



SYLLABUS

(Applicable from 2022-23 session)

**NATIONAL INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH
GUWAHATI**

Sila Katamur (Halugurisuk), P.O.: Changsari
Dist: Kamrup, Assam, Pin: 781101, Assam, India
Website: www.niperguwahati.ac.in

NIPER Ordinance 2014 Clause no 26

- a) The student with M.S. (Pharm.) degree from this Institute shall be required to complete Doctoral courses of minimum 12 credits.
- b) The student with qualifications from other Institute shall be required to complete minimum of 28 credits, out of these 16 credits shall be from specialization, and remaining 12 credits shall be Doctoral courses.

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SYLLABUS

Ph.D.

PHARMACY PRACTICE

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Ph.D. Syllabus

PHARMACY PRACTICE

Course No.	Course Name	Credits
Semester-I		
*CS-701	Research Methodology (Compulsory)	2

Course No.	Course Name	Credits
Semester-II		
*CS -801	Research and Publication Ethics (Compulsory)	2
PP-810	Advanced Pharmacy Practice	2

***Detailed Syllabus is available at Page No. 39-40**

Ph.D. Pharmacy Practice SEMESTER - II

PP-810:- Advanced Pharmacy Practice

(2 Credits)

1. ***Drug Effectiveness Evaluation:*** Post-marketing surveillance, real-world evidence, observational study designs, experimental and quasi-experimental study designs, pragmatic randomized controlled trials, single-arm trials, self-controlled case-series design, case-crossover design, and mixed methods research. Confounding, biases (including immortal-time bias and channeling bias), propensity score matching, intention-to-treat analysis, per-protocol analysis, as-treated analysis, and benefit-risk assessment. Importance of machine learning, artificial intelligence, and big data mining in drug discovery and development.
2. ***Drug Safety Evaluation:*** Pharmacovigilance methods, signal detection, risk assessment, risk management, risk communication, and drug safety evaluation in special populations. The importance of pharmacogenomics for individual variation in adverse drug reactions. Regulatory requirements for pharmacovigilance, Good Pharmacovigilance Practices (GVP), and qualified person for pharmacovigilance. Ecopharmacovigilance, vaccine pharmacovigilance, hemovigilance, materiovigilance, and pharmacovigilance of biologics.
3. ***Pharmacoeconomic Evaluation:*** Pharmacoeconomic methods, budget impact analysis, health status measures, decision analysis, Markov modeling, and health technology assessment in India.
4. ***Evidence Synthesis:*** Scoping review, systematic review, meta-analysis, network meta-analysis, GRADE approach, and consensus approach.
5. ***Databases, Registries, and Guidelines:*** Spontaneous reporting databases and insurance & claims databases. Drug & disease registries and pregnancy exposure registries. ICMR ethical guidelines for human research, Good Clinical Practice (GCP, certification is mandatory) and Good Pharmacy Practice guidelines, and Drugs, Medical Devices and Cosmetics Bill 2022.
6. ***Societies and Associations:*** International Society for Pharmacoepidemiology (ISPE), International Society for Pharmacoeconomics and Outcomes Research (ISPOR), International Society of Pharmacovigilance (ISoP), Institute for Safe Medication Practices (ISMP), American College of Clinical Pharmacy (ACCP), American Society of Health-System Pharmacists (ASHP), and Board of Pharmacy Specialties (BPS).



SYLLABUS

Ph.D.

PHARMACOLOGY AND TOXICOLOGY

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Ph.D. Syllabus

PHARMACOLOGY AND TOXICOLOGY

Course No.	Course Name	Credits
Semester-I		
Core Subjects (All compulsory): Any 4 Credits		
PC- 710	Receptor Mechanism	2
PC-720	Free Radicals in Drug Research	2
PC- 730	Regulatory Toxicology and Drug Safety Evaluation	2
*CS -701	Research Methodology (Compulsory)	2
EL/PC-701	Application of Biotechnology in Parasitic Disease Research	2
EL/PC-702	Phytopharmaceuticals and its Standardization Aspects	2
	Choose any core course of other department (MC/PA/PE/MD)	2

Course No.	Course Name	Credits
Semester-II		
Core Subjects (All compulsory): Any 4 Credits		
PC- 810	Epigenetics and Diseases	2
PC-820	Diabetes, Pathophysiology and Discovery of new Drugs	2
PC -830	Current topics in Cancer Research	2
*CS -801	Research and Publication Ethics (Compulsory)	2
	Elective Subjects (Any 2 credits)	
EL/PC- 801	Pharmacological Interventions for Ischemic Brain Injury	2
EL/PC- 802	Nanotoxicology	2
EL/PC -803	Neuropharmacology	
EL/PC- 804	Pharmacological Interventions for Ischemic Brain Injury	2
Choose any core course of other department (MC/PA/PE/MD)		

***Detailed Syllabus is available at Page No. 39-40**

Ph.D. Syllabus SEMESTER - I

PC- 710 :- Receptor Mechanism

(2 Credits)

Chapter 1: Biochemical mechanisms of cell signalling; Plasma membrane and cytosolic receptor structure; Plasma membrane as a signal transduction element; Mechanisms of receptor mediated signalling; Ion gated channels; Ligand activated receptors with intrinsic enzyme activity; Amplification of transmembrane signals.

Chapter 2: Structure of G proteins, subclassification of G proteins; Role of heterotrimeric G proteins in signalling; Generation of intracellular second messengers; Modulation of G protein activity. Calcium as second messenger, PIP2, IP3 receptors, calcium influx and efflux, intracellular sources of calcium and release.

Chapter 3: Molecular and chemical characterization of membrane receptors; Use of monoclonal antibodies in receptor characterization and purification; Immunoprecipitation and electrophoretic analysis of membrane proteins; Peptide mapping; Molecular weight determination; Solubilization of the receptors; Reconstitution of membrane receptors.

Chapter 4: Intracellular signaling: signaling by cAMP, signaling by NF-kB, signaling by STAT, the MAPK signaling pathway, apoptosis, Role of mitochondria in apoptosis and aging, Transcription factors, mechanisms, pharmacological targets and their role in different diseases conditions.

PC- 720 :- Free Radicals In Drug Research

(2 Credits)

1. Introduction to free radicals: Free radicals, reacting oxygen species, production of free radicals in cells, damaging reactions of free radicals, defences against free radicals, free radicals in human disease.
2. Measurement of free radicals: Lipid peroxidation products, lipid hydroperoxide, malondialdehyde, measurement of antioxidants.
3. Antioxidants: Endogenous antioxidants- enzymatic and nonenzymatic; Regulation of antioxidant defences, pharmacological antioxidants.
4. Free radicals in neurological and neurodegenerative diseases: Free radical scavengers in the treatment of brain injury. Peroxynitrite induced toxicity: Interaction of nitric oxide with oxygen radicals and scavengers in ischemic damage, role of poly (ADP) polymerase in cell death and PARP inhibitors in ischemic injury. Oxidative stress and MAP kinases. Oxidative stress and apoptosis. Free radicals involvement in other disorders. Free radicals' theory of ageing.
- 5.

PC 730 :- Regulatory Toxicology And Drug Safety Evaluation (2 Credits)

1. **Concept and Development of Regulatory Toxicity Testing Models:** Bio assays and endpoints: Human pharmaceutical products; Exposure characterization; Routes of exposure; ADME profiles.
2. Stages of drug development: Drug laws, FDA, OECD, ICH, Schedule Y; Design of preclinical toxicity studies and clinical development, clinical risk/benefit analysis. Safety evaluation of medical devices and bio materials. Good Laboratory Practices (GLP), issues and implementation.
3. Different methods in toxicity testing: Dose determination, response characterization, NOAEL.
4. MTD and threshold limitations: Hormesis, lower dose extrapolation, in vitro and in vivo correlation, animal to human extrapolation; Flow chart.
5. Mechanism of toxicity: Evaluation across different models: Target organs, cell death, necrosis, apoptosis, oxidative stress, chromosome and DNA damage.
6. Acute and chronic toxicity, genetic toxicity: Types of genetic toxicity testing; Principles of detection; Genotoxicity of marketed drugs, test batteries, Salmonella test, micronucleus test, chromosome aberration test, Comet assay, New-bio assays.
7. Reproductive toxicity: Germ cell toxicant, effect on gonads, F1 generation study. Neonatal toxicity; Transplacental mutagenesis and carcinogenesis.
8. Carcinogenicity, carcinogen identification: Carcinogenesis process, drug induced carcinogenicity, lifetime carcinogenicity bio assays, neonatal mouse models; Short and medium term bio assays, limitations and impacts.
9. Regulations, discovery/development gap: Risk characterization; Management and Communication.
10. Future of regulatory toxicology in drug safety evaluation.

EL/PC- 701 - Application Of Biotechnology In Parasitic Disease Research (2 Credits)

**EL/PC -701 Application of Biotechnology in Parasitic Disease Research,
2 Credits (Kept as elective)**

EL/PC- 702 : - Phytopharmaceuticals and Its Standardization Aspects (2 Credits)

1. Introduction of Phytopharmaceuticals, Nutraceuticals, Herbal Cosmetics, Natural food colours and other value added products from natural resources; product development, advantages, market size and regulations.
2. Identification and Authentication of Plant Drugs: Taxonomical Identification of plant, morphological and anatomical description, Natural habitat, geographical distribution of plant, source (wild or cultivated), Season and time of collection, post-harvest processing.

3. Quality Control of Plant Drugs: Foreign matter, total ash, acid insoluble ash, Pesticide residue, Heavy metals, Microbial load, Chromatographic finger print with respect to four phytochemical reference markers, bio assay for phytochemicals.
4. Process for extraction and subsequent fractionation: Steps involved in processing of plant material by retaining the medicinal and nutritional values (phytochemical active principal ingredient -pAPI). Examples: Spray Drying, Lyophilization and Bead milling.
5. Quality specification of pAPI: Details of solvent used, Extractive values, Solvent residue, Microbial load, Heavy metals, Chromatographic finger print profile with respect to reference markers.
6. Biological Activity/ Efficacy Data of pAPI: Primary screen detail [with reference] (target-based/phenotypic with comparator/ standard drug at appropriate concentration); EC₅₀ of pAPI and bioactive Marker, CC₅₀ (cell line used), Selectivity Index (SI). Secondary screen detail (in-vivo model; if more than one, please provide details for all); ED₅₀/dose for curative efficacy, Criterion for Go/No-Go decision (superiority/non-inferiority with standard of care).
7. Stability data of pAPI: Procedures, predictable chemical and galenical changes, technical limitations, testing methods. Stability data of the finished product in the pack intended for marketing.
8. Bioavailability and pharmacokinetics (PK) aspects for Phytopharmaceuticals with examples. Phytoequivalence, pharmaceutical equivalence. PK in mice/rat (dose and route); primary parameters wrt bioactive marker.

Importance of monographs of standards of medicinal plants and their parts, comparative study of BHP, API, Chinese, Japanese Herbal Pharmacopoeia, USP.



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BIOTECHNOLOGY

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Ph.D. Syllabus

BIOTECHNOLOGY

Course No.	Course Name	Credits
Semester-I		
BT-710	Advanced Techniques in Biotechnology	2
BT-720	Principles of Drug Discovery and Development	2
*CS-701	Research Methodology (Compulsory)	2

Course No.	Course Name	Credits
Semester-II		
BT-730	Molecular Oncology and Therapeutics	2
BT-740	Metabolic Disorders	2
*CS- 801	Research and Publication Ethics (Compulsory)	2

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Ph.D. Syllabus SEMESTER - I

BT-710 :- Advanced Techniques in Biotechnology

(2 Credits)

1. **Genetic Manipulation In Cells** – Mammalian gene manipulation techniques and its applications.
2. **Advanced Microscopic Techniques** – Fluorescence and Near IR Imaging, Confocal, Flow Cytometry, AFM, SEM and TEM.
3. **Genomics And Transcriptomics** – Next generation sequencing, data analysis and its applications.
4. **Proteomics** – Advances in proteomics, data analysis and its application in biomarker discovery.
5. **Metabolomics and Lipidomics**– Approaches and its applications.
6. **In vivo Imaging** – Fluorescence and Micro – CT imaging.
7. **Advances In Assay Development** – Bead based assays and Multiplexing assay development.

