokinetics, immunogenicity, Approaches for improvement - PEGylation, glycosylation, encapsulation, etc.

8. **Enzyme-based Therapeutics**: Enzyme-based therapeutics under development, recombinant enzymes in clinical uses, their status and markets.

9. **Enzyme replacement therapies**: Laronidase, Idursulfase, Agalsidase beta, Sebelipase alfa, Alglucosidase alfa, Galsulfase, etc.

10. **Other examples of Enzyme-based Therapeutics**: Enzymes as anti-cancer agent, asparaginase, arginase etc, Enzymes as thrombolytic agent, t-PA, streptokinase.

Recommended books:

1. Lehninger Principles of Biochemistry by David L. Nelson & Michael M. Cox (W.H. Freeman & Company)
2. Biochemistry by Stryer (W. H. Freeman & Company)
3. Review Articles (will be provided by Coordinator)

BT-650 Analysis, Diagnostics and Cell Based Screening (2 credits)

1. **Total protein assay:** Quantitative amino acids analysis, Folin-Lowry protein assay, BCAassay,UVspectrophotometry,*etc*.
2. **Purity:** Protein impurities, contaminants, electrophoretic analysis, HPLC based analysis,DNAcontentanalysis,immunologicalassaysforimpurities,combinedimmunologicalandelectrophoreticmethods,host-cellimpurities,etc.ICHguidelines.
3. **Potencyassays:**In-vitrobiochemicalmethods,MTTassay,assayforapoptosis,cell-linederivedassays,wholeanimalassays,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: GTPγS, 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, β-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

BM-670 Artificial Intelligence, Machine Learning and Computational (1 credit)

Biopharmaceuticals

1. **Pattern recognition**: Introduction to pattern recognition and data mining, clustering vs. classification;applications; data handling and preprocessing, feature selection, normalization, dataset preparation:training, test, external; training of model; validation of model: internal validation, k-fold cross validation,external validation, y-randomization; applicability domain analysis, learning paradigms: supervised andunsupervised.
2. **Machinelearningalgorithmsforclassification**:k-NN,PNN,SVM
3. **Machinelearningalgorithmsforclustering**:Differentdistancefunctionsandsimilaritymeasures,K-meansclustering,singlelinkageandcompletelinkageclustering,hierarchicalclustering,logicbehindthesealgorithms.
4. **Artificialintelligence**:Overviewonbasicconceptsanditsapplicationin Biopharmaceuticals.
5. **Artificial neural network**: Overview of biological neuro-system, mathematical models of neurons, ANNarchitecture,learningrules,ANNtrainingalgorithms-perceptions,trainingrules,delta,backpropagationalgorithm,multilayerperceptronmodel,applications of ANNs.
6. **Genetic algorithms**: An overview, GA in problem solving, implementation of GA, selection, mutations,crossover.
7. **Fuzzylogic**:Introductiontofuzzylogic,classicalandfuzzysets:overviewofclassicalsets,membershipfunction,fuzzyrulegeneration,operationsonfuzzysets:compliment,intersections,unions,combinations ofoperations,aggregationoperations;applicationoffuzzy logic inmedicine.

Recommendedbooks:

1. PatternRecognitionandMachineLearningbyBishop,Christopher,Springer
2. PatternRecognitionbySergiosTheodoridisandKonstantinosKoutroumbas,AcademicPress
3. DataMiningandAnalysisFundamentalConceptsandAlgorithmsbyMohammedJ.ZakiandWagnerMeira,Jr,CambridgeUniversity Press
4. DataMining:PracticalMachineLearningToolsandTechniquesbyIanH.Witten,EibeFrank,MarkA.HallandChristopherJ.Pal,MorganKaufmann
5. NeuralNetworksforChemists:AnIntroductionbyJohannGasteiger,Wiley
6. ArtificialIntelligenceandMolecular BiologybyLawrenceE.Hunter, AAAIPress
7. AHandbookofStatisticalAnalysesUsingRbyTorstenHothorn,BrianS. Everitt,CRCPress

BM-680 Omics in Drug Discovery (1 credit)

1. **Genomics**: Introduction to genomics and genome sequencing technologies; annotating genomes; comparative genomics; single nucleotide polymorphisms (SNPs); cancer genomics, understanding pathogenesis, identification of disease genes, discovery of putative drug targets

2. **Transcriptomics**: Evolution of sequencing technologies; quantification of the gene, transcript and isoform expression; gene and transcript annotation; single-cell transcriptomics; comparative transcriptomics; disease mechanisms, mode of action of compounds; early prediction of adverse drug target effects, microarrays

3. **Next-Generation Sequencing**: Introduction to next generation sequencing; basic NGS practices, NGS data acquisition, processing raw data, construction of *de novo* assemblytranscript annotation and transcript quantification; applications of NGS

4. **Metabolomics**: Introduction to metabolomics, challenges and potential applications, targeted metabolomics, untargeted metabolomics, analytical platforms for data acquisition and processing.

5. **Experimental Approaches in Proteomics**: Introduction, applications, methods of protein resolution from complex mixtures: Cell lysates, Serum proteins using 2DE, DIGE, stable isotope labeling by amino acids in cell culture (SILAC), isotope coded affinity tag (ICAT). Biomarker identification from cells, tissue as well as biological fluids; understanding post-translational modification, drug target efficacy and safety evaluation.

6. **Mass spectrometry**: Principles and applications. Protein identification by Mass spectrometry; Study of post-translational modifications and glycoprotein analysis by 2DGE and MS.

7. **Lipidomics**: Application of lipidomics in biomedical sciences, metabolic syndrome, cancer, cardiovascular diseases, analytical tools.

8. **Immunomics**: Introduction, traditional vaccinology, reverse vaccinology, immunomics based vaccinology, computational methods for prediction, immunomics of viruses, immunomics of parasites, immunomics of bacteria,

immunomic microarrays, lymphochip, T-cell and B-cell epitope mapping tools, role in clinical development

9. **Single-Cell Multi-omics and its Techniques**: Introduction, single cell data generation, Flow Cytometry, Mass Cytometry, IsoLight, mutiparametric tissue imaging, genomic cytometry, biomarker discovery and novel target identification.

10. **Multi-omics in drug discovery**: Tumor and Cancer, Malaria, Viral diseases, Fungal diseases, Bacterial infections, Biomarkers.

Recommended books:

Bioinformatics and Functional Genomics, Pevsner (3rd edition)

Practical Computing for Biologists, Haddock and Dunn

Primrose SB, Twyman RM (2006). Principles of gene manipulation and genomics. Blackwell Publishing

Simpson R (2002). Proteins and proteomics: A laboratory manual. Cold Spring Harbor Laboratory Press.

LS-610 GeneralLaboratoryExperience-10hours/week (2credits)

1. Expression and purification of a target protein by pseudoaffinity chromatography; monitoring purification by SDS-PAGE.
2. Characterization of purified protein by western blotting and ELISA. Estimation of protein by different techniques.
3. Studying kinetic parameters of an enzyme (Enzyme kinetics, time course,effect of pH, temperature, ionic strength, inhibition studies and characterization)
4. Use of spectroscopic tools to monitor chemical denaturation of a protein; estimating physiological stability of a protein; role of stabilizers in maintaining protein integrity.

Pharmacoinformatics

PI-610

Pharmacoinformatics-Bioinformatics (2credits)

1. Bioinformaticsbasics:Computersinbiologyandmedicine,InformationChaos,Challengesinpostgenomicera,Database concept,Proteinandnucleicaciddatabases, specialized genome databases (HGD, MGD, SGD, TIGR, and ACeDB).
2. Databasesandsearchtools:Structuraldatabases,Genedatabases,Proteindatabases,Searchingdatabases,TheNCBI;Pub liclyavailabletools,ResourcesatEBI,Resourcesontheweb;Databaseminingtools, Alphafold.
3. Proteinfolding:Diversityinproteinsfunctionandproteinstructure,Linkbetweensequence,structureandfunction,Misfo ldingproblem,Anfinsen'sdogma,Lavinthal'sparadox,Challengesinunderstandingstructure,Methodsfordetermining3 Dstructure,Proteindatabank,Visualizationofmacromolecules.
4. ProteinFlexibility:Dynamicmotioninbiologicalprocesses,Motionandfunction,Examples,Typesofmolecularmotions ,Timescaleofproteinmotion,Methodstostudyproteinmotion,Databaseofmacromolecules,Onlineserversandsoftware tools.
5. Molecularrecognition:Processofrecognition,Complementaryfeaturesuponbinding,Toleranceuponbinding,Inducedf ittheory,Adaptationofenzymeandligand,Dominoeffect,Ensembleofconformations,Forcesinvolvedinrecognition,So lventeffect,Hydrophobiceffect.
6. Secondaryandtertiarystructureofproteins:Proteinarchitecture,Conformation,Ramachandranplot,Characteristicsofs econdarystructuralelements,Alphahelices,Betasheetandreverseturns,Supersecondarystructure,Domains,Newlevels ofproteinarchitecture.
7. Classificationofproteinfoldsandtopology:Allalphatopology,Allbetatopology,Alpha-betatopology,Alpha+betatopol ogy,Classificationofproteins,CATH,SCOP.
8. SequenceAlignment:DNA/proteinsequencesanalysis,Alignment,pairwiseandglobalalignment,Multiplealignment,s tructurebasedalignment,softwaretools,BLAST,FASTA,CLUSTAL,Scoringmatrices,Algorithms,Needleman-Wun schandSmith-Watermanalgorithms,Dynamicsprogramming, Molecular Phylogenetics.
9. Structurepredictionofproteins:Homologymodeling,Templateselection,Sequencealignment,Secondarystructurepre dictionmethods,Onlineserversandsoftware,Proteinmainchainandsidechainmodeling,Loopmodeling, Tweak Algorithm,Refinementandevaluationofmodels,StructurepredictionofGPCRs, Fold recognition methods, *Ab initio* method for structure prediction, software used for 3D structure prediction Structural genomics and its application.
10. Applicationsofbioinformatics:Proteinshistory,Proteinsandpharmaceuticalindustries,Diseaseareas,Complexprotein s,Applications,structurebaseddrugdesign.

Recommendedbooks:

1. EssentialsofGenomicsandBioinformaticsbySensen,ChristophW.D.,Wiley-VCH
2. EssentialBioinformaticsbyXiong,Jin,CambridgeUniversityPress

3. SequenceAnalysisinaNutshell:AGuidetoCommonToolsandDatabasesbyMarkel,Scott,O'Reilly
4. StructuralBioinformaticsbyBourne,PhilipE.,Wiley-Blackwell
5. ComputationalBiologyandGenomeInformaticsbyWang,JasonT.L.,WorldScientific
6. ComputationalMolecularBiology:AnIntroductionbyClote,Peter,John-Wiley
7. IntroductiontoBioinformaticsbyLesk,ArthurM.,OxfordUniversityPress
8. Bioinformatics:APrimerbyNarayanan,P.,NewAgeInternationalPublishers
9. Bioinformatics:Concepts,Skills&ApplicationsbyRastogi,S.C.,CBSPublishers&Distributors
10. DiscoveringGenomics,ProteomicsandBioinformaticsbyCampbell,A.Malcolm,Pearson

PI-620

Pharmacoinformatics-Chemoinformatics (2credits)

1. Structurepredictionmethods:2D,3D,representingchemicalstructuresin1Dnotationssearchinganalyzing.4D-7Ddefinitionofstructure.Morganalgorithm.Similaritysearching:Tanimotocoefficient,Sorensencoefficient,Carbocoefficient,Euclideandistance,powerdistance,Soergeldistance,Hammingdistance.Fullstructuresearchandpartialstructuresearch.
2. Matricesofchemicalstructures:Adjacencymatrix,bondmatrix,distancematrix,etc.,Hashcodes,bitmapgeneration,fragmentbasedmethods.Coordinatematrix,z-matrix;theirinterconversion.Descriptorgeneration:Moleculargraphsandmoleculartrees,2DQSAR:structure-activityrelationships;Weinerindex,Hosayaindex,Randicindex,Balabanindex,etc.topologicaldescriptorgeneration.
3. Chemoinformatictools:CDKtools,CCSDtools;Scifindertoolsandalgorithmsassociateswiththesetools,algorithmsassociatedwithsearchtools.Webbasedapplicationsinchemoinformatics:MolEngine,ChemAxon,sysmentreactiontool.Combinatoriallibrary:designandmoleculardiversity;Applicationsinstructure-baseddrugdesign,enumerationtechniques.
4. Algorithmsinchemoinformatics:C++codegenerationforsmilesnotation,matrices,linearregression,Newton-Raphsonmethod,conformationalsearch.Geneticalgorithms.Chemoinformaticsdatabases:Creation,analysisofchemoinformaticsdatabases.Generatereportsfromthechemicaldatabases.
5. Pharmacoinformatics:IntegrationofBioinformatics,Chemoinformatics,genomicsandproteomics.*Insilico*identificationandvalidationofnoveltherapeutictargets:Bioinformaticsfollowedbycomputationalbiology,Homologymodeling.Patternsearchingmethodsindrugidentification.Abinitiogenepredictiontechniquestopredictnovelgenetargets.Casestudies.
6. Databasesinpharmacoinformatics:Evaluationofdiversecompoundsubsetsfromchemicalstructuredatabases.Recognitionofhypotheses,validationofhypothesesusingpharmacophorepatternsearchingmethodsinchemoinformatics.SpectralandCrystallographicdatabases.3Ddatabasesearchmethods:Artificialneuralnetworkmethods,Geneticalgorithmmethodsinchemoinformatics.
7. Virtualscreening:Leadcompoundselectionandleadoptimizationusingvirtualscreening.Filteringmethods.RapidQSARmethodsforvirtualscreening,Rapidmoleculardockingmethodsforvirtualscreening.

8. Receptorselectivitymapping.Testingtheleaddrugcandidates(fromchemoinformaticsmethods)fortheirselectivityacrossabroadpaneloftargets(frombioinformaticsmethods).Scoringfunctionsandtheirimportanceinvirtualscreening.Casestudies.Internetcomputingindrugdiscovery.
9. AlgorithmsinpharmacoinformaticsDevelopmentofsmallpackagesforPharmacoinformaticsanalysis.Advancedalgorithmsindescriptordevelopment.AlgorithmsforQSAR.
10. Casestudies:Pharmacoinformaticsinanti-diabeticdrugdesign,Pharmacoinformaticsinanti-malarialdrugdesign.Quantumchemicalmethodsintroglitazonetoxicity,metabolismofomeprazole,proguanil,mechanismbasedinhibition.

Recommendedbooks:

1. ChemoinformaticsbyJ.Gasteiger,Wiley-VCH
2. IntroductiontoChemoinformaticsbyA.R.Leach,Springer
3. Chemoinformatics:Concepts,Methods,andToolsforDrugDiscoverybyJ.Bajorath,HumanaPress
4. ChemoinformaticsandComputationalChemicalBiologybyJ.Bajorath,HumanaPress
5. TextbookofDrugDesignandDiscoverybyUlfMadsen,T.Liljefors,PovlKrogsgaard,CRCPress

PI-650

Pharmacoinformatics-DatabaseManagement (1credit)

1. DatabaseManagement:Data,database,databasevsfileorientedapproach,databasemanagementsystem,typesofdatabases,databasesmodels,three-schemaarchitecture,dataindependence,datadictionary,generalarchitectureofadatabasemanagementsoftware,componentsofDBMS,deriveddatabases,datamining,datawarehouse,datalake.
2. RelationalDatabaseDesign:BasicDBMSterminology,Entities,Attributes,Relationships,ER-Diagram,Dependencies,Normalizationforms,dataintegrity
3. SQL:IntroductiontoSQL,FundamentalsofSQL,SQLdatatypes,typesofstatements,createanddropdatabase
4. DataDefinitionLanguage(DDL):creatingtables,constraints,altertable,addanddropcolumns,createview,truncatetable,renametableandcolumn,droptableandview
5. DataManipulationLanguage(DML):Insertingrecords,deletingrecords,modifyingrecords,retrievingandmanipulatingdata:where,orderby,groupby;operators:arithmetic,logical,comparison;SQLfunctions;aggregatefunctions:maximum,minimum,countingrecords,average,sum;joins:typesofjoin,havingclause;inlineviews,subqueries,wildcards,distinct
6. DatabaseSecurityandPrivileges,GRANTCommand,REVOKECommand,COMMITandROLLBACK,BackupandRecovery
7. PHPProgramming:Datatypesandvariables,constants,operators,statements,strings,selections,loops,comments,functions,arrays.
8. DatabaseConnectivity:Connecttomysql:createdatabaseandtable,insertrecords,deleterecords,updaterecords,retrievedata.
9. FileOrganization:Heap,Sequential,IndexingandHashing.

10. SystemDevelopmentLifeCycle:SystemAnalysisandDesign,Development,Testing,Implementation,Maintenance,SDLCModels.

Recommendedbooks:

1. LearningSQLbyAlanBeaulieu,O'Reilly
2. DatabaseSystemsbyRobCoronel,Thomson/CourseTechnology
3. PrinciplesofDatabasesbyJDUllman,GalgotiaPublications
4. LearningPHP,MySQL&JavaScript:WithJQuery,CSS&HTML5byRobinNixon,O'Reilly
5. FileOrganizationandProcessingbyAlanL.Tharp,Wiley-India
6. AnalysisandDesignofInformationSystemsbyArthurM.Langer,Springer

PI-660

DataAnalytics (2credits)

1. Patternrecognition:Introductiontopatternrecognitionanddatamining,clusteringvs.classification;applications;datahandlingandpreprocessing,featureselection,normalization,datasetpreparation:training,test,external;trainingofmodel;validationofmodel:internalvalidation,k-foldcrossvalidation,externalvalidation,y-randomization;applicabilitydomainanalysis,learningparadigms:supervisedandunsupervised.
2. Machinelearningalgorithmsforclassification:k-NN,PNN,SVM
3. Machinelearningalgorithmsforclustering:Differentdistancefunctionsandsimilaritymeasures,K-meansclustering,singlelinkageandcompletelinkageclustering,hierarchicalclustering,logicbehindthesealgorithms.
4. Artificialintelligence:Overviewonbasicconceptsanditsapplicationin Pharmacoinformatics.
5. Artificialneuralnetwork:Overviewofbiologicalneuro-system,mathematicalmodelsofneurons,ANNarchitecture,learningrules,ANNtrainingalgorithms-perceptions,trainingrules,delta,backpropagationalgorithm,multilayerperceptronmodel,applicationsofANNs.
6. Geneticalgorithms:Anoverview,GAinproblemsolving,implementationofGA,selection,mutations,crossover.
7. Fuzzylogic:Introductiontofuzzylogic,classicalandfuzzysets:overviewofclassicalsets,membershipfunction,fuzzyrulegeneration,operationsonfuzzysets:compliment,intersections,unions,combinationsofoperations,aggregationoperations;applicationoffuzzylogicinmedicine.
8. Expertsystems:Expertsystems(knowledge-basedsystems),expertsystemexamples,expertsystemarchitectures,rulebasedexpertsystems,statisticalsystems,hybridsystems,non-monotonicexpertsystems,decisiontreebasedexpertsystems.
9. Rlanguage:IntroductiontoRprogramming,functions,variables,datatypes,operators,datastructuresinR,objects,classes
10. ApplicationofmachinelearningalgorithmsusingR

Recommendedbooks:

1. PatternRecognitionandMachineLearningbyBishop,Christopher,Springer
2. PatternRecognitionbySergiosTheodoridisandKonstantinosKoutroumbas,AcademicPress

3. DataMiningandAnalysisFundamentalConceptsandAlgorithmsbyMohammedJ.ZakiandWagnerMeira,Jr,CambridgeUniversityPress
4. DataMining:PracticalMachineLearningToolsandTechniquesbyIanH.Witten,EibeFrank,MarkA.HallandChristopherJ.Pal,MorganKaufmann
5. NeuralNetworksforChemists:AnIntroductionbyJohannGasteiger,Wiley
6. ArtificialIntelligenceandMolecularBiologybyLawrenceE.Hunter,AAAIPress
7. AHandbookofStatisticalAnalysesUsingRbyTorstenHothorn,BrianS.Everitt,CRCPress

PI-670

Pharmacoinformatics–PerlProgramming (1credit)

1. Introduction to Perl: History, Applications, Built in functions, Data types, introduction to operators, print function, command line program, user input using <STDIN> operator, Perl and operating systems, Shebang Directive.
2. Perl operators: Arithmetic operators, Relational operators, Logical operators – And, Or, Not, assignment operator, Bitwise operators, precedence of operators, auto increment and decrement operators, chomp, comma operators and usage, placing increment operators before and after variable, significance.
3. Scalar variable:Identifier, Special characters in scalar variable names, Assignment of scalar variable, Strings and Numbers, Single quoted and Double quoted strings, back slash interpretation, variable interpolation, scalar variable in number and string context
4. Regular arrays and Hash arrays: Identifiers, Creating arrays, Accessing and retrieval of elements, Array slices, Array operators- Push & Pop, Unshift & Shift, Hash arrays, Keys, Values, Retrieval of elements.
5. Control structures: Statement blocks, Branching structures, if/else, nested if/else statements, Looping Structures, The while statement, The until statement, do…while and do…until structures, The for loop, initial expression, test expression, increment expression, Variations of the for loops, for loops as timing mechanisms for programs, foreach loop, for loops and operators,Perl programs using control structures.
6. Subroutines: Subroutine data types, Declaring subroutines, Calling subroutines in Perl, Writing subroutine, Return function, Scope of variables in subroutines, Globalvariables, Local variables-dynamics and lexical variable, Advantage and disadvantages of variables, Returning value from subroutines, Examples using Perl programs.
7. File handles: Standard input and Standard output, Formatted output, printf functions, printf for character, decimal and floating point numbers, Angle operators, Here strings, Here as markers, Printing with here strings, File input/output, Opening and closing files, reading, writing, appending, File tests, Handling file opening errors, warn and die functions, File tests, Examples using Perl programs.
8. Pattern matching and Regular expressions: Special character for pattern matching, Writing regular expressions, Meta characters for beginning and ending of strings, Special variables, Wild cards, Quantifiers, Matching specific types of characters- single digit, single word, white space character, Invert digits, words, white space, invert character classes, Flags for case insensitive, Sub expressions, Examples using Perl programs.
9. **Biocomputing**: Introduction to BioPerl, Retrieval. Installing Procedures, Architectures, General BioPerl Classes, Sequences -Bio::Seq, Bio::SeqIO, Bio::Align class etc, Sequence Manipulation, Features and Location Classes-Extracting CDS, Alignments -AlignIO, Analysis -Blast, Databases- Database Classes, Accessing a Local Database alignment of sequences using applications

RecommendedBooks:

1. ProgrammingPerlbyLarryWall,O'Reilly
2. BeginningPerlforBioinformaticsbyJamesTisdall,O'Reilly
3. EffectivePerlProgrammingbyJosephN.Hall,AddisonWesley
4. PerlfromtheGroundUpbyMichaelMcmillan,OsborneMcGraw-Hill
5. TheCompleteReferencePerlbyMartinC.Brown,TataMcGraw-Hill

PI-680

Pharmacoinformatics – Python Programming (1 credit)

1. **Introduction to Python**: History of python, setting up python environment, Anaconda installation, Jupyter or Py-Charm Notebook, executing simple python programs, working of python, python character, print() function, variables, literals and data types.
2. **Operators and data types**: formatting numbers and strings, escape characters and quotes, string methods (length, string traversal, slicing, comparison, find, looping, counting, etc), operators (arithmetic, assignment, comparison, membership, boolean), string operators, introduction to numpy and pandas.
3. **Control flow or decision statements in Python**: Introduction to if, else and elseif, if statements, for and while loops, nested loops, break and continue statement
4. **Regular expression and functions**: concept and type of regular expression, basics of function, use of functions, parameters and arguments, local and global scope of a variable, return statement and recursive functions.
5. **Data structure**: creating lists, basic list operators, slicing, inbuilt function of lists, splitting, need of dictionary, creating dictionary, adding and replacing values, retrieving values, deleting items and traversing dictionaries. Tuples and sets: creating tuples, tuple function, inbuilt tuple functions, operations on tuples. Stacks, queue, sorting (obvious sort) and search (naïve search) lists.
6. **Classes and objects**: Introduction to object, atom class, molecule class, creating class, instance methods, overloading, inheritance, polymorphism, overriding, public and private data, exception classes and custom exceptions
7. **Libraries and Data visualization in python**: introduction to libraries, importing libraries, visualization library (Matplotlib library, seaborn library), panda and numpy library, sklearn library, other libraries.
8. **File handling**: need of file handling, file types (text, binary, CSV), reading/writing text and numbers to/from a file; file opening modes (r, r+, w, w+, a, a+), reading (read(), readline(), readlines()), importing files, handling directories, using try-except blocks, else block, handling file not found error exception.
9. **GUIs in Python**: Introduction to GUI, components and events, example of GUI, root component, adding buttons, entry widgets, text widgets, check buttons etc
10. **Python SQL database Access**: Introduction to sql, installation, DB connection, creating DB table, database operation (INSERT, READ, UPDATE, DELETE, COMMIT, ROLLBACK), handling errors
11. **Machine learning**: introduction to algorithms (random forest, support vector machine, etc) and libraries, build your own model on small dataset and compare between different algorithms.

LS-610

GeneralLaboratoryExperience-10hours/week (2credits)

Total180hours:

- Bioinformaticsbasics (40hours)
  - Analysesofproteinstructurecomplexes
  - Energyminimizationofmacromolecules
  - Sequencealignment
  - Homologymodeling
  - Usageofonlineserversandapplications
- Databasedesignanddevelopmentinmysql (40hours)
  - Insertionofdata
  - Updationofdata
  - Deletionofdata
  - Retrievalofdata
- PHPProgramming (40hours)
  - Connectingmysql
  - Creatingwebserverfordevelopeddatabase
- ADME/Tox.Informatics (20hours)
  - DiscoveryStudio/TOPKAT/DEREK
- Molecularmodeling/drugdesign (40hours)
  - Conformationalanalysesofsmallmolecules
  - MolecularDocking

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 pharmacoeconomics:** 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 Pharmacoeconomics, Karen Rascati (Author), Lippincott Williams and Wilkins, Editor-Barrett Koger
4. Understanding Health Outcomes and Pharmacoeconomics by George E. MacKinnon III
5. Principles of Pharmacoeconomics, 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.
6. *Experimental Designs in Clinical Trials (explaining the strengths and limitations):* Non experimental study, quasi-experimental study and observational study.
7. *Meta Analysis*: Definitions, limitations, validity of the results and flaws in Meta analysis. Funnel And forest plot.
8. *EBM (Therapy)*: Types of therapeutic reports, Analyzing the reports of individual studies. Levels of evidence for evaluating clinical literature about harm / benefit. Evaluation of the validity And genralizability of a research article about therapy.
9. *Clinical Practice Guidelines*: Understanding concepts of clinical guidelines;validity of the recommendations and relevance of clinical guidelines in the Indian scenario.

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, Dynomill 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. Remingtons'sPharmaceutical 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
4. 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.

Pharmacutical 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 forthe same.

2. Safety aspects: Fire, explosion, toxicity, hazards of some selected organic/ inorganic chemicals and methods to handle them safely, basic process safety aspects

3. Disaster planning: Hazard appraisal and control, “on-sight” and “off-sight” disaster planning. Corrosion and its prevention:

4. Corrosion characteristics of selected organic/ inorganic chemicals and compatible materials of construction.

5. Documentation and regulatory record keeping: Record keeping as required by different statutorybodies.

6. Management information systems (MIS): Information management, need, users, systems.

7. Concept and type of pollution, ecology and ecological balance, pollution and health hazards, gaseouspollution 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

PT-630

Synthetic Bulk Drug Technology (2 credits)

1. Unit Processes: Oxidation, Reduction, Sulfonation, Nitration, Halogenation and their applications to the manufactureof 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, chiral amine synthesis, C-H functionlizations

4. Industrial synthesis of chiral drugs: Project development, medicinal chemistry route, pros and cons of the early route, process development, chemistry development, commercial synthesis of APIs.

5. Bulk organic chemicals as building blocks for drugs and drug intermediates: List of raw materials, their manufacturer in India

and abroad and their uses

6. Continuous flow synthesis of APIs

7. Use of protecting group in bulk drug synthesis: Protecting groups for different functional groups, their applications in bulk drug synthesis

8. Catalysis in industrial organic synthesis: Use of achiral and chiral heterogeneous and homogeneous catalysts, their recovery and reuse.

9. Biocatalysis in bulk drug synthesis: Use of enzymes, immobilized enzymes/cells in bulk drug synthesis, deracemization of amines, biocatlytic dynamic kinetic resolution

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 chracterize 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 chracterization using polarmenter and chiral HPLC methods.

Pharmaceutical Technology (Biotechnology)

PT-690

Bioprocess and Downstream Engineering (2 credits)

1. **Production of industrially important metabolites:** Process technology for the production of primary and secondary metabolites and their uses
2. **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.
3. **Antibiotics:** Beta-lactam antibiotics; Amino acid antibiotics; Peptide antibiotics; Carbohydrate antibiotics; Macrocyclic lactone antibiotics; Tetracycline, Anthracycline; Nucleoside antibiotics;Aromatic antibiotics.
4. **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.
5. **Pre-treatment:** Importance of pre-treatment; Dealing with high viscosity fermentation broth; Coagulation; Flocculation; Pasteurization; Sterilization; Adsorption on filter aids;heating etc.
6. **Filtration and Centrifugation:** Theories of filtration, Conventional and Non-conventional filtration, Darcy's equation, Various forms of Darcy's equation, Microfiltration, Ultrafiltration, Centrifugal sedimentation; Stoke's equation; Batch and continuous centrifuges; Determination of molecular weight and particle size from centrifugation data;Sedimentation coefficient; Various forms of Stoke's equation.
7. **Cell disruption:** Different methods of cell disruption, advantages, disadvantages, solid shear method and liquid shear method; Factors affecting the rate of cell disintegration andsolving of numerical thereof.
8. **Adsorption:** Langmuir adsorption isotherm; Equilibrium relationship for adsorption; Adsorbate; Adsorbate; Freundlich adsorption isotherm; Fixed bed adsorber, analysis thereof; Antibody recovery by adsorption; case studies.
9. **Evaporation and Crystallization:** Theories of evaporation; Evaporator cum crystallizer; Factors influencing the rate of evaporation; Rate of nucleation and rate of crystal growth; Particle size distribution of crystals; Batch and continuous crystallizers.
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 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.

Medical Devices

MT-610

Bioengineering and regenerative devices (2 Credits)

1. **Module 1:** Introduction to tissue Engineering and Artificial Organ. Applications of tissue engineering- Bionics and prosthetics.

2. **Module II:** Potential Biomaterials for Regenerative Devices. Optimization of Biomaterial composition, Design and fabrication of implantable devices/scaffold- Electrospinning, Rapid Prototyping, 3D Printing. SelfAssembling, Prosthetic devices.

3. **Module III***:* Stem Cell Basics: types-sources, and therapeutic Application, Stem cell Expansion. Stem cell Growth Kinetics and influencing factors, Stem Cell Differentiation -bone, cartilage, neural tissue, Cell signaling Molecules, Stem Cell Characterisation,

4. **Module IV:** Bioreactor - importance, basic configurations and design, Static and Dynamic bioreactor systems for cell seeding and culturing, Factors influencing regenerative device production-mechanical, electrical and fluid flow.

5. **Module V:** Stem Cell- biomaterial interaction- cell adhesion, migration & aggregation, genervation of tissue construct devices for transplantation & the irin vitro and in vivo (animal model) assessment,

6. **Module VI:** Case studies –bone, cartilage, joints (knee & hip joints) and neural tissue regenerative devices, Ethical & Safety Issues,tutorials, Student presentations.

References:

1. Shu Q. Liu, Bioregenerative Engineering: Principles and Applications, Wiley Interscience, New York, 2007.
2. N. Hakim (ed), Artificial Organs, Springer-Verlag London, 2009, ISBN:1848822812, 9781848822818.
3. A. Hasan (ed), Tissue engineering for artificial organs: regenerative medicine, smart diagnostics and personalized medicine, Wiley VCH, 2017, ISBN 978-3-527-68993-4, 3527689931, 978-3-527-68994-1.

4. W.W. Minuth, R. Strehl, K. Schumacher, Tissue Engineering: From Cell Biology to Artificial Organs, Wiley-VCH, 2005, ISBN: 9783527311866,3527311866, 0471253944,0470844817,0471852139,3527308954,3527301984
5. R. Lanza, R. Langer, J. Vacanti, Principles of Tissue Engineering, 3 rd Edition, Academic Press, 2007, ISBN 9780123706157, 0123706157
6. Meyer, U., Meyer, Th., Handschel, J., Wiesmann, H.P., Fundamentals of Tissue Engineering and Regenerative Medicine, Springer Nature, 2009, Hardcover ISBN 978-3-540-77754-0, Softcover ISBN 978-3-662-51830-4

MT-620

Drug Delivery Engineering (2 Credits)

1.Medical devices versus drug delivery carriers: Strategies to prevent devicerelated nosocomial infections; Importance of lipid-and polymer-based antimicrobial delivery carriers in medical devices

2. Drug Delivery: Targeted Drug Delivery and Novel Carrier Systems:

Drug targeting: Basics of drug targeting
Different levels of drug targeting: First order, second order and third order targeting, active and passive targeting, EPR effect, receptor-mediated endocytosis, prodrug based drug targeting, brain targeting, tumor targeting
NDDS: Fundamentals of novel drug delivery systems
Biopharmaceutics and pharmacokinetic aspects of CRDDS: Strategies and design, factors affecting controlled release drug delivery systems, computation of desired release rate and dose for CRDDS. Pharmacokinetic design for DDS; invitro/in-vivo considerations. Intermittent zero order and first-order release

C. Additive Manufacturing (AM) Engineering

3D Printing in Drug Delivery: Introduction, Classification of AM technologies, Advantages, AM versus Pharmaceutical Conventional manufacturing processes.
AM Technologies: Vat polymerization, powder fed fusion, Material extrusion, Material jetting, etc.
AM for various Engineered Drug Delivery Systems: Oral solid dosage forms, Transdermal patches, Drug delivery implants, Delivery to other routes.
AM Materials: Details with drug delivery application domains.
Bio printing for in vitro drug testing: Bioprinted organ-on-a-chip models and cellladen models.

Product Evaluation &Quality for drug delivery engineering perspective: Stability, Safety, Efficacy, Scalability of AM technology, AM ecosystem, Regulatory challenges, Cost-effectiveness.

Reading material:

1. Biofilm Eradication and Prevention: A Pharmaceutical Approach to Medical Device Infections, Author: Tamilvanan Shunmugaperumal, First published: 29 June 2010, Print ISBN:9780470479964 |Online ISBN:9780470640463.
2. Introduction to Biopharmaceutics, by Gibaldi, M.
3. Textbook of Biopharmaceutics and Clinical Pharmacokinetics by Niazi, S.K.
4. Modeling in Biopharmaceutics, Pharmacokinetics, and Pharmacodynamics: Homogeneous and Heterogeneous Approaches, by Macheras, P. and A. Iliadis.
5. Applied Biopharmaceutics& Pharmacokinetics, by Shargel, L., S. Wu-Pong.
6. Lan Gibson, David W. Rosen and Brent Stucker, Additive Manufacturing Technologies: Rapid Prototyping to Direct Digital Manufacturing, Springer, 2010.
7. Andreas Gebhardt, Understanding Additive Manufacturing: Rapid Prototyping, Rapid Tooling, Rapid Manufacturing, Hanser Publisher, 2011.
8. C.Y. Liaw, M. Guvendiren, Current and emerging applications of 3D printing in medicine, Biofabrication 9 (2017), 024102.
9. Drug Delivery: Engineering Principles for Drug Therapy, W. Mark Saltzman, Oxford University Press, 2001
10. Drug Delivery: Fundamentals and Applications, Anya M. Hillery and Kinam Park, 2nd Edition, CRC Press, 2016
11. M. Palo, J. Hollander, J. Suominen, J. Yliruusi, N. Sandler, 3D printed drug delivery devices: Perspectives and technical challenges, Expert Rev. Med. Devices 14 (2017) 685-696.

MT-630

Biomaterials (2 Credits)

Overview of Biomaterials and their use in Medical Devices; Physical and Mechanical requirements for Medical Device Materials; Metallic Materials; Failure Analysis of Metallic Orthopedic Implants; Hip Joint Prosthesis Fixation: Problems and Possible Solutions; Ceramic Materials; Polymeric Materials; Meta materials; Soft Tissue Replacement: Sutures, Skin, Maxillofacial Implants, and Blood Interfacing Implants; Hard Tissue Replacement: Long Bone Repair and Joints;

Practical aspects of biomaterials: Introduction, Sterilization of Implants and Devices, Implant and Device Failure, Implant Retrieval and Evaluation; Fundamentals of nanotechnology and its applications orthopedic materials, regenerative medicine.

Reading material:

1. ASM Handbook Volume 23, Materials for Medical Devices
2. B.D. Ratner, Alan S. Hoffman, Frederick J. Schoen, Jack E. Lemons, Biomaterials Science: An Introduction to Materials in Medicine 2004, Edition: 2nd Revised edition (ISBN-10: 0125824637 and ISBN-13: 978-0125824637)
3. J.B. Park and J.D. Bronzino. Biomaterials: Principles and Applications. CRC Press. 2002. ISBN: 0849314917
4. Joon Park, R.S. Lakes. Biomaterials: An Introduction, Springer, ISBN 978-0-387-37879-4, 2007
5. Lei Yang. Nanotechnology Enhanced Orthopedic Materials: Fabrications, Applications and Future Trends, Elsevier, 2015 ISBN: 978-0-85709-844-3

MT-640

Biosensor (1 Credit)

1. Module 1: Introduction; Definition and fundamental principles; Generations of biosensors; Basic transduction system in biosensors: electrochemical, optical, acoustic, piezoelectric, and calorimetric biosensors.

2. Module 2: Biological recognition systems / bioreceptor: antibody, Fab and Fc fragments, nucleic acid, cell, and tissue; property of materials for bioreceptor. Design engineering of biosensor and characterization techniques. BIO-MEMS, Micro / Nanofluidics

3. Module 3: Analytical parameters: Calculation of LOD, LOQ, Dynamic Range, Selectivity coefficient, electrode/chip performance, Models of real sample analysis; Invitro, invivo, exvivoanalysis systems, sample processing, standard addition method, spike-recovery method. Case studies and tutorials.

4. Module 4: Materials for biosensors: conducting polymers, natural / synthetic polymers, paper matrix, nanocomposite materials, metal oxides / dendrites, porous silicons, Application of biosensors for pharmaceutical testing and clinical diagnostics. Student presentations.

Text books and Reference books:

1. Buerk, Donald, G., “Biosensors: Theory and Applications”, CRC Press, 1995.
2. Manz, A., & Becker, H.(Eds.), “Microsystem Technology in Chemistry and Life Sciences”, Springer-Verlag, New York, 1999. ISBN: 3-540- 65555-7.
3. Nanobiosensors for personalized and onsite biomedical diagnosis, ISBN No: 978-184-91-9950-6, Pranjal Chandra (Ed.) Publisher: The Institution of Engineering and Technology, Michael Faraday House, London, United Kingdom, Year: 2016
4. Next-generation point-of-care biomedical sensors technologies for cancer diagnosis, ISBN No: 978-981-10-4725-1, Pranjal Chandra, Tan Yen Nee, Surinder P. Singh (Eds.), Publisher: Springer, Singapore, Year: 2017

MT-650

Artificial Intelligence in Medical Devices (2 Credits)

1. Use of computers in physiological data acquisition and analysis:

Programming, storage and display of data with reference to bioelectric potentials. Applications of Microprocessor and Microcontroller in medicine. Python scripting for data analysis.

2. Digital filters: FIR and IR type and their application to biomedical signal filtering.

3. Data reduction techniques: Spectrum analysis.

4. Intelligent computing systems in medicine: Introduction to Intelligence and Artificial Intelligence. Heuristic search method, knowledge Based system.

5. Artificial Neural Networks: Introduction, Pattern and data, methods for pattern recognition tasks, Artificial neural networks: Terminology, Models of neurons, Topology. Activation and synaptic dynamics: Activation dynamic models, synaptic dynamic models, learning methods. Functional units of ANN for pattern recognition tasks: Pattern recognition problems, basic functional units, Feed forward neural networks: Analysis of pattern association networks, analysis of pattern classification networks, Feedback neural networks: Analysis of linear associative, FF Networks. Competitive learning neural networks:

Components of competitive learning network, analysis of pattern clustering network.

6. Biomedical applications of ANN: Modelling and diagnosing the cardiovascular system, Pattern recognition of pathology images, ultrasound and magnetic resonance medical images textures analysis using ANN.

7. Introduction to Imaging: Need of Imaging, invasive and non-invasiveimaging, concept of resolution and sensitivity. Use of electromagnetic spectrum for non invasive imaging, Importance of mathematics in imaging.

8. Imaging modalities: Introducing modalities based on increasing mathematical complexity.

9. Evolutionary computing and Genetic Algorithm (EC-GA).

10.Fuzzy Logic and its application in decision making.

11.Application of EC, GA, FL in Medical data analysis and diagnosis.

Reading material: MT650

1. Biomedical Informatics: Computer Applications in Health Care and Biomedicine, Editors: Shortliffe, Edward H., Cimino, James J. (Eds.), 2021. (ISBN 978-3-030-58720-8).
2. Neural Networks and Artificial Intelligence for Biomedical Engineering, M. E. Cohen, D. L. Hudson, Wiley-IEEE Press 1999, (Print ISBN:9780780334045; Online ISBN:9780470545355; DOI:10.1109/9780470545355)
3. Principles of Computerized Tomographic Imaging", A. C. Kak, M. Slaney and G. Wang. 2002 American Association of Physicists in Medicine, (DOI: 10.1118/1.1455742)
4. Introduction to the Mathematics of Medical Imaging, Charles L. Epstein, 2nd Edition, 2008, (ISBN 978-0-89871-642-9)
5. The Mathematics of Medical Imaging: A Beginner's Guide", T. G. Feeman, 2015, (ISBN 978-3-319-22664-4)

MT-660

Regulatory in Medical Devices (1 Credits)

1. Overview of medical devices: Definition, Classification, Difference between drug and medical device, *In-vitro* diagnostics, Labelling of medical devices and *in-vitro* diagnostics, Overview of combination products.

2. Medical device regulation - Global requirements: Medical Device regulation in India (CDSCO), Medical Device regulation in USA (USFDA), Medical Device regulation in European Union (EMA)/European Medical Device Regulations, Medical Device Regulations-WHO.

3. Regulatory requirements for medical devices and approvals: Regulatory requirements of biocompatibility of medical devices (ISO10993), Clinical Investigation of medical devices, Regulation of investigational medical devices, Post marketing surveillance and materiovigilance, Dossier preparation of common technical document (CTD) and eCTD submission, How to obtain a license to manufacture a medical device, Import and export of medical device and in-vitro diagnostics.

4. Standards of medical devices, Quality Management Systems: National and international standard system for medical devices, Performance evaluation of medical devices with reference laboratories in India, Material selection for medical devices, Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP), Good Documentation Practice (GDP).

5. Medical Device safety and risk management: Quality management system for medical devices, Total product life cycle, Effective of medical device, Adulteration, Misbranding.

Reading material:

1. Medical Devices Rules, 2017, Related Guidance documents available at CDSCO websites.
2. US-FDA Regulation of Medical Devices
3. European Union Regulation of Medical Devices
4. Medical Device regulations: global overview and guiding principles, World Health Organization.
5. Book: Medical Devices: Regulations, Standards and Practices; 1st Edition, Imprint: Woodhead Publishing; Hardcover ISBN: 9780081002896 (Authors:

Seeram Ramakrishna, Lingling Tian, Charlene Wang, Susan Liao, Wee Eong Teo)
6. Book: Inventing Medical Devices: A Perspective from India. (Author: Jagdish Chaturvedi), Publisher: Createspace Independent Pub; (ISBN-10: 1519467184; ISBN-13: 978-1519467188).
7. Book: Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices (Authors: John J. Tobin, Gary Walsh); ISBN: 978-3-527-31877-3; Wiley-Blackwell publisher; 2008.

MT-680

MT-680 Elective 4; Biomedical Signal Processing (1 Credit)

1. Signals: classification of signals; signal operations: scaling, shifting and inversion; signal properties: symmetry, periodicity and absolute integrability; elementary signals; Signal representation: signal space and orthogonal bases.
2. Sources of bioelectric potential, resting potential, action potential, propagation of action potentials innerves; rhythmic excitation of heart; Electrocardiogram, Electroencephalogram, Electromyography, Photoplethysmography and Phonocardiogram
3. Pre-processing, waveform recognition, morphological studies and rhythm analysis, Application ofsignal processing techniques for extraction of physiological parameters; introduction to wavelets &time frequency models and their applications

Texts:

1. Rangaraj M. Rangayyan, Biomedical Signal Analysis, 2nd Edition, Wiley-IEEE Press, 2016
2. M. J. Roberts and G. Sharma, Fundamentals of Signals and Systems, 2 nd edition. McGraw-Hill Education, 2017.
3. V. Oppenheim, A. S. Willsky, and H. S. Nawab, Signals and Systems, 2nd edition. Pearson, 2015.

References:

1. E.N. Bruce, Biomedical Signal Processing and Signal Modelling, John Wiley and Sons, 2001.
2. W. J. Tompkins, Biomedical Signal Processing; Prentice Hall, 1995.

LS-610 Bio and Pharmaco-engineering Laboratory (1 Credit)

1. Fabrication and evaluation of engineered filaments/biofilamentsthrough extrusion mediated AM techniques.
2. Rapid prototyping using various platform technologies related to AM/3D Printing such as FDM, SLS, SLA, etc.
3. Computer-aided design, prototyping and evaluation of cutting-edge translational pharmaceutical devices to justify drug delivery applications
4. Understanding the mathematical concept behind the calculations for the estimation of pharmacokinetics parameters.
5. Evaluation of *In-vitro* drug release kinetics for the sustained release formulations.

LS-620 AI & Machine Learning Laboratory (1 Credit)

As per the laboratory manual

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 2023
Semester-III

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 2023
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 withone 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 HillManagement 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, Poison.
   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 2 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 Compulation, 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, netware basics, tools and services on internet, browsing the net. Gopher Eile systems, netware 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 treties-I:** Introduction to TRIPS. Concept behind GATT/TRIPS. Emergence of WTO.
7. **International treties-II:** DOHA declaration and its significance for Indian pharma industry. Cancum 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 polices and India, trade barriers, foreign trade polices, 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 Bhall 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 marking; 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:** Evoluation of Production / operations management; Nature of production/operations management; Production function and it 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 unfavou(2 credits)
rable, order, order
acknowledgement. Thank you letters, claims, answers to claims, ba
d 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 Maczma
rch, S.K., Effective
3. Business Communication by Murphy, H.A; Hilderlrand, 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 Ray
mond, L. and
Flately, M.

PM-606
Human Resource Management

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 Res

ources 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

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. (3 credits)
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 Cristropher
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 entrapreneurship
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) Preclincial 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 Behariour 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-mea surement 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 andZeigler
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 2023
Ph.D. Courses

Medicinal Chemistry
Semester-I

MC-750 : Medicinal chemistry strategies and late-stage synthesis (2 credits)

1. **NP-inspired strategy in drug discovery**: Natural products as sources of new drugs; NPs-conserved motifs, NP-Inspired as a concept
2. Molecular medicinal properties, Target-binding efficiency, Selectivity, Solubility, cLogP, Metabolic stability, drug-like profile, Bioavailability, Circumventing resistance, Low toxicity, Pharmacokinetics (PK)
3. NP-Inspirednew inhibitors, NP-Inspired strategy in discovery of various therapeutic drugs and agents in pharmaceutical industries and academia.

Scaffold-hopping strategy in drug discovery:

4. Scaffold hopping as a concept, Structural class and patentability island
5. Classes of Scaffold hopping in drug discovery; Heterocycle replacement, Ring opening and closure, Pseudopeptides and peptidomimetics, Topology or shape-based scaffold hopping, Integration of heterocycle replacement and bioisosterism
6. Molecular medicinal properties – focused scaffold hopping; Drugs-scaffold hopping; NPs-scaffold hopping, Successful innovation of marketed drugs and agents in pharma industries and academia.

Late-stage structural modulation-based synthesis

7. Late-stage C-H functionalization (arylation, C–N, C–O and other C–heteroatom bonds formations), Selectivity, and Molecular diversity
8. Late-stage molecular modulations of bioactive molecules as multifunctional synthons
9. Skeleton editing and various transformations of advanced stage scaffolds
10. Magic methyl effect; Magic chloro effect; Discovery of new drugs and agents.

References Books:

MC-740 (2 credits)

Advanced Heterocyclic Chemistry

1. Introduction; general reactivity of important class of heterocycles.
2. Reaction and reactivity of Pyridine, Diazine, Pyrrole, Furan, Thiophene, Quinoline, Isoquinoline, Indole, aza-Indoles,etc;
3. Various ionic and radical transformations involving heterocycles.
4. Cross-coupling and photo-redox reactions.
5. Recent strategies for the synthesis of saturated heterocycles.
6. Recent trends in medicinal chemistry for three-dimensional scaffolds: escape from the flatland.
7. Spiro(hetero)cyclic compounds in medicinal chemistry.

8. Important bioisostere in medicinal chemistry (BCP, ABB systems).
9. Case studies on the use of privileged heterocycles in drug development.
10. Selective synthesis of recent heterocyclic FDA-approved drugs.

Recommended Books/Literature:

1. HETEROCYCLIC CHEMISTRY, 5TH Ed. 2010, John A. Joule, Keith Mills. ISBN: 978-1-405-13300-5
2. Strategic Applications of Named Reactions in Organic Synthesis: Background and Detailed Mechanisms. 2005, by Barbara Czako, Laszlo Kurti.

Semester-II

MC-810 : Principles of Peptide Chemistry (2 CREDITS)

1. Importance of peptides in drug discovery
2. Protection and Deprotection:
3. 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, 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:
6. Deletion peptides, side reactions initiated by proton abstraction, protonation, over-activation and side reactions of individual amino acids
7. Segment and sequential strategies for solution phase peptide synthesis with case studies
8. Principle of Merrifield solid phase peptide synthesis, t-BOC and FMOC protocols, various solid supports and linkers, activation procedures, peptide bond formation
9. Deprotection and cleavage from resin, low and high HF cleavage protocols, formation of free peptides and peptide amides, purification and case studies.
10. Site-specific chemical modifications of peptides.Ligation in peptide/protein synthesis. Greener approaches for the peptide synthesis

Reference Books:

MC 830 : Advanced topics in Drug Action and Drug Design (2 credits)

1. **Molecular basis of drug action**: Receptor specificity andsingnal transduction, Channelcontaining receptors, intracellular receptors, Receptor desensitization, Drug action in cell not mediated through receptors. GPCRs.
2. **Drug metabolism** : Inhibitions, induction, species and sex differences in drug metabolism, age on drug metabolism, CYP 450, Glutathone S-transferases, UDPGlucuronosyltransferase.
3. **Resistance, Allergy, Tolerance**: Immunologic basis of drug allergy, origin of drug resistance, resistance to the b-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 passivediffusion, lipophilicity of metabolites.
6. **Drug-Receptor thermodynamics**: Thermodynamic models of drug-receptor interactions, Effector-receptor interactions. Basics of correlations, relevance to enthalpy-entro compensation.
7. **Drug action of some agents**: Steroid biosynthesis and action, neurotransmitter action and metabolism, memberane-active agents, hormonalmodulators,mictrotubule action.
8. **Recent developments:** Epigenetics, PROTACS, immune checkpoints, TNFα, cell penetrating peptides, peptidomimetics.
9. **Metals in Medicine :** Recent trends in the organometallic compounds in drug discovery especially in anti-cancer treatment.
10. **Case studies**: PfDHFR-TS, TopoIIα, FstZ, mechanism based inhibition of cytochromes, Glygogen Synthase Kinase (GSK), PPARγ, Influenza A.

PhD.

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 glycopetpide 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 discoverd from Traditional Chinese Medicine
10. (TCM). Chemistry, design and synthesis of analogues, SAR study, Artemisinin as a scaffold for the development of novel trioxane and tetraoxane anti-malarials agents.
11. **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. **1H-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. **13C-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, MSn, 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

Pharmaceutical Analysis Semester-I

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.
6. **identification using radioligand techniques.**
7. **Case studies**: Impurity profiling, isolation and characterization.
8. **Case studies**: Metabolite profiling, isolation and characterization.

Pharmacology and Toxicology
Semester I

PC-750

Mitochondrial Pharmacology inHuman Diseases

Credits: 2

Topics included in course

1. Mitochondria: Structure, function and DNA inheritance
2. Mitochondria control of physiology and Disease, mitochondrial import machinery, subunits of respiratory chain complexes, mtDNA maintenance and expression
3. Mitochondriogenesis and Quality control system, fission and fusion, UPR, chaperons, HSP, LONP1 and ClpP serine protease, Mitophagy

4.Mitochondria as Signalling organelle, mitochondrial dysfunction cross talk with other pathophysiological pathways

5. Mitochondrial bioenergetics, Redox regulation, mitochondrial ROS production
6. Mitochondrial dysfunction in human diseases: Inflammatory diseases, cardiovascular diseases, neurological disorders etc.
7. *In vitro* and *in vivo* Methods for studying mitochondrial activity, mitochondrial respiratory capacity, membrane potential and ROS production
8. Pharmacological modulators targeted at Mitochondrial dysfunction, Mitochondrial targeted antioxidants, natural products and other pharmacological interventions.

Reference Books:

- Mitochondrial Medicine: Volume I ,ISBN: 978-1-4939-2257-4 Edited by VolkmarWeissig, Marvin Edeas
- Mitochondria, 2nd Edition, ISBN: 978-0-470-04073-7, Immo E. Scheffler
- Mitochondrial Signaling in Health and Disease: 30 (Oxidative Stress and Disease), CRC Press Inc; 1st edition, Enrique Cadenas, Lester Packer, StenOrrenius
- The Functions, Disease-Related Dysfunctions, and Therapeutic Targeting of Neuronal Mitochondria (Wiley Series on Neuropharmacology) by V Gribkoff , ISBN-13 :

- John Wiley and Sons , 1118709238-978

Semester-II

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-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 C

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tion.

10. Future of regulatory toxicology in drug safety evaluation.

PC-860

Epigenetics and Diseases (2 credits)

1. Toxicogenomics, pharmecogenomics, pharmecognetics 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.

PE-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 pharmacodynamicmodelling: 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).

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 **Phsico-chemical approaches of targeting:** Stimuli responsive : Magnetically, thermal and pH assisted drug delivery systems, Chemical drug delivery (prodrugs), Lipid-drug/drug/Polymer-drug conjugates.

1. **Carrier based approach for targeteddrug delivery : Functionalized liposomes.**

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_2, 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. **Immunogenecity 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 oligonucelotides, mechanism of action of antisense oligonucelotides, antisense oligonucelotides 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

StrategiesinLeadOptimization (2credits)

1. **Introduction**:Overviewofstrategies;Leadoptimization;Drugdiscoverycycle;Successstoryofcaptopril.
2. **Denovoliganddesign**:Overview;Activesiteanalysismethod;Wholemoleculemethod;Connectionmethods;Genetic algorithmforligandbuilding;Limitations;Software.
3. **Structurebaseddrugdesign**:Introduction;Bioactiveconformation;Ligandanchoring;Desolvationeffect;Entropicef fect;Roleofwater;Analogdesign;Databasesearching;Denovodesign;Successstories.
4. **IterativeProteincrystallographicanalysis**:Introduction;Experimentalapproaches;Roleofcrystallographyindrugd esign;Conformationandbiologicalac.Advantagesandlimitationsofcrystallography;Applications;Casestudies.
5. **DockingandScoring:**Molecularrecognition.Methods,algorithms,conformationalensemble,moleculardeterminant sforbinding,scoringfunctions,solvationeffect.Insilicotools,flexibledocking,Applications,casestudies.
6. **Smallmolecularcrystallography:**Introduction,directandindirectdesign,CSD,bioactiveconformation,polarandno n-polarmolecules,crystalpackingandligandproteininteraction.Databasemining,CHOhydrogenbonding,andapplica tions.
7. **Peptidomimetics:**Introduction,typesofpeptidomimetics,conformationalrestriction,templatemimetics,peptidebon disosteres,transitionstateanalogs,rationaldrugdesign.Casestudies.
8. **ADMETandDuggability:**Propertybaseddrugdesign,absorption,distribution,metabolism,excretionandphysicoche micalproperties.Descriptors,bioisosterism,prodrugandsoftdrugapproaches.
9. **MetabolismbyCytochromes:**Introductions,significanceofcytochromeP450s,substratesandinhibitors,predictingc ytochromeP450metabolism;Ligandbasedandstructurebasedmodelsforcytochrome P450.Casestudies.
10. **Humanether-a-go-go-relatedgene(hERG):**Introduction,cardiacarrhythmias,SARaroundhERG,insilicoapproac hes.Examples.

PI-810

Artificial Intelligence in Drug Discovery (2credits)

1. **Introduction to Deep Learning:**Definition and characteristics of deep learning, comparison with traditional machine learning approaches, Deep learning architectures, an overview of popular libraries: TensorFlow, Keras, PyTorch, scikit. Activation functions (softmax, sigmoid, ReLU), Loss functions. Handling overfitting and regularization techniques, learning rate tuning, and early stopping
2. **Convolutional Neural Network (CNN):**Architecture and components of CNNs, Convolutional layers, and filters, Role of pooling layers, and feature reduction. Transfer learning: utilizing pre-trained models, fine-tuning, benefits and limitations of transfer learning. CNN applications in image recognition and drug design.
3. **Recurrent Neural Network (RNN):**Understanding sequential data, RNN architectures, and working principles. Long Short-Term Memory (LSTM) networks, applications in natural language processing, and time-series data.
4. **Generative Adversarial Networks (GANs):**Basic idea and concept of GANs, components of GAN (generator and discriminator), conditional GAN architecture, case studies of GAN for generating novel molecules with desired properties, property prediction, understanding protein-ligand interactions, Challenges and limitations of GANs in drug discovery (mode collapse, overfitting, generalization, etc)
5. **Reinforcement Learning (RL):** Introduction to reinforcement learning, Components of RL: Agent, environment, actions, rewards. RL algorithms (Q-Learning, Deep Q Networks (DQNs), etc). Application of RL in drug discovery: drug lead optimization, de novo drug design, etc.
6. **AI applications in Pharmacoinformatics:** Sequence-to-sequence models for SMILES generation, RNN for molecule generation, feature engineering for drugs and targets, Drug-target interaction, Case studies of successful drug repurposing, and virtual and high-throughput screening using AI.
7. **Ethical and Regulation in AI-driven drug discovery:** Bias and fairness issues, ensuring data privacy and security concerns in drug discovery datasets, transparency and interpretability of AI models, addressing challenges and limitations in deep learning, regulatory challenges, and guidelines, responsible AI practices in the Pharma and Biotech Industry.

Pharmacy Practice

Semester-I

PP-701

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 propor- tion; 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-801

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, photoredox 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. Green chemistry in the synthesis of pharmaceuticals

8. Green chemistry approaches for application in pharmaceutical industry: Amide bond formation, oxidation, reduction, halogenations, Baylis-Hillman 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

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.

Semester-II

PT 820 Topicsin OrganicProcess Chemistry (2credits)

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 benzofused heterocycles-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 aqueousmedia.

7. Process chemistry: Approaches to process R&D, route selection, solvent selection, optimization and troubleshooting.

PT-830 The Organic Chemistry of Drug Synthesis (2 credits)

1. Antiviral drugs synthesis

2. Synthesis of aromatase inhibitors for breast cancer

3. Synthesis of anti-inflammatory Cyclooxygenase-2 selective inhibitors

4. Synthesis of quinolinone antibiotics

5. Synthesis of triazole antifungals

6. Drugs for type 2 diabetes

7. H^+/K^+-ATPase Inhibitors: Esomeprazole

8. Atypical Antipsychotic drugs

9. Angiotensin AT1 antagonists for hypertension

10. GABA receptor agonists for insomnia

11. Synthesis of α2d ligands: Gabapentin and Pregabalin

12. PDE 5 Inhibitors for Erectile Dysfunction: Sildenafil, Tadalafil, and Verdenafil

Pharmaceutical Management
Semester-I

PM – 701 Strategic Market Management 2 credits

Objective: The main objective of this course is to develop skills in analyzing a business situation and then formulating, implementing and monitoring marketing strategy in a competitive situation. The course will focus specifically on issues such as selecting a segment in which to compete, developing meaning points of differentiation and positing statements and positioning statements, allocating resources, designing products and managing prices, managing distribution strategies and developing and managing promotion strategies.

1. An overview of Strategic Market Management. External Analysis – competitor analysis, Market analysis, Environment analysis.
2. Internal Analysis – Self analysis and Porfolio analysis
3. Alternative Business Strategies – Obtaining sustainable competitive advantage, differentiation strategies, diversification strategies
4. Strategies in different market situations and Global strategies
5. Implementation and Planning process

Suggested Readings:

1. David Aaker Startegic Market Management , John wiliy & Sons
2. Armstrong and Kotlar Principles of Marketing. Prentice Hall
3. Bendle J, Farris and Pfeifer Marketing Pearsons Education
4. Stanton and Walker Fundamentals of marketing Mcgeaw Hill
5. Alexander Chernev, Startegic Marketing Cerebellum Press
6. HBR's 10 Must Reads on Strategic Marketing (with Featured Article "Marketing ...Theodore Levitt, Clayton M. Christensen, Fred Reichheld, Harvard Business Review Press (

PM – 702 Corporate Restructuring and Valuation 2 credits

Objective: *To familiarise students with the financial and strategic issues associated with corporate restructuring and valuation and enable to identify research issues and future directions on corporate value creation through restructuring.*

1. Introduction to Corporate Restructuring- Forms of corporate restructuring- expansion strategies (mergers, acquisitions, tender offers, joint ventures, alliances), sell off strategies (spin-offs, split offs, split ups, equity carve-outs, divestitures),
2. Corporate control strategies (premium buy backs, standstill agreements, antitakeover defenses); Strategies Regarding Change in Ownership Structure- exchange offers, share repurchases, going private, leverage buyouts.
3. Research Issues and Future Directions in Corporate Restructuring- empirical evidence on restructuring issues such as timing and methods of payment; Impact of Restructuring Strategies on Value Creation.
4. Introduction to Valuation- role, purpose and process; Valuation Techniques - discounted cash flow valuation, relative valuation and contingent claim valuation; Valuation of Intangibles - valuation of brands, goodwill, human resources and customer relations; Valuation of a Merged Firm - valuation of synergies, accretion-dilution analysis, growth synergies and efficiency synergies.
5. Research Issues and Future Directions in Valuation; Synergy and Value Creation; Valuing Declining and Distressed Companies; Trends in Valuation for Corporate Restructuring.

RECOMMENDED READINGS:

1. Arzac, E.R. *Valuation for Mergers, Buyouts and Restructuring*. John Wiley & Sons.
2. Bruner, Robert F. and Joseph R Perella. *Applied Mergers & Acquisitions*. John Wiley & Sons
3. Damodaran, A. *Damodaran on Valuation*. John Wiley & Sons.
4. DePamphilis, D. *Mergers, Acquisitions, and Other Restructuring Activities.* Academic Press.
5. Gaughan, P.A. *Mergers, Acquisitions, and Corporate Restructurings*. John Wiley & Sons.
6. Pidnataro, P. *Mergers, Acquisitions, Divestitures, and Other Restructurings.* John Wiley & Sons.
7. Sudi, Sudarsanam. *Creating Value from Mergers and Acquisitions*. Pearson Education
8. Van Horne, James C. and John M. Wachowicz Jr., *Fundamentals of Financial Management*, Eastern Economy Edition.
9. Watkins, M. *Harvard Business Review on Mergers and Acquisitions*. Harvard Business Review Press.

PM – 703 Corporate Governance and Financial Sustainability 2 credits

Objective: The objective of the course is to provide students with a firm grounding in range of basic issues at stake in governance, environmental finance, and sustainable investing. At the end of the

course students will be able to identify the research issues and future directions in the domain of corporate governance and financial sustainability.

1. Theories, Concepts and Practices of Corporate Governance; international Corporate Governance;
2. Board Committees; Role, Selection, Compensation, Removal of Board of Directors; Succession Planning; Governance of Financial and Other Reporting;
3. Strategic Planning and Governance of Risk; External Corporate Governance Stakeholders; Empirical Evidence on Issues such as Board Processes,Executive Remuneration, Risk Management and Globalisation and How They Impact Corporate Governance; Future Directions and Trends in Corporate Governance.
4. The Emergence of Financial Sustainability; Concepts and Tools for Developing Financial Sustainability; Sustainable Investments; Strategies for Managing Environmental Change;
5. Research Issues and Future Directions in Financial Sustainability; Research related to the Relationship between Finance and Sustainability, including Environmental Products, Emissions Trading, and Socially Responsible Investing, Future Directions and Trends in Financial Sustainability.

RECOMMENDED READINGS:

1. Krosinsky, C., & Robins, N., & Viederman, S. Sustainable Investing: Strategies, Funds and Thought Leadership. John Wiley & Sons.
2. Krosinsky, C., & Robins, N. Sustainable Investing: The Art of Long-Term Performance. Earthscan Publications.
3. Larcker, D., & Brian, T. Corporate Governance Matters: A Closer Look at Organizational Choices and their Consequences. Pearson Education.
4. Mallin, C. Corporate Governance. Oxford University Press.
5. Monks, R.A.G., & Minow, N. Corporate Governance. John Wiley & Sons.

Tricker, B. Corporate Governance: Principles, Policies, and Practices. Oxford University Press

Semseter-II

PM – 801 Contemporary issues in Pharmaceutical Management 2 credits

Objective: The main objective of this course is to develop analytical skills in analyzing current trends in Pharmaceutical Industry with special reference to regulatory compliance and trend. The course will focus on specifically on CRAMS, R&D and Marketing trends

1. CRAMS : Contract research and Manufacturing in global pharmaceutical Industry – Current scenario in CM and Research.
2. Outsourcing, it's benefits and trends in outsourcing. Pharmaceutical Industry scenerio after WTO accord.
3. Research and Development : Understanding R&D, Role of research in economic development and economic progress, Trends in R&D, spending and output of Drugs, Practical scenario of current R&D
4. Interface betweenR&D, manufacturing and marketing. National perspective on R&D collaborations with Industry
5. Regulatory compliance with respect to manufacturing, marketing and approval process

Suggested Readings:

1. Milind Antani – CRAMS in India
2. Magdalena Krekora Contract manufacturing of Medicines Kluwer Law International
3. Reglaions og Pharmaceutical Industry Palagrave Macmillion
4. Food and Drug Regulations in an era of Globalised Markets Ed. Sam F Halabi Academic Press

PM – 802 ISSUES IN GLOBAL STRATEGIC MANAGEMENT 2 credits

Objective: The purpose of this course is to develop skills for the implementation phase of strategic management. The course will focus specifically on issues related to convergence, cross cultural aspects and Corporate Governance.

1. Theories of International Trade; Research on Global Convergence- 'Death of Distance'; Frameworks for Selection of Foreign Markets;
2. Research on Comparison of Bilateral Agreements and Multilateral Agreements; Challenges Faced by Indian Companies in their Globalization Efforts; Managing Political Risk and Trends in Corporate Governance in Globalised scenario.
3. Modes of Entry Especially Foreign Direct Investment, Franchising, Build Operate Lease Transfer;
4. Research on Adaptation vs Standardization; Research on 'born global' Firms; ecommerce and Global Strategy;
5. Cross Cultural Negotiation; Unique Implementation Issues of Global Firms; Research Methods for Global Strategic Management.

Suggested Readings :

1. Morrison, J. *Global Business Environment, Meeting the Challengers.* Palgrave Macmillion.
2. Nelson, C. A. *International Business-A Manager's Guide to Strategy in the Age of Globalism*.Emerald Group Publishing Limited.
3. Porter, M.E. *Competitive Strategy and Competitive Advantage.* Free Press.
4. Watson, G.H. *Strategic benchmarking: How To Rate Your Company's Performance against theWorld's Best*. John Wiley & Sons.
5. Yip, G. S. *Total global strategy: Managing for Worldwide Competitive Advantage*. Prentice Hall.
6. Miller and Dess, Strategic Management, Mcgraw Hill

PM – 803 Strategy for Entrepreneurship in Pharmaceuticals and allied areas 2 credits

Objective: *This subject focuses on the key and advanced concepts which are of importance to researchers for research in the area of entrepreneurship strategy.*

1. Distinguishing Features of Entrepreneurial Ventures in general and with specific reference to Pharmaceutical Sector, Entrepreneurship and Public Policy;
2. Research on Legal and Sustainability Issues in Entrepreneurship; Research on Ethical Issues in Entrepreneurship; Research on Technology and Entrepreneurship; Research on e-commerce and Entrepreneurial Opportunity.
3. Research on Entrepreneurship and Family business; Entrepreneurship in Small Business; Corporate Entrepreneurship;
4. Social Entrepreneurship; Rural Entrepreneurship; Global Entrepreneurship.

RECOMMENDED READINGS:

1. Bessant, J., & Tidd, J. *Innovation and Entrepreneurship*. John Wiley & Sons.
2. Bygrave, W.D., & Zacharakis, A. *Entrepreneurship*. John Wiley & Sons.

3. Kuratko, Donald F. and Richard M. Hodgetts. *Entrepreneurship: A Contemporary Approach*, Harcourt College Publishers
4. Fayolle, A. *Handbook of Research in Entrepreneurship Education.* Edward Elgar Publishing.
5. Gundry, L.K., & Kickul, J.R. *Entrepreneurship Strategy: Changing Patterns in New Venture Creation, Growth, and Reinvention*. SAGE Publications.
6. Kaplan. Patterns of Entrepreneurship. John Wiley & Sons
7. Prahalad, C.K. *The Fortune at the Bottom of the Pyramid*. Wharton School Publishing
8. Raymond W. Y. Kao and Tan Wee Liang. *Enterprise and Enterprise Development in Asia*, Prentice Hall.
9. Sexton, D.L., & Landstrom, H. *The Blackwell Handbook of Entrepreneurship*. Blackwell Publishing.
10. Timmons, J.A. *New Venture Creation: Entrepreneurship for the 21st century*. McGraw-Hill

PM – 804 Cross-functional Issues in Pharmaceutical management 2 credits

Objective: *The objective of this course is to help the students appreciate the inter play of accounting and finance with the areas of marketing and human resource management and grasp the cross-functional implications of managerial research.*

1. Interface of Accounting and Finance with Pharmaceutical Marketing- financial aspects of product line and Product Life Cycle (PLC); Financial Implications of Pricing Policies - measurement of price sensitivity; Market Share Variance Analysis; Advertising and its Impact of Financial Metrics;
2. Cost Issues in Supply Chain Management; Customer Profitability Analysis, Customer Lifetime Value Analysis; Brand Valuation. Impact of Government Policies and programmes on competition, pricing and reimbursement, and access to pharmaceutical products, medical devices and diagnostic products
3. Interface of Marketing with Human Resource Management- PLC, career pathing, cross-functional pollination and building vibrant teams.

4. Interface of Accounting and Finance with Human Resource Management- Business Process Reengineering; Behavioural Finance- investor psychology, heuristics and biases; Interface of Finance with Research and Development (R&D),
5. Contemporary Issues in Performance Evaluation; Valuation of Human Resources- methodologies and practices; Structure of a Fluid Organization.

RECOMMENDED READINGS:

1. Belkaoui, J.M., Janice, & Belkaoui, A.R. *Human Resource Valuation: A Guide to Strategies and Techniques.* Quorum Books.
2. Forbes, W. *Behavioural Finance.* John Wiley & Sons.
3. Mossman, F.H., Crissy, W.J.E., & Fischer, P.M. *Financial Dimensions of Marketing Management.* John Wiley & Sons.
4. Roslender, R., & Wilson, R.M.S. *The Marketing/Accounting Interface.* Routledge.