ADITYA UNIVERSITY

School of Pharmacy

(Pharmaceutical Sciences)

Ph.D. Course Work

(Applicable for the scholars admitted from the AY: 2025-26)

The credit requirement for the Ph.D. coursework is a minimum of 12 credits, including the courses on 'Research Methodology' and 'Research and Publication Ethics' for 2 credits each. The candidate must complete two domain-specific courses of 3 credits each, recommended by the respective Department Research Committee (DRC). These courses can be completed through MOOCs.

The candidate must present two research seminars before the completion of coursework, typically within the first year. The first research seminar shall be before the end of first semester on introduction to the proposed research work, and the second seminar shall be before the end of the second semester or after the completion of course work on the research proposal, as per the format provided. Each research seminar will have one credit weightage. The course structure is presented in Table 1 and list of domain-specific courses is presented in Table 2.

Table 1: Course Structure

S.No.	Course Code	Name of the Course	Credit (s)
1	2517UC01	Research Seminar –I	1
2	2517UC02	Research Seminar –II	1
3	2517UC03	Research Methodology	2
4	2517UC04	Research and Publication Ethics	2
5	-	Domain Specific Course –I	3
6	-	Domain Specific Course –II	3
Total			**12**

Table 2: List of Domain-Specific Courses

S. No.	Course Code	Name of the Course
1.	2517PY01	Modern Pharmaceutics
2.	2517PY02	Regulatory Affairs
3.	2517PY03	Nano Technology and Targeted Drug delivery systems
4.	2517PY04	Advanced Biopharmaceutics & Pharmacokinetics
5.	2517PY05	Cosmetics and Cosmeceuticals
6.	2517PY06	Pharmaceutical Formulation Development
7.	2517PY07	Novel drug delivery systems
8.	2517PY08	Drug delivery: Principles and Engineering
9.	2517PY09	Advanced Organic Chemistry
10.	2517PY10	Advanced Medicinal chemistry
11.	2517PY11	Chemistry of Natural Products
12.	2517PY12	Pharmaceutical Process Chemistry
13.	2517PY13	Scale up and Technology Transfer
14.	2517PY14	Principles of Drug Discovery
15.	2517PY15	Artificial Intelligence in Drug Discovery and Development
16.	2517PY16	Computer Aided Drug Design
17.	2517PY17	Advanced Pharmaceutical Biotechnology
18.	2517PY18	Proteins and protein Formulation
19.	2517PY19	Biological Evaluation of Drug Therapy
20.	2517PY20	Bioinformatics and Computer Technology
21.	2517PY21	Bioprocess Engineering and Technology
22.	2517PY22	Microbial And Cellular Biology
23.	2517PY23	Experimental Biotechnology
24.	2517PY24	Immunotechnology
25.	2517PY25	Modern Pharmaceutical Analytical techniques
26.	2517PY26	Food Analysis
27.	2517PY27	Advanced Instrumental Analysis
28.	2517PY28	Herbal and Cosmetic Analysis
29.	2517PY29	Quality Control and Quality Assurance
30.	2517PY30	Modern Bio-Analytical Techniques
31.	2517PY31	Advanced Spectral Analysis
32.	2517PY32	Interpretative molecular spectroscopy
33.	2517PY33	Clinical Research
34.	2517PY34	Clinical Pharmacokinetics and Therapeutic Drug Monitoring
35.	2517PY35	Pharmacoepidemiology & Pharmacoeconomics

36.	2517PY36	Cellular and Molecular Pharmacology
37.	2517PY37	Advanced Pharmacology and therapeutics
38.	2517PY38	Pharmacological and Toxicological Screening Methods
39.	2517PY39	Neuro Biology
40.	2517PY40	Cancer Biology
41.	2517PY41	Indian system of medicine
42.	2517PY42	Industrial Pharmacognostical Technology
43.	2517PY43	Medicinal Plant biotechnology
44.	2517PY44	Herbal cosmetics
45.	2517PY45	Advanced Pharmacognosy
46.	2517PY46	Regulatory Aspects of Herbal & Biologicals
47.	2517PY47	Phytochemistry
48.	2517PY48	Pharmacognosy & Metabolic Engineering

Research Methodology

Course Code: 2517UC03

UNIT -I:
Research Design
Overview of research process and design, Use of Secondary and exploratory data to answer the research question, Qualitative research, Observation studies, Experiments and Surveys. Case studies.

UNIT-II:
Data Collection and Sources
Measurements, Measurement Scales, Questionnaires and Instruments, Sampling and methods. Data - Preparing, Exploring, examining and displaying.

UNIT-III:
Data Analysis and Reporting
Overview of Multivariate analysis, Hypotheses testing and Measures of Association. Presenting Insights and findings using written reports and oral presentation.