Book Suggestion:

1. Green and Sambrook. Molecular Cloning: A Laboratory Manual (Fourth Edition).
2. Melanie Kappelman-Fenzl. Next Generation Sequencing and Data Analysis. ISBN-13 : 978-3030624897.
3. Ron Wehrens, Reza Salek. Metabolomics- Practical Guide to Design and Analysis. 2021. ISBN 9781032242637.
4. Simon R. Cherry, Ramsey D. Badawi, Jinyi Qi. Essentials of In Vivo Biomedical Imaging. 2015. ISBN 9781439898741.

BT- 720 :- Principles of Drug Discovery and Development

(2 Credits)

1. **A general introduction and historical perspective on drug discovery and development:** General introduction to drug discovery research and development, history of drug discovery research and development, Examples of few drug discovery in old days and recent times, Small molecules vs Biopharmaceuticals, different stages of drug discovery and development.
2. **Target identification and validation:** Concept of target, different approaches to identify drug targets, Target validation, Single target versus multi-targets approaches, Off target and adverse effects, Drug repurposing.
3. **In-silico drug designing:** Basics of structural bioinformatics, Role of Bioinformatics in drug design, Target understanding at molecular level, lead optimization and in-silico validation, Structure- and ligand-based drug design, Molecular docking and docking algorithms, de-novo ligand design and molecular dynamics simulation.
4. **Drug Screening:** Understanding protein-protein, protein-small molecule interaction study, Role of Structural Biology in Drug Discovery, Cell-free and cell-based assays, exploiting cell biology to design assay platforms, High-throughput screening, Introduction to High Content Screening, Designing and development of disease model.
5. **Medicinal Chemistry, Pharmacology and Drug Development:** Small molecules as drugs, Lipinski rule five, hit identification to lead development process,

Chemistry Manufacturing and Control (CMC), Pre-clinical study, Clinical study, IND, NDA.

- 6. Drug Repurposing:** Drug discovery via drug repurposing, Strategies of drug repurposing, Approaches and methodologies of drug repurposing, Examples of Repositioned drugs in different diseases, Opportunities and challenges, Regulatory and intellectual property issues.

Book Suggestion

1. Madhu Dikshit. Drug Discovery and Development. Springer Nature
2. Benjamin E Blass. Basic Principles of Drug Discovery and Development. Academic Press; 2nd edition (March, 2021).

BT-730 : - Molecular Oncology and Therapeutics (2 Credits)

1. **Cancer:** Different cell types and their cancer, rare cancers. Carcinogens and DNA damage. Cancer registry.
2. **Genes and Cancer Cell Signalling:** Tumor heterogeneity, Cellular oncogene, Tumor suppressor genes, Growth factor receptors and cancers.
3. **Tumor Metabolism:** Warburg effect, cancer cell metabolic homeostasis.
4. **Metastasis and Angiogenesis:** Seed and Soil Hypothesis, Tumor microenvironment, Metastasis. Tumor Angiogenesis.
5. **Tumor Immunology:** Introduction, immune evasion of cancer cells, TAM, CAF, cancers of the immune cells and their molecular mechanism.
6. **Biological Models in Cancer Research:** Cell Lines, Tumor Organoid Models, Small Rodent Models, Zebrafish Models, Drosophila Models, other animal models.
7. **Cancer Therapy and Resistance:** Chemotherapy, Natural anticancer, Radiation Therapy, Immune Therapy, Gene therapy, Antibody based therapies, Personalized medicine, Drug resistant cancers.
8. **Cancer Stem Cells:** Cancer stem cells and relapse, Cancer therapy associated health complications.

Book Suggestion

1. Francesco Pezzella, Mahvash Tavassoli, and David J. Kerr. Oxford Textbook of Cancer Biology. 2019. ISBN-13: 9780198779452.
2. Kleinsmith. Principles of Cancer Biology. 2016. ISBN-13: 978-9332577480.
3. Lauren Pecorino. Molecular Biology of Cancer: Mechanisms, Targets, and Therapeutics. 5th Edition. 2021. ISBN-13 : 978-0198833024.
4. Vincent T. DeVita Jr., Theodore S. Lawrence, Steven A. Rosenberg. Cancer: Principles and Practice of Oncology Primer of Molecular Biology in Cancer. 3rd edition. 2020. ISBN-13 : 978-1975149116.

BT- 740 :- Metabolic Disorders	(2 Credits)
<ol style="list-style-type: none"> 1. Introduction: General principles of metabolic disorders and focuses on pathways, enzyme mechanisms, and diseases associated with defects in metabolism. 2. Metabolic Pathways: Pathways related to carbohydrate, protein and fat metabolism, Urea cycle, Fatty acid oxidation, Citric acid cycle. 3. Disorders related to Cellular Metabolism: Carbohydrate disorder, protein disorder, fat disorder, amino acid disorder, Urea cycle disorder, Organic acid disorder, Glycogen storage disease. 4. Metabolic syndrome: Definition, risk factors, causes and complication. Prevention and treatment of metabolic syndrome. 5. Type 2 diabetes and obesity: Insulin signalling and resistance, Metabolic consequences of type 2 diabetes, Adipose biology, Leptin signalling pathway, GLP1, Newer therapy. 6. Cardiovascular diseases and heart failure: Energy metabolism in heart, Dyslipidemia, hypertension and associated cardiac disorder, recent therapy for cardiac disorders. 	
Book Suggestion	
<ol style="list-style-type: none"> 1. Goodman & Gilman's: The Pharmacological Basis of Therapeutics, 13e 2. Paramjit S Tappia, S K Bhullar, Niranjana S Dhalla. Biochemistry of Cardiovascular Dysfunction in Obesity. Springer Nature Switzerland AG. 2020. 3. Enid Gilbert-Barnes, Lewis A. Barnes, Philip M. Farrell. Metabolic Disease: Foundations of Clinical Management, Genetics, and Pathology. (2nd Edition). IOS Press, Amsterdam. 	



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Ph.D.

PHARMACEUTICAL ANALYSIS

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Ph.D. Syllabus

PHARMACEUTICAL ANALYSIS

Course No.	Course Name	Credits
Semester-I		
PA-710	Chromatography in Pharmaceutical Analysis	2
PA-720	Advances in Chiral Chromatography	2
PA-730	Mass Spectrometry in Pharmaceutical Analysis	2
GE-711	Seminar and Assignments	0
CS -701	Research Methodology (Compulsory)	2

Course No.	Course Name	Credits
Semester-II		
PA-740	Omics studies by Mass Spectrometry	2
PA-750	Analytical Chemometrics	2
PA-760	Reference standard development and its applications	2
PA-770	Workshops/Presentations/Assignments	2
CS -801	Research and Publication Ethics (Compulsory)	2

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Ph.D. Syllabus SEMESTER - I

PA-710 :- Chromatography in Pharmaceutical Analysis (2 Credits)

1. **Sample preparation techniques:** Extraction of analytes from non-biological, biological, and plant-based matrices including Soxhlet extraction, Liquid-liquid extraction, solid-phase extraction, solid-phase microextraction, protein precipitation, Ultrafiltration, direct injection methods. Concept and need for derivatization in pharmaceutical analysis with specific examples.
2. **Theory and practice of HPLC in pharmaceutical research:** HPLC method development and validation approaches for analytical and bioanalytical applications including a selection of mobile phase, stationary phase, detectors. Applications of HPLC in impurity profiling, related substance, dissolution testing, entrapment efficiency, drug loading, and release kinetics. Scale-up of HPLC to preparative applications.
3. **HPLC Troubleshooting:** troubleshooting approaches to remedy chromatographic output like broad and unsymmetrical peaks, peak fronting and tailing, noisy and drifting baseline, ghost peaks. Instrument-related troubleshooting approaches like high back-pressure, system leakage, flow cell blockage, check valve-related problems.
scale-up of HPLC method to preparative HPLC
4. **Advancements in Liquid chromatography:** Ultra and nano-HPLC, HPLC method development for biomolecules, monolithic stationary phases-applications, stationary phases packed by core-shell technology, molecularly imprinted polymers as sorbents for separation and extraction.
5. **Theory and practice of GC in pharmaceutical research:** GC method development and validation approach for analytical and environmental applications including the selection of carrier gas, columns, detectors. GC analysis with special emphasis given to headspace and SPME. Applications of GC in residual solvent and impurity analysis, forensic and environmental science, volatile organic content analysis. and GC Troubleshooting
6. Case studies

Recommended books:

1. Grinberg N, Carr PW, editors. Advances in Chromatography, Volume 57. CRC Press; 2020 Aug 9.
2. Snyder LR, Kirkland JJ, Dolan JW. Introduction to modern liquid chromatography. John Wiley & Sons; 2011 Sep 20.
3. Snyder LR, Kirkland JJ, Glajch JL. Practical HPLC method development. John Wiley & Sons; 2012 Dec 3.
4. Sparkman OD, Penton Z, Kitson FG. Gas chromatography and mass spectrometry: a practical guide. Academic press; 2011 May 17.

PA-720 Advances in Chiral Chromatography (2 Credits)

1. Fundamentals: Nomenclature and CIP rules, types of chirality, types of isomers, configurations, and classification, eutomer, distomer, enantiomeric excess, chiral switching and bridging strategies.
2. Regulatory guidelines about chiral pharmaceutical compounds
3. Techniques for identification of isomers and absolute configurations: NMR, Polarimeter,

XRD, DSC.

4. Separation techniques for chiral separation: HPLC, LC-MS, GC-MS, SFC, CE and other advanced techniques, Chiral derivatizing agents and mechanism.
5. HPLC- method development in various modes of separation (normal, reverse, PO, HILIC, preparative), chiral columns: coated vs immobilized, applications, chiral recognition/separation mechanism
6. Chirality in human body (proteins, receptors, enzymes, etc.) and role of chirality in pharmacokinetics, interconversion, dynamics, and toxicity of pharmaceuticals, natural products, and pesticides.
7. Practical's on separation of enantiomers by various chromatographic modes.

Recommended books:

1. Stereochemistry of organic compounds by Ernest L. Eliel
2. Chirality in biological nanospaces reactions in active sites by Nilashis Nandi
3. Chiral separations by liquid chromatography and related technologies by Hassan Y. Aboul-Enein
4. Chiral analysis by Kenneth W. Busch
5. Regulatory guidelines and review/research papers

PA-730:- Mass Spectrometry in Pharmaceutical Analysis (2 Credits)

1. Basic principles of Mass Spectrometry

Instrumentation: Ionization techniques: Electron ionization, Chemical ionization, Atmospheric pressure ionization (Electrospray ionization, APCI, and APPI), other sources: MALDI, ICP, etc.

3. Mass Analyzers: Quadrupole, Time of flight, Ion traps, LIT, FTICR, Orbitrap, High Resolution Mass Spectrometry

4. Hyphenated Mass Spectrometry: GC/MS, HPLC/UPLC-MS and Tandem Mass Spectrometry (Product ion scan, Precursor ion scan, neutral loss scan, SIM and MRM)

4. Interpretation of mass spectra: Isotopes and ion abundances, the Fragmentation pattern of organic molecules with different functional groups, Qualitative analysis, Quantitative analysis

5. Liquid chromatography-electrospray ionization-mass spectrometry (LC-ESI-MS) to the detection and determination of various drugs

5. Applications: Application of mass spectrometry in Pharmacology/Toxicology, Environmental Monitoring/Analysis and Organic chemistry (Structure elucidation of organic molecules, A brief outline of omics study including the scope of biomarkers study. Impurity profiling and drug metabolite profiling, reference standards development

6. Development, Validation, and transfer for high throughput bioanalytical LC-MS/MS Methods.

Recommended books:

1. A Textbook of Mass Spectrometry by Jürgen H Gross, ISBN: 978-3-319-54398-7
2. Mass Spectrometry: Principles and Applications, Book by Edmond de Hoffmann, Jean Joseph Charette, and Vincent Stroobant
3. Gas Chromatography and Mass Spectrometry: A Practical Guide, Book by Fulton G. Kitson, ISBN: 9780080920153
4. Liquid Chromatography-Mass Spectrometry By Wilfried M.A. Niessen, ISBN 9780367577827
5. Medical Applications of Mass Spectrometry, Editors: Karoly Vekey, Andreas Telekes, Akos Vertes, ISBN: 9780444519801

GE-711: Seminar (0 Credit)

This subject is introduced to develop presentation skills of students

Ph.D. Syllabus

SEMESTER - II

PA-740 Omics study by Mass Spectrometry

(2 Credits)

A: Fundamentals and analytical methodologies in metabolomics

- (a) Metabolomics: Significance in clinical research
- (b) Collection and preparation of clinical samples for metabolomics
- (c) Preparation of external and internal standards for quality control
- (d) Targeted and untargeted Metabolomic profiling by gas chromatography/liquid chromatography-mass spectrometry
- (e) Data interpretation and statistical analysis
- (f) Application of metabolomics in clinical cases

B: Lipidomics

- (a) Basic fundamentals and importance of lipidomics
- (b) Sample preparation and internal standards for lipidomics
- (c) Lipids classification and characterization using mass spectrometry.
- (d) Shotgun lipidomics and LC-MS/MS based lipidomics
- (e) Targeted and global lipidomics.
- (f) Application of Lipidomics in Biomedical Research
- (g) Data interpretation and statistical analysis

C: Proteomics

- (a) Basics and importance of proteomics.
- (b) Strategies in proteomics: Gel based and gel-free proteomics
- (c) Database and search engines in proteomics.
- (d) Applications of proteomics: Understanding mechanism of pathogenesis, Drug discovery, Disease diagnosis, identification, and characterization of novel proteins
- (e) Quantitative proteomics: Labeled and label-free proteomics
- (f) PTM (post translational modifications) sample prep, enrichment and separation
- (g) Interactomics and its applications in biological sciences.
- (h) Advanced topics – Proteogenomics, Top-down proteomics
- (i) Data interpretation and statistical analysis
- (j) Bioinformatics for protein analysis: RAW files conversion (msconvert), analysis of MS data (PMF), analysis of MS/MS data, Quantitation tools and methods, DIA analysis tools, Blind PTM search, PTM site localization and annotation, Targeted protein, and PTM analysis

D. Phyto Metabolomics

- (a) Collection of Plant Material: Planning, Pressing, Drying, Poisoning, Mounting, Labeling, Storing
- (b) Extraction Techniques: Maceration, Infusion, Digestion, Decoction, Percolation, Soxhlet extraction, Microwave-assisted extraction, Ultrasound-assisted extraction, Supercritical fluid extraction, Pressurized hot water extraction, Pressurized fluid extraction, Membrane-assisted solvent extraction, Stir-Bar sorptive Extraction.
- (c) Derivatization Techniques: (1) Silylation, Alkylation/Methylation, Acylation, Esterification for GCMS analysis (2) Derivatization method of amine, carboxyl, phenols, hydroxyl, carbonyl, thiols functional group for LC-MS/MS analysis

- (d) Analytical Techniques: Phyto metabolomics analysis by NMR, GC-MS, GC-QTOF, LC-MS, LC-QTOF, CE-MS, FTICR-MS
 (e) Data interpretation and statistical analysis

Recommended books:

1. Metabolomics: From Fundamentals to Clinical Applications edited by Alessandra Sussulini. Cham : Springer International Publishing ISBN: 9783319476568
2. Metabolomics in Practice: Successful Strategies to Generate and Analyze Metabolic Data
 Editors: Wolfram Weckwerth, Michael Lämmerhofer, Wiley-VCH, ISBN: 9783527330898
3. Metabolomics, Editors Paul L. Wood, ISBN: 978-1-0716-0864-7
4. Lipidomics: Current and Emerging Techniques (ISSN) 1st Edition, by William Griffiths (Editor, Contributor), Yuqin Wang (Editor, Contributor), Jonathan M Curtis (Contributor), Yu Xia (Contributor), Ruth Andrew (Contributor), Giuseppe Astarita (Contributor), Steven Wilson (Contributor), Jonas Abdel-Khalik (Contributor), J Griffin (Contributor), Royal Society of Chemistry, ISBN 978-1788011600
5. Mass Spectrometry-Based Lipidomics Methods and Protocols, Editors, Fong-Fu Hsu, ISBN: 978-1-0716-1410-5
6. Lipidomics in Health & Disease: Methods & Application (Translational Bioinformatics Book 14) 1st ed. 2018 Edition by Xiangdong Wang (Editor), Duoqiao Wu (Editor), Huali Shen (Editor), ISBN 978-9811306198
7. LC-MS/MS in Proteomics: Methods and Applications Book in Methods in molecular biology (Clifton, N.J.) · January 2010 DOI: 10.1007/978-1-60761-780-8

PA-750 CHEMOMETRICS IN ANALYTICAL CHEMISTRY (2 Credits)

1. Descriptive Statistics: Normal Distribution, Lorentzian Distribution, handling Multivariate Data,
2. Pattern Recognition: Unsupervised Analysis: Choice of Variables, Measures between Objects, Clustering Techniques, Hierarchical Techniques, K-Means Algorithm, Principal Component Analysis (PCA) case studies
3. Pattern Recognition: Supervised Learning: Discriminant Functions, Bayes' Theorem, Linear Discriminant Function, Nearest Neighbours, Artificial Neural Networks
4. Calibration and Regression Analysis: Linear Regression, Errors, and Goodness of Fit, Polynomial Regression, Multivariate Regression
5. Uncertainty in pharmaceutical method development and validation, Process capability and approaches in uncertainty calculation
6. Software for chemometric based calculation: Case studies based interpretation

Recommended books:

- 1.0 Mike J Adams, Chemometrics in Analytical Spectroscopy, 2nd edition, 2004, RSC Analytical Spectroscopy Series.
- 2.0 Alexey L. Pomerantsev, Chemometrics in Excel, first edition, 2009, Wiley publications.
- 3.0 Kurt Varmuza, Peter Filzmoser, Introduction to Multivariate Statistical Analysis in Chemometrics, first edition, 2009, CRC press.
- 4.0 James N. Miller, Jane C. Miller, Robert D. Miller. Statistics and Chemometrics for

Analytical Chemistry, Seventh edition, 2018, Pearson Publications.

5.0 Łukasz Komsta, Yvan Vander Heyden, Joseph Sherma. Chemometrics in Chromatography. first edition, 2009, CRC press.

6.0 Hardeo Sahai, Mario M. Ojeda. Analysis of Variance for Random Models, Volume 2: Unbalanced Data: Theory, Methods, Applications, and Data Analysis. volume 1 and 2. 2004. Birkhäuser Publications.

PA-760:- Reference Standard Development and Its Applications (2 Credits)

1. Introductions: Basics, purpose, importance, and sources of reference standards
2. Various types of reference standards (ARS/WS/authentic material) and quality control tests for certified reference material
3. Standardization procedures of ARS from WS, method validation, and uncertainty of method
4. Production and planning: selection of candidate material, measurement and testing procedures, validation of measurement procedures, verification and calibration of measuring equipment, homogeneity assessment, stability studies(long term/short term and transport), assigning property values based on results of measurements, the uncertainty of assigned values
5. Characterization of reference standards: physical test, purity test, assay development, HPLC, UV, FT-IR, DSC, TGA, LC-QTOF, Muffle furnace, and ICP-MS for the standardization of certified reference materials
6. Various methods for loss on drying, loss on ignition, potency, and purity assessments
7. Labeling, containers, and storage of reference materials
8. Various formats of certificate of analysis for RF/CRF/Analytical standards
9. NABL, WHO, and ISO guidelines: special focus on ISO 17034:2016 general requirements for the competence of reference material producers
10. Various pharmacopeia guidelines for the reference standards
11. Case studies (a) research article study of melamine reference material
(b) POP and NEM reference material development for dope control research
© Phytopharmaceuticals/herbal reference standard

Recommended books:

1. Zschunke A, editor. Reference materials in analytical chemistry: a guide for selection and use. Springer Science & Business Media; 2000 Jun 21.
2. Medvedevskikh SV, Kremleva ON, Vasil'eva IE, Sobina EP, editors. Reference Materials in Measurement and Technology: Proceedings of the Third International Scientific Conference. Springer Nature; 2020.
3. Stoeppler M, Wolf WR, Jenks PJ, editors. Reference materials for chemical analysis: certification, availability and proper usage. John Wiley & Sons; 2008 Jul 11
4. ISO 17034:2016 general requirements for the competence and consistent operation of reference material producers.
5. Hon PY, Chu PW, Cheng CH, Lee TC, Chan PK, Cheung ST, Wong YC. Development of melamine-certified reference material in milk using two

different isotope dilution mass spectrometry techniques. Journal of Chromatography A. 2011 Sep 28;1218(39):6907-13.

6. WHO guidelines for the reference materials (<https://www.who.int> › guidelines › quality-control)
7. USP, IP, and BP guidelines

PA-770:- Workshops/Presentations/Assignments (2 Credits)

This course is designed to give training about research-based case studies and their presentations along with practical exposure.



SYLLABUS

Ph.D.

PHARMACEUTICS

**NATIONAL INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH
GUWAHATI**

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Dist: Kamrup, Assam, Pin: 781101, Assam, India
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Ph.D. Syllabus

PHARMACEUTICS

Course No.	Course Name	Credits
Semester-I		
PE-710	Implications of Solid State Properties in Drug Delivery (Prerequisite to course PE-660)	2
PE-720	Technological Aspects of Oral Modified Release Formulations	2
*CS-701	Research Methodology (Compulsory)	2

Course No.	Course Name	Credits
Semester-II		
PE-810	Novel Approaches for Targeted Drug Delivery	2
PE-820	Advanced Drug Delivery System	2
*CS-801	Research and Publication Ethics (Compulsory)	2

***Detailed Syllabus is available at Page No. 39-40**

Ph.D. Syllabus SEMESTER - I

PE-710:- Implications of Solid State Properties in Drug Delivery (2 Credits)

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 nanocrystalline solid dispersions, small molecule assisted nano-crystalline solid dispersions. (b) Crystal habit-surface anisotropy and its impact on dissolution behavior.

PE-720:- Technological Aspects of Oral Modified Release Formulations (2 Credits)

1. Human anatomy physiology and CR products.
2. Types, selection of drug candidates.
3. Strategies involved in development and marketing.
4. Selection of polymer: Polymer characterization, polymer properties influencing drug permeation, factors influencing kinetics of solute release
5. Osmotic drug delivery systems.
6. Relevance of chrono-therapeutics: Site-specific absorption and metabolism, software Solutions.
7. Intellectual property opportunities: Existing patented technologies.
8. Formulation and technology development processes for oral MR formulations.
9. Scale up issues in oral MR products: SUPAC technology transfer protocols.
10. Setting up of specifications for API: Excipients and drug product; Dissolution specifications; Regulatory aspects

Ph.D. Syllabus SEMESTER - II

PE-810:- Novel Approaches for Targeted Drug Delivery (2 Credits)

1. **Principles of drug targeting and molecular basis of targeted drug delivery:** Receptor mediated endocytosis; Different levels of targeting-first order, second order and third order targeting; Different types of targeting-active and passive targeting.
2. **Disease based targeting approaches:** Novel approaches to target diseases and disorders such as cancer and infectious diseases, exploitation of disease environment for the targeted delivery of therapeutics.
3. **Organ based targeting:** Novel strategies for CNS, pulmonary, liver, and colon targeting.
4. **Cell/Organelles based targeting:** Mitochondria, Nuclear targeting, lymphatics/M cells, liver parenchymal cells/macrophages, hepatocytes and bone marrow cells.
5. **Physico-chemical approaches of targeting:** Stimuli responsive: Magnetically, thermal and pH assisted drug delivery systems, Chemical drug delivery (prodrugs), Lipid-drug/Polymer drug conjugates.
6. **Carrier based approach for targeted drug delivery:** Functionalized liposomes, polymeric and lipid nanoparticles, liquid crystalline nanoparticles, polymeric micelles, functionalized carbon nanotubes and inorganic nanoparticles.
7. **Gene Delivery:** Barriers to gene delivery, novel approaches based on viral and non viral vectors for site specific gene delivery, their advantages and limitations, siRNA delivery.
8. **Advanced characterization techniques for nanocarriers:** Nanoscale characterization techniques, Biophysical characterization of nanoparticles and In vivo imaging techniques Fluorescence Gamma scintigraphy, X rays.
9. **Miscellaneous Topics:** Emerging roles of Emulsomes, transferosomes, ethosomes, bilosomes, virosomes etc. for drug/ macromolecule delivery.
10. **Nanotoxicology and regulatory issues:** Toxicity and regulatory hurdles of nanocarriers, Nanotoxicity in lungs.

PE-820:- Advanced Drug Delivery Systems (2 Credits)

1. **Dendrimers: a versatile targeting platform:** Dendrimers in biomedical applications; Characterization of dendrimers; Dendrimer-drug interactions; Dendrimer biocompatibility and toxicity; Supramolecular structures from dendrons and dendrimers; Dendrimers in gene delivery; Targeted drug delivery with dendrimers.
2. **Drug-eluting stents: an innovative multidisciplinary drug delivery platform.** Role of stent design and coatings on restenosis and thrombosis; Mechanisms of controlled drug release from drug-eluting stents; Factors governing local pharmacokinetics; The Taxus™ drug eluting stent; Zotarolimus (ABT-578) eluting stents; Clinical experience

and applications of drug-eluting stents in the noncoronary vasculature, bile duct and esophagus.

3. Polymer drug conjugates (PDCs) in drug delivery: Need of PDCs as polymeric prodrugs in drug delivery; Polymers used in PDCs; linkers, Design of PDCs, Factors affecting PDCs; PDCs in cancer therapy.

4. Mucoadhesive polymeric drug delivery systems: Mucoadhesive polymers: strategies, achievements and future challenges; basics and underlying mechanisms of mucoadhesion; mucoadhesion tests for polymers and polymer-coated particles to design optimal mucoadhesive drug delivery systems; Nasal mucoadhesive drug delivery; buccal mucoadhesive drug delivery; mucoadhesive polymers in ocular drug delivery.



SYLLABUS

Ph.D.

MEDICINAL CHEMISTRY

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Ph.D. Syllabus

MEDICINAL CHEMISTRY

Course No.	Course Name	Credits
Semester-I		
MC-710	Stereoselective and Stereospecific Synthesis	2
MC-730	Organometallic and Sustainable Chemistry in Synthesis of Pharmaceuticals	2
MC-810	Principles of Peptide Chemistry	2
*CS-701	Research Methodology (Compulsory)	2

Course No.	Course Name	Credits
Semester-II		
MC-720	Synthetic Strategies in the Total Synthesis of Complex	2
MC-820	Carbohydrates: Occurrence, Structure, Reactions, Syntheses, Functions and Applications in Present Day Drugs	2
MC-830	Advanced Topics in Drug Action and Drug Design	2
*CS- 801	Research and Publication Ethics (Compulsory)	2

***Detailed Syllabus is available at Page No. 39-40**

Ph.D. Syllabus SEMESTER - I

MC-710 :- Stereoselective and Stereospecific Synthesis (2 Credits)

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

MC-730:- Organometallic and Sustainable Chemistry in the Synthesis of Pharmaceuticals (2 Credits)

- Carbon-carbon coupling reactions:** Suzuki, Hiyama, Stille, Negishi, Kumadacoupling reactions; Mechanistic aspects of these reactions, comparison in mechanism, relative reactivities of organometallic coupling partners; Palladium and other metalcatalysis, controlling parameters; Heck (α - and β -arylation) and Sonogashira coupling reactions; Palladium- and Coppercatalysis, mechanism; Synthesis of biaryls, multisubstituted alkenes, alkynes, and various scaffolds.
- Carbon-heteroatom coupling reactions:** Ullmann, Chan-Lam, and Buchwald-Hartwig reactions. Mechanistic aspects, comparison; Synthesis of various amines, ethers, thioethers, and heterocycles.
- Cross-coupling of unactivated arenes:** Direct arene C-H bond arylation; oxidative couplings; two- and multi-fold C-H bond arylations; various approaches and mechanistic aspects; synthesis of biaryls and various scaffolds.
- Application of coupling reactions (as mentioned in 1-3) in the synthesis of pharmaceutically-relevant compounds; Importance in the drug discovery research.
- Metathesis:** Grubbs (first and second generation) and Schrock catalysts, advantages and disadvantages, Importance of Ru and molybdenum catalysis; olefin, alkyne, ring closing, ring opening and multiple metathesis; Mechanism of these reactions, aspects of reaction conditions, and structural aspects of reactants.
- Application of metathesis-reactions in the synthesis of various structural motifs including heterocycles, natural products, and pharmaceuticals; Importance in the drug discovery research.
- Green chemistry:** Principles, metrics, perspective of pharmaceutical industries; Green discoveries; greener reactions, catalysis, alternative reaction media, green technologies; Sustainable synthesis of pharmaceuticals.
- Click chemistry:** Click reaction-criteria, water as solvent, various classes of reactions, thermodynamics; Huisgen cycloaddition and its modification, and nucleophilic ring opening of epoxide and aziridine.
- Alkyne-azide click chemistry in the drug discovery research:** Synthetic and medicinal chemistry advantageous aspects of the reaction; Combinatorial, structure-based and approach of click chemistry in drug discovery research.
- Multicomponent reactions (MCR):** Ugi, Passerini, Biginelli, Hantzsch, Mannich, Petasis, Strecker, Kabachnik-Fields reactions, Mechanism of these reactions, Conceptual discovery of MCR, Ugi-deprotection-cyclization (UDC) approach and synthesis of various biologically-relevant scaffolds, multi MCRs in synthesis, Diversity-oriented and convergent synthesis of pharmaceutically-relevant compounds. Interface

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

- Importance of peptides in drug discovery.
- Protection and deprotection: General aspects, need for protection, minimal

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

Ph.D. Syllabus SEMESTER - II

MC-720 :- Synthetic Strategies in the Total Synthesis of Complex Organic Molecules (2 Credits)

1. **Retrosynthetic analysis disconnections and reliability of reactions, synthons:** Donor and acceptor, functional group interconversions, one group carbon-heteroatom and carbon-carbon disconnections, two group carbon-heteroatom and carbon-carbon disconnections, chemo-, regio- and stereo-selectivity considerations, natural reactivity and umpolung.
2. **General synthetic reaction patterns and strategies:** Aliphatic nucleophilic and electrophilic substitutions, aromatic nucleophilic and electrophilic substitutions, addition to carbon-carbon and carbon-heteroatom multiple bonds, eliminations, rearrangements, oxidations and reductions.
3. **Chemistry of protecting groups:** Protection for alcohols, carbonyl groups, carboxylic groups and amino groups.
4. **Applications of synthetic strategies in the total synthesis of selected organic molecules:** Cholesterol (b) Estrone (c) Progesterone (d) Reserpine (e) Penicillin (f) Prostaglandin (g) Longifolene (h) Taxol.

MC-820:- Carbohydrates: Occurrences, Structure, Reactions, Syntheses, Functions and Applications in Present Day Drugs (2 Credits)

1. **Overview:** Introduction; importance of carbohydrates in food & nutrition and biology.
2. **Sources, Structure & Shape:** This will complement course # MC-630 in certain respects. Methods of structure elucidation.
3. **Recognition of carbohydrates by proteins:** Relevance in disease; discussion on the process of infection by microorganisms and possible methods of intervention; specific examples holera, flu, etc.
4. **Reactions at the anomeric centre:** Methods of glycosylation; details on the various types of glycosyl donors used; their preparation and methods of activation.
5. **Reactions at centres other than the anomeric centre:** Selective transformations; strategies for selective and global protection & deprotection of carbohydrates and their significance.
6. **Chemical synthesis:** Highlights on the need for synthesis; various approaches adopted for the chemical methods of oligosaccharide synthesis with examples.
7. **Enzymatic & chemo-enzymatic oligosaccharide syntheses:** Scope & limitation; discussion with examples relevant to medicinal chemists.

8. Solid-phase oligosaccharide synthesis: Relevance & its importance; different strategies used; applications.
9. Carbohydrate-based drugs: Discussion on various drugs (aminoglycoside antibiotics including glycopeptides, enediynes, macrolides, anthracyclines, etc; alkaloid, steroid and terpenoid glycosides; polyphenol glycosides etc.) that contain carbohydrate moiety (moieties) including polysaccharide therapeutics.
10. Polysaccharide vaccines: Relevance; discussion on the isolation and modification of bacterial polysaccharides, specifically capsular polysaccharides; protein conjugation.

MC-830 :- Advanced Topics in Drug Action and Drug Design, (2 Credits)

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

9. **Case study 2:** Mechanism based inhibition, carbene reactive metabolites, epoxidereactivemetabolites, nitroso reactive metabolites, S-oxidation vs epoxidation in thiophene.
10. **Case study 3:** Drug action of agents acting at Glycogen Synthase Kinase (GSK), seven different methods of lead action on GSK3, drug design strategies for anti-diabetic drugs acting at GSK3.

(Syllabus for Compulsory Courses)**Semester-I**

CS- 701 :- Research Methodology	(2 Credits)
<p>Unit 1: Objectives and types of research: Motivation and objectives, research methods vs methodology. Types of research – descriptive vs analytical, applied vs fundamental, quantitative vs qualitative, conceptual vs empirical. Introduction to drug discovery & development research, objectives, flowchart from discovery to post-marketing research, overview of research methodology in various areas of drug discovery and development research.</p> <p>Unit 2: Research formulation and Literature review– Defining and formulating the research problem, selecting the problem, the necessity of defining the problem, the importance of literature review in defining a problem, Literature review - primary and secondary sources, reviews, monographs, patents, research databases, web as a source, searching the web, critical appraisal of literature, identifying gap areas from literature review and research databases, and development of a working hypothesis.</p> <p>Unit 3: Research design and methods: Research design – basic principles, need of research design, features of good design, important concepts relating to research design, observation and facts, laws and theories, prediction and explanation, research databases, development of models, developing a research plan – exploration, description, diagnosis, and experimentation.</p> <p>Unit 4: Execution of the research, data collection and analysis: Aspects of method validation, observation and collection of data, methods of data collection, sampling methods, data processing and analysis strategies and tools, data analysis with statistical packages (GraphPad Prism, SPSS for Student t-test, ANOVA, etc), hypothesis testing, generalization, and interpretation.</p> <p>Unit 5: Safety measures in the laboratory: Handling of hazardous chemicals, incompatible chemicals, flammable solvents, toxic chemicals and forms of toxic materials. Approaches for prevention and management of fire, electrical, chemical, biological, and gaseous hazards, good laboratory practices. General safety rules, waste minimization approaches and safety practices for disposal of chemical waste, biologicals and other laboratory waste.</p>	

(Syllabus for Compulsory Courses)**Semester-II****CS- 801 :- Research and Publication Ethics****(2 Credits)****Unit 1: Research Ethics:**

- a) Ethics – ethical issues, ethical committees (human & animal)
- b) Ethics with respect to science and research
- c) Intellectual honesty and research integrity
- d) Scientific misconducts: Falsification, Fabrication, and Plagiarism
- e) What is plagiarism? Similarity report software like iThenticate/ Turnitin/ Urkund.
- f) Redundant publications: duplicate and overlapping publications, salami-slicing
- g) Selective reporting, and misrepresentation of data

Unit 2: Publication Ethics:

- a) Publication ethics: definition, introduction, and importance.
- b) Best practices / standards-setting initiatives and guidelines: COPE, WAME, etc.
- c) Conflicts of interest
- d) Publication and Research misconduct: definition, concept, problems that lead to unethical behavior and vice versa, types
- e) Violation of publication ethics, authorship, and contributorship
- f) Identification of publication misconduct, complaints, and appeals
- g) Predatory publishers and journals.
- h) Journal finder/journal suggestion tools.

Unit 3: IPR and scholarly publishing:

Intellectual Property Rights (IPR) and patent law, commercialization, copyright, royalty, trade-related aspects of intellectual property rights (TRIPS)

Unit 4: Report and thesis writing:

- a) Structure and components of scientific reports, types of reports, technical reports, and thesis.
- b) Thesis writing – different steps and software tools (Word processing, etc) in the design and preparation of the thesis, layout, structure (chapter plan), and language of typical reports, Illustrations and tables, bibliography, referencing, and footnotes.
- c) Oral presentation – planning, software tools, creating and making an effective presentation, use of visual aids, the importance of effective communication
- d) Writing a research proposal and research grant
- e) Scholarly publishing – IMRaD concept and design of research paper, citation and acknowledgment, reproducibility, and accountability.
- f) Graphical Abstract and Artwork preparation

Unit 5: Databases and Research Metrics

- a) Indexing databases: PubMed, Embase, etc.
- b) Citation databases: Web of Science, Scopus, etc.
- c) Impact Factor of the journal as per Journal Citation Report, SNIP, SJR, IPP, Cite Score, *etc.*
- d) Metrics: h index, g index, i10 index, altmetrics