UNIT-IV:
Intellectual Property Rights
Intellectual Property – The concept of IPR, Evolution and development of concept of IPR, IPR development process, Trade secrets, utility Models, IPR & Bio diversity, Role of WIPO and WTO in IPR establishments, Right of Property, Common rules of IPR practices, Types and Features of IPR Agreement, Trademark, Functions of UNESCO in IPR maintenance

UNIT-V:
Patents
Patents – objectives and benefits of patent, Concept, features of patent, Inventive step, Specification, Types of patent application, process E-filling, Examination of patent, Grant of patent, Revocation, Equitable Assignments, Licenses, Licensing of related patents, patent agents, Registration of patent agents.

Text Books:

1. Research Methodology: A Step-by-Step Guide for Beginners, Ranjit Kumar, Sage Publications, 4th Edition, 2015.
2. Intellectual Property: A Very Short Introduction, Siva Vaidhyanathan, Oxford University Press, 2017.
3. Intellectual Property: The Law of Trademarks, Copyrights, Patents, and Trade Secrets. Deborah E. Bouchoux, Cengage India, 4th Edition, 2013.

Reference Books:

1. Research methodology: an introduction for science & engineering students, Stuart Melville and Wayne Goddard, Juta Academic, 2nd Edition, 2014.
2. Research design: Qualitative, quantitative, and mixed methods approaches, Creswell, J.W. and Creswell, J.D., Sage publications, 2017.
3. Intellectual Property in New Technological Age, Robert P. Merges, Peter S. Menell, Mark A. Lemley, Clause 8 Publishing; Volume I: Perspectives, Trade Secrets & Patents; 2023.

Web Links:

1. https://archive.nptel.ac.in/courses/121/106/121106007/#
2. https://onlinecourses.swayam2.ac.in/ntr24_ed08/preview

Research and Publication Ethics

Course Code: 2517UC04

UNIT-I:
Philosophy & Ethics
Introduction to Philosophy:
Definition, Nature & Scope, Concept, Branches
Ethics:
Definition, Moral Philosophy, Nature of Moral Judgements & Reactions

UNIT-II:
Scientific Conduct
Ethics with respect to Science and Research, Intellectual Honesty & Research Integrity
Scientific Misconduct:
Falsification, Fabrication & Plagiarism
Redundant Publications:
Duplicate & Overlapping Publication, Salami Slicing, Selective Reporting & Misrepresentation of Data

UNIT-III:
Publication Ethics:
Definition, Introduction and Importance
Best Practices/Standard Setting Initiatives and Guidelines:
COPE, WAVE, etc., Conflicts of Interest
Publication Misconduct:
Definition, Concept, Problems that lead to unethical behaviour and vice-versa, types, Violation of Publication Ethics, Authorship and Contributorship, Identification of Publication Misconduct, Complaints and Appeals, Predatory Publishers and Journals

UNIT-IV:
Open Access Publishing
Open Access publications and Initiatives, SHERPA/RoMEO online resource to check publisher copyright and self-achieving policies, Software tool to identify predatory publications developed by SPPU, Journal Finder/Journal Suggestion tools viz. JANE, ELSEVIER, SPRINGER, Journal Suggester, etc.

UNIT-V:
Publication Misconduct
A: Group Discussions:
Subject-specific Ethical issues, FFP, Authorship, Conflicts of Interest, Complaints and Appeals: Examples and fraud from India and Abroad
B: Software tools:
Use of Plagiarism software like Turnitin, Urkund and other open-source software tools

Unit VI:
Database and Research Metrics
A: Database:
Indexing database, Citation database: web of science, Scopus etc.
Impact factor of journal as per the Journal Citation Report, SNIP, SJR, IPP, cite score

B. Metrics:
h-index, g-index, i-10 index, AL metrics, etc.

Text Books:
1. Philosophy in Science, Bird A, Routledge, 2006.
2. A Short History of Ethics, MacIntyre, London, 1967.

Reference Book:
1. Ethics in Science, Education and Governance, Indian National Science Academy, 2019.

Web links:
1. www.niehs.nih.gov/research/resources/bioethics/whatis
2. https://onlinecourses.swayam2.ac.in/nou22_ge73/preview

Modern Pharmaceutics

Course Code: 2517PY01

UNIT-I:
Targeted Drug Delivery Systems
Concepts, events, and biological processes involved in drug targeting. Tumor targeting and brain-specific delivery.

UNIT-II:
Targeting Methods
Introduction, preparation, and evaluation. Nanoparticles and liposomes: types, preparation, and evaluation.

UNIT-III:
Microcapsules / Microspheres
Types, preparation and evaluation. Monoclonal antibodies: preparation and application. Preparation and application of niosomes, aquasomes, phytosomes, and electrosomes.

UNIT-IV:
Pulmonary Drug Delivery Systems
Aerosols, propellants, containers: types, preparation and evaluation. Intra-nasal route delivery systems: types, preparation, and evaluation.

UNIT-V:
Nucleic Acid-Based Therapeutic Delivery System
Gene therapy introduction (ex-vivo and in-vivo). Potential target diseases for gene therapy (inherited disorders and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems. Biodistribution and pharmacokinetics. Knowledge of therapeutic antisense molecules and aptamers as drugs of the future.

Text Books:

1. Y. W. Chien, *Novel Drug Delivery Systems*, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. S.P. Vyas and R.K. Khar, *Controlled Drug Delivery - Concepts and Advances*, Vallabh Prakashan, New Delhi, First edition 2002.

Reference Books:

1. N. K. Jain, *Controlled and Novel Drug Delivery*, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint 2001).
2. Vasant V. Ranade and Mannfred A. Hollinger, *Drug Delivery Systems*, CRC Press, 2nd edition, 2003.

Web links:

1. https://www.fda.gov/science-research/nanotechnology-programs-fda
2. https://www.ich.org/page/quality-guidelines
3. https://www.journals.elsevier.com/journal-of-controlled-release

Regulatory affairs

Course Code: 2517PY02

UNIT-I:
Pharmaceutical Documentation and Generic Drug Development
Documentation in pharmaceutical industry: Master Formula Record (MFR), Batch Manufacturing Record (BMR), Distribution Records, and Standard Operating Procedures (SOPs). Drug Master File (DMF) — purpose, types (Type I–V), format, and submission process. Generic drug product development: introduction, Hatch–Waxman Act, Code of Federal Regulations (CFR), and regulatory pathways for generic drug approval (ANDA). Bioequivalence (BE) studies

UNIT-II:
Regulatory Requirements for Product Approval
Approval processes for APIs, biologics, and novel therapies. Steps involved in obtaining NDA, ANDA, and BLA approvals. Post-approval regulatory requirements and lifecycle management. Overview of ICH CTD and eCTD submission format.

UNIT-III:
Chemistry, Manufacturing, and Controls (CMC) and Global Regulatory Framework
Overview of CMC sections in regulatory submissions — product composition, specifications, stability, analytical validation, and process validation. ICH guidelines. Comparative study of global regulatory agencies — FDA (USA), EMA (Europe), MHRA (UK), TGA (Australia), and PMDA (Japan). Regulatory strategy for emerging markets (ROW countries).

UNIT-IV:
Non-Clinical and Clinical Drug Development
Global submission of IND, NDA, ANDA, and IMPD (Investigational Medicinal Product Dossier). Investigator's Brochure (IB) — contents and structure. Clinical trial phases I–IV: objectives, design, and regulatory requirements. Institutional Review Board (IRB) / Independent Ethics Committee (IEC) functions.

UNIT-V:
Pharmacovigilance and Post-Marketing Surveillance
Pharmacovigilance system master file (PSMF). Adverse Drug Reaction (ADR) reporting and signal detection. Periodic Safety Update Reports (PSUR) and Development Safety Update Reports (DSUR). Overview of electronic submission standards (eCTD 4.0 and RPS).

Text Books:

1. Ira R. Berry and Robert P. Martin (Eds.), *The Pharmaceutical Regulatory Process*, 2nd Edition, Informa Healthcare, 2008.
2. Leon Shargel and Isadore Kaufer, *Generic Drug Product Development: Solid Oral Dosage Forms*, 2nd Edition, Marcel Dekker, 2005.

Reference Books:

1. Richard A. Guarino, *New Drug Approval Process: Accelerating Global Registrations*, 5th Edition, CRC Press, 2010.

2. Douglas J. Pisano and David Mantus, *FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics*, CRC Press, 2013.

Web Links:

1. https://www.fda.gov/drugs/development-approval-process-drugs
2. https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation
3. https://www.ich.org

Nano Technology and Targeted Drug delivery systems

Course Code: 2517PY03

UNIT-I:
Principles of Targeted Drug Delivery Systems
Concept, events, and biological processes involved in drug targeting. Principles of passive and active targeting. Tumor targeting and brain-specific drug delivery systems. Barriers to drug targeting (physiological, cellular, and biochemical) and strategies to overcome them.

UNIT-II:
Nanoparticles and Liposomes
Definition, types, preparation, and characterization of nanoparticles and liposomes. Formulation methods: solvent evaporation, polymerization, nano-precipitation, and microfluidic methods. Surface modification techniques (PEGylation, ligand conjugation) and evaluation parameters particle size, zeta potential, entrapment efficiency, in-vitro release studies, and stability. Pharmacokinetics and biodistribution of nanoparticulate drug delivery systems.

UNIT-III:
Microspheres, Microcapsules, and Vesicular Systems
Preparation and evaluation of microspheres and microcapsules (spray drying, coacervation, solvent evaporation). Monoclonal antibodies, niosomes, aquasomes, phytosomes, transfersomes, and electrosomes: methods of preparation, characterization, and therapeutic significance.

UNIT-IV:
Pulmonary and Nasal Drug Delivery Systems
Pulmonary DDS: formulation aspects of aerosols, propellants, containers, and evaluation methods particle size analysis, aerodynamic behavior, and in-vitro deposition. Nasal DDS: types, principles, Applications in systemic drug delivery and CNS targeting.

UNIT-V:
Nucleic Acid-Based Therapeutic and Gene Delivery Systems
Introduction to gene therapy (ex-vivo and in-vivo). Liposomal and nanoparticle-based gene delivery systems — mechanism, biodistribution, and safety evaluation. Therapeutic applications of antisense oligonucleotides, siRNA, aptamers, and CRISPR-based gene editing delivery systems.

Text Books:

1. Y. W. Chien, *Novel Drug Delivery Systems*, 2nd Edition, Revised and Expanded, Marcel Dekker, Inc., New York, 1992.
2. S. P. Vyas and R. K. Khar, *Controlled Drug Delivery: Concepts and Advances*, Vallabh Prakashan, New Delhi, 2002.

Reference Books:

1. N. K. Jain, *Controlled and Novel Drug Delivery*, CBS Publishers & Distributors, New Delhi, 1997.

2. Vasant V. Ranade and Mannfred A. Hollinger, *Drug Delivery Systems*, CRC **Press,** 2nd Edition, 2003.

Web Links:

1. https://www.fda.gov/science-research/nanotechnology-programs-fda
2. https://www.nano.gov/
3. https://www.journals.elsevier.com/journal-of-controlled-release

Advanced Biopharmaceutics & Pharmacokinetics

Course Code: 2517PY04

UNIT-I:
Drug Absorption and Distribution
Mechanisms of drug absorption from the gastrointestinal tract. Physicochemical and physiological factors influencing absorption. pH–partition theory, dissolution rate, Noyes–Whitney equation, and factors affecting drug dissolution. Drug distribution: volume of distribution, protein binding, tissue permeability, and redistribution phenomena.

UNIT-II:
Pharmacokinetic Models
Compartmental models: one-compartment and multi-compartment models: concepts, assumptions, and equations. Determination of pharmacokinetic parameters such as absorption rate constant (Ka), elimination rate constant (Ke), volume of distribution (Vd), and clearance (Cl). Non-compartmental analysis and statistical moment theory. PBPK modelling

UNIT-III:
Drug Elimination and Nonlinear Pharmacokinetics
Renal excretion of drugs: glomerular filtration, tubular secretion, and reabsorption processes. Hepatic metabolism: Phase I and Phase II reactions, enzyme kinetics, and intrinsic clearance. Nonlinear pharmacokinetics (dose-dependent kinetics): Michaelis–Menten equation, enzyme saturation, and clinical implications. Influence of disease states (renal and hepatic impairment) and age on drug kinetics.

UNIT-IV:
Bioavailability, Bioequivalence, and Drug Interactions
Absolute and relative bioavailability, measurement and interpretation. Design and analysis of bioavailability and bioequivalence studies as per regulatory guidelines (USFDA, EMA, and CDSCO). Drug interactions influencing absorption, distribution, metabolism, and excretion. Applications of pharmacokinetics in dosage form design and individualization of therapy.

UNIT-V:
Clinical Pharmacokinetics and Dose Optimization
Concepts of loading and maintenance doses. Therapeutic Drug Monitoring (TDM) — purpose, methods, and interpretation. Population pharmacokinetics and interindividual variability. Design of multiple dosing regimens — steady-state kinetics and accumulation index. Applications of pharmacokinetic principles in clinical practice and patient care.

Text Books:

1. Gibaldi M. and Perrier D., *Pharmacokinetics*, 2nd Edition, Marcel Dekker, New York, 1982.
2. Rowland M. and Tozer T.N., *Clinical Pharmacokinetics: Concepts and Applications*, 4th Edition, Wolters Kluwer Health, 2011.

Reference Books:

1. Wagner J.G., *Fundamentals of Clinical Pharmacokinetics*, Drug Intelligence Publications, Hamilton, 1975.
2. Shargel L., Wu-Pong S., and Yu A.B.C., *Applied Biopharmaceutics and Pharmacokinetics*, 7th Edition, McGraw-Hill Education, 2016.

Web Links:

1. https://www.fda.gov/media/87219/bio
2. https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-investigation-bioequivalence_

Cosmetics and Cosmeceuticals

Course Code: 2517PY05

UNIT-I:
Fundamentals of Cosmetics and Cosmeceuticals
Definition and classification of cosmetics and cosmeceuticals. Difference between cosmetics, drugs, and cosmeceuticals. Regulatory provisions and legal requirements for cosmetics as per Drugs and Cosmetics Act (India), FDA (USA), and EU Regulations. Harmonized guidelines for safety assessment, labeling, and claims substantiation.

UNIT-II:
Formulation of Cosmetic Products – Skin and Hair Care
Formulation and evaluation of Skin-care products: creams, lotions, powders, and gels. Sunscreens: mechanism of UV protection, SPF determination, and safety testing. Anti-aging and skin-lightening formulations. Hair-care products: shampoos, conditioners, hair colorants, hair oils, and styling agents.

UNIT-III:
Oral, Nail, and Eye Cosmetics
Formulation and evaluation of Oral care products: toothpaste, mouthwash, tooth powder, and whitening agents. Nail care products: nail lacquers, removers, and cuticle softeners. Eye cosmetics.

UNIT-IV:
Cosmeceuticals and Active Ingredients
Introduction to cosmeceuticals and their role in dermatological therapy. Bioactive ingredients in cosmeceuticals: antioxidants, vitamins (A, C, E), peptides, ceramides, retinoids, alpha hydroxy acids (AHAs), and botanical extracts.

UNIT-V:
New Trends and Technologies in Cosmetic Science
Nanotechnology in cosmetics — liposomes, niosomes, nanoemulsions, and nanogels in topical delivery. Herbal cosmetics: formulation, standardization, and regulatory considerations. Sustainable and green cosmetics.

Text Books:

1. Harry R. G., *Harry's Cosmeticology*, 8th Edition, Chemical Publishing Co., New York, 2000.
2. Poucher W. A., *Poucher's Perfumes, Cosmetics and Soaps*, 10th Edition, Springer, 2008.

Reference Books:

1. Zatz J. L. (Ed.), *Cosmetics Science and Technology Handbook*, Marcel Dekker, New York, 1999.
2. Mitsui T. (Ed.), *New Cosmetic Science*, Elsevier Science, Amsterdam, 1997.

Web Links:

1. https://www.fda.gov/cosmetics
2. https://health.ec.europa.eu/system/files/202306/cosmetic_1223_2009_regulation_
3. https://www.scconline.org/

Pharmaceutical Formulation Development

Course Code: 2517PY06

UNIT-I:
Preformulation Studies
Objectives, significance, and stages of preformulation in formulation development. Physicochemical characterization of Active Pharmaceutical Ingredients (APIs) Drug-excipient compatibility studies

UNIT-II:
Solid Oral Dosage Forms
Formulation design of tablets and capsules: Granulation methods (wet, dry, direct compression). Optimization of excipients. Coating technologies, Packaging considerations and evaluation of stability under environmental conditions

UNIT-III:
Liquid and Semi-Solid Dosage Forms
Formulation and evaluation of solutions, suspensions, and emulsions. Rheological properties and their influence on product stability. Semi-solid formulations

UNIT-IV:
Parenteral and Ophthalmic Products
Preformulation considerations in parenteral dosage forms. Solvents, stabilizers, antioxidants, buffers, and tonicity adjusters. Sterilization methods and validation. Formulation of ophthalmic products.

UNIT-V:
Advanced Formulation Approaches and Regulatory Aspects
Introduction to Quality by Design (QbD) and Design of Experiments (DoE) in formulation development. Emerging formulation technologies: 3D printing, microneedle patches, and orodispersible films.

Text Books:

1. Leon Lachman, Herbert A. Lieberman, and Joseph L. Kanig, *The Theory and Practice of Industrial Pharmacy*, 3rd Edition, Varghese Publishing House, Bombay, 1987.
2. Yie W. Chien, *Novel Drug Delivery Systems*, 2nd Edition, Marcel Dekker, New York, 1992.

Reference Books:

1. Remington, *The Science and Practice of Pharmacy*, 22nd Edition, Pharmaceutical Press, London, 2013.
2. Banker G. S. and Rhodes C. T., *Modern Pharmaceutics*, 4th Edition, Marcel Dekker, New York, 2002.

Weblinks:

1. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ich-q8-r2-pharmaceutical-development
2. https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-guidelines/quality
3. https://www.pharmaexcipients.com/

Novel drug delivery systems

Course Code: 2517PY07

UNIT-I:
Introduction to Novel Drug Delivery Systems
Concept and significance of novel drug delivery systems (NDDS). Limitations of conventional dosage forms and the need for novel approaches. Advantages, challenges, and design considerations for NDDS. Classification: controlled, sustained, targeted, and site-specific delivery systems.

UNIT-II:
Controlled and Sustained Release Drug Delivery Systems
Principles of controlled drug delivery — physicochemical, biological, and kinetic factors influencing release. Design and formulation approaches for oral controlled release systems. Mechanisms of drug releasediffusion, dissolution, erosion, and osmosis. Mathematical modeling and in-vitro–in-vivo correlation (IVIVC). Applications of controlled release formulations in chronic therapy.

UNIT-III:
Targeted and Site-Specific Drug Delivery Systems
Carriers for targeted delivery: liposomes, niosomes, microspheres, nanoparticles, dendrimers, and magnetic systems. Mechanisms of cellular uptake and intracellular trafficking. Tumor-targeted drug delivery and brain-targeted systems (BBB transport).

UNIT-IV:
Transdermal, Mucosal, and Implantable Drug Delivery Systems
Transdermal systems: structure of skin, penetration enhancers, formulation and evaluation of transdermal patches. Buccal and nasal delivery systems — mucoadhesion principles, polymers, formulation methods, and evaluation.

UNIT-V:
Advanced and Emerging Drug Delivery Technologies
Stimuli-responsive ("smart") delivery systems: pH, temperature, enzyme, and redox-sensitive carriers. Protein, peptide, and vaccine delivery systems: formulation, stability, and release challenges. Gene delivery systems: viral and non-viral vectors.

Text Books:

1. Chien, Y.W. — *Novel Drug Delivery Systems*, 2nd Edition, Marcel Dekker, New York (1992).
2. Robinson, J.R. & Lee, V.H.L. — *Controlled Drug Delivery Systems*, Marcel Dekker, New York (1992).

Reference Books:

1. Chein, Y.W. — *Transdermal Controlled Systemic Medications*, Marcel Dekker, Inc.
2. J.S. Patton, R.E. Byron — *Inhalation Delivery of Therapeutic Peptides and Proteins*, Marcel Dekker.

Web Links:

1. https://www.fda.gov/media/70814/download
2. https://www.journals.elsevier.com/journal-of-controlled-release
3. https://pubmed.ncbi.nlm.nih.gov/?term=novel+drug+delivery+systems

Drug delivery: Principles and Engineering

Course Code: 2517PY08

UNIT-I:
Fundamental Principles of Drug Delivery
Introduction to drug delivery systems; pharmacokinetics — bioavailability, elimination, therapeutic index. Prodrugs and controlled release concepts.

UNIT-II:
Material Science & Polymers in Drug Delivery
Synthesis and properties of polymers; crystallinity vs amorphousness, biopolymers — natural and synthetic; biocompatibility and biodegradation. Polymer-drug conjugates, PEGylation.

UNIT-III:
Controlled Release Mechanisms and Dosage Forms
Diffusion-controlled systems (Fick's law), reservoir systems, non-erodible and bio-erodible matrix systems; hydrogels (physical/chemical), pore-size calculations, in-situ cross-linking.

UNIT-IV:
Particulate Systems and Biomaterials for Delivery
Nano- and micro-particles: dendrimers, liposomes, micelles; metal vs polymeric particles — effect of particle shape, charge, elasticity. Protein adsorption, tissue engineering, biomaterial interactions in drug delivery.

UNIT-V:
Routes, Smart Systems and Translational Aspects
Route-specific delivery: oral, subcutaneous, intramuscular, transdermal, inhalation, intravenous; implants and infection considerations. Smart responsive drug delivery, targeted delivery, cell & gene delivery, nanotoxicology and market translation.

Text Books:

1. W. Mark Saltzman, *Drug Delivery: Engineering Principles for Drug Therapy*, Oxford University Press, 2001.
2. Anya M. Hillery & Kinam Park, *Drug Delivery: Fundamentals and Applications*, 2nd Edition, CRC Press, 2016.

Reference Books:

1. Nicholas A. Peppas, *Intelligent Therapeutics: Biomimetic Systems and Nanotechnology in Drug Delivery*, Oxford University Press, 2005.
2. Yong C. Lam & Sang Cho (Eds.), *Advanced Drug Delivery: Technologies and Applications*, Wiley-Blackwell, 2018.

Web links:

1. https://nptel.ac.in/courses/102108077 NPTEL
2. https://onlinecourses.nptel.ac.in/noc24_bt62/preview NPTEL Online Courses
3. https://be.iisc.ac.in/wp-content/uploads/2024/04/Drug-Delivery_-Principles-and-Applications.pdf be.iisc.ac.in

Advanced Organic Chemistry

Course Code: 2517PY09

UNIT-I:
Reaction Mechanisms – Structure and Reactivity
Reaction intermediates: carbocations, carbanions, free radicals, carbenes, nitrenes, and benzynes — structure, stability, and generation. Types of organic reactions: substitution, addition, elimination, and rearrangement reactions. Effect of structure on reactivity. Kinetic vs thermodynamic control in organic reactions.

UNIT-II:
Reaction Mechanisms and Stereochemistry
Mechanistic and stereochemical aspects of: Nucleophilic substitution (SN1, SN2, SNi, and neighboring group participation). Electrophilic substitution (SE1, SE2, and SEAr). Elimination reactions (E1, E2, and E1cb mechanisms).

UNIT-III:
Reactive Reagents and Synthetic Applications
Organometallic reagents — organolithium, organomagnesium (Grignard), organozinc, and organocuprates in organic synthesis. Applications of reagents such as $LiAlH_4$, $NaBH_4$, DCC, PCC, OsO_4, NBS, and DDQ. Use of protecting groups for hydroxyl, carbonyl, amino, and carboxylic acid functionalities. Mechanistic study and synthetic utility of oxidation and reduction reactions. Catalytic hydrogenation, selective oxidations, and reductions in complex molecule synthesis.

UNIT-IV:
Pericyclic Reactions and Photochemistry
Types of pericyclic reactions — electrocyclic, cycloaddition, sigmatropic, and cheletropic reactions. Woodward–Hoffmann rules and conservation of orbital symmetry. Molecular orbital correlation diagrams.

UNIT-V:
Advanced Synthetic Methods and Green Chemistry
Modern synthetic methodologies — cross-coupling reactions (Suzuki, Heck, Sonogashira, and Negishi). Microwave-assisted and ultrasound-assisted organic synthesis. Multicomponent reactions and solid-phase synthesis. Concepts of green chemistry — atom economy, solvent-free reactions, catalysis, and biodegradable reagents.

Text Books:

1. Jerry March, *Advanced Organic Chemistry: Reactions, Mechanisms and Structure*, 6th Edition, Wiley-Interscience, 2007.
2. Jonathan Clayden, Nick Greeves, Stuart Warren, and Peter Wothers, *Organic Chemistry*, 2nd Edition, Oxford University Press, 2012.

Reference Books:

1. Carey F. A. and Sundberg R. J., *Advanced Organic Chemistry, Part A & B*, 5th Edition, Springer, 2007.
2. Fleming I., *Frontier Orbitals and Organic Chemical Reactions*, Wiley, 1976.

Web Links:

1. https://nptel.ac.in/courses/104106120
2. https://www.organic-chemistry.org/
3. https://www.rsc.org/journals-books-databases/about-journals/organic-biomolecular-chemistry/

Advanced Medicinal chemistry

Course Code: 2517PY10

UNIT-I:
Drug Design and Molecular Modification
Fundamentals of drug design: approaches to new drug discovery — analog design, lead identification, and optimization. Structure–Activity Relationship (SAR) and physicochemical parameters (Hammett, Hansch, and Free–Wilson analysis). Molecular modifications to improve activity and reduce toxicity — bioisosterism, homologation, and rigid analogs. Prodrugs and soft drugs: rationale, design, and applications. Receptor theory and drug–receptor interactions — types of bonding, affinity, and intrinsic activity.

UNIT-II:
Enzyme and Receptor Chemistry in Drug Action
Mechanism of enzyme catalysis and enzyme inhibition — competitive, noncompetitive, and allosteric. Design of enzyme inhibitors and transition-state analogs. Receptor-based drug design — receptor models, agonists, antagonists, and allosteric modulators. Introduction to molecular docking, QSAR, and pharmacophore modeling.

UNIT-III:
Synthetic Strategies in Medicinal Chemistry
Synthetic approaches to biologically active molecules: Antihypertensives (e.g., Losartan, Enalapril), Anticancer agents (e.g., Imatinib, Methotrexate), Antiviral agents (e.g., Zidovudine, Oseltamivir). Concept of combinatorial chemistry and high-throughput screening (HTS). Microwave-assisted and green synthetic techniques in medicinal chemistry.

UNIT-IV:
Drug Metabolism and Toxicity
Phase I and Phase II metabolic pathways — oxidation, reduction, hydrolysis, conjugation reactions. Role of cytochrome P450 enzymes in metabolism. Drug–drug interactions and metabolic activation (bioactivation). Toxicological aspects — mutagenicity, carcinogenicity, and teratogenicity. Strategies to minimize toxicity through molecular modification.

UNIT-V:
Recent Advances and Case Studies
Computer-aided drug design (CADD) — molecular docking, dynamics, and QSAR techniques. Recent developments in targeted drug discovery: kinase inhibitors, monoclonal antibodies, and peptide-based drugs. Applications of artificial intelligence and machine learning in drug design. Drug repurposing and personalized medicine.

Text Books:

1. Wilson and Gisvold's, *Textbook of Organic Medicinal and Pharmaceutical Chemistry*, 12th Edition, Wolters Kluwer Health, 2011.
2. Patrick G. L., *An Introduction to Medicinal Chemistry*, 6th Edition, Oxford University Press, 2017.

Reference Books:

1. Thomas Nogrady and Donald F. Weaver, *Medicinal Chemistry: A Molecular and Biochemical Approach*, 3rd Edition, Oxford University Press, 2005.
2. Graham L. Patrick, *Instant Notes in Medicinal Chemistry*, BIOS Scientific Publishers, 2001.

Web Links (Specific and Authoritative):

1. https://go.drugbank.com
2. https://pubchem.ncbi.nlm.nih.gov/
3. https://www.rcsb.org

Chemistry of Natural Products

Course Code: 2517PY11

UNIT-I:
Introduction to Natural Products
Classification, sources, and general methods of isolation, purification, and characterization of natural products. Biosynthetic pathways: acetate, shikimic acid, mevalonate, and mixed biosynthetic routes. Role of secondary metabolites in plants and microorganisms.

UNIT-II:
Alkaloids and Terpenoids
Classification and structural features of alkaloids and terpenoids. General methods of isolation and structure elucidation. Biogenesis and chemistry of representative examples: atropine, quinine, reserpine, morphine, and nicotine. Monoterpenes and sesquiterpenes: citral, menthol, and camphor.

UNIT-III:
Steroids and Hormones
Structural features and stereochemistry of steroids. Biosynthesis of cholesterol and its conversion to steroidal hormones. Structure and functions of testosterone, progesterone, and estradiol. Steroidal drugs: corticosteroids and contraceptive agents.

UNIT-IV:
Flavonoids and Glycosides
Classification, general properties, and biosynthesis of flavonoids. Isolation, structure elucidation, and biological significance of rutin, quercetin, and catechin. Cardiac glycosides — digitalis and strophanthin; saponins and their therapeutic importance.

UNIT-V:
Recent Developments and Applications
Application of spectroscopic techniques (UV, IR, NMR, MS) in structure determination of natural products. Natural products as leads for drug discovery — examples from anticancer, antimicrobial, and anti-inflammatory agents. Introduction to marine and microbial natural products.

Text Books:

1. Gurdeep R. Chatwal, *Organic Chemistry of Natural Products*, Vol. I & II, Himalaya Publishing, 2003.
2. O.P. Agarwal, *Natural Products: Chemistry and Applications*, Krishna Prakashan, 2014.

Reference Books:

1. T.E. Wallis, *Textbook of Pharmacognosy*, 5th Ed., CBS Publishers, 2002.
2. P. S. Kalsi, *Spectroscopy of Organic Compounds*, 6th Ed., New Age International, 2017.

Web Links:

1. https://www.sciencedirect.com/topics/chemistry/natural-products
2. https://pubchem.ncbi.nlm.nih.gov
3. https://www.nature.com/subjects/natural-products

Pharmaceutical Process Chemistry

Course Code: 2517PY12

UNIT-I:
Introduction to Process Chemistry
Scope and importance of process chemistry in the pharmaceutical industry. Difference between research-scale and industrial-scale synthesis. Route selection and process optimization — cost, yield, safety, and environmental considerations. Overview of scale-up and technology transfer.

UNIT-II:
Reaction Mechanisms and Reagent Selection
Common organic reactions used in bulk drug synthesis — oxidation, reduction, halogenation, acylation, alkylation, and condensation. Criteria for reagent and solvent selection. Use of catalysts and phase-transfer reagents. Green chemistry principles and eco-friendly synthesis approaches.

UNIT-III:
Process Development and Optimization
Design of experiments (DoE) in process optimization. Critical process parameters (CPP) and critical quality attributes (CQA). Process analytical technology (PAT) and in-process control. Case studies of process development for selected APIs (e.g., Paracetamol, Ibuprofen, Atorvastatin).

UNIT-IV:
Purification, Isolation, and Crystallization Techniques
Purification strategies — distillation, crystallization, and chromatography. Polymorphism and solid-state characterization. Crystallization control and solvent recovery. Safety aspects in handling hazardous reactions and scale-up.

UNIT-V:
Regulatory and Quality Aspects in Process Chemistry
Process validation and documentation as per ICH Q7 & Q11. Good Manufacturing Practices (GMP) in API production. Regulatory submissions — DMF, CMC documentation, and post-approval changes. Case studies of industrial process development highlighting yield improvement and impurity control.

Text Books:

1. K. C. Nicolaou and E. J. Sorensen, *Classics in Total Synthesis*, Wiley-VCH, 1996.
2. A. Cywar and M. E. Kopcha, *Process Chemistry in the Pharmaceutical Industry*, CRC Press, 2017.

Reference Books:

1. Peter J. Dunn, Andrew Wells, and Michael T. Williams, *Green Chemistry in the Pharmaceutical Industry*, Wiley-VCH, 2010.
2. Neal G. Anderson, *Practical Process Research & Development – A Guide for Organic Chemists*, 2nd Ed., Academic Press, 2012.

Web Links:

1. https://www.fda.gov/drugs/guidances-drugs
2. https://www.ich.org/page/quality-guidelines
3. https://pubs.acs.org/journal/oprd

Scale Up and Technology Transfer

Course Code: 2517PY13

UNIT-I:
Principles of Scale-Up
Concept and significance of scale-up in pharmaceutical manufacturing. Fundamental differences between laboratory, pilot plant, and commercial scale. Steps involved in scale-up from R&D to production. Key factors affecting scale-up — mixing, heat transfer, mass transfer, and process control. Case studies illustrating common scale-up challenges.

UNIT-II:
Technology Transfer Process
Definition, need, and importance of technology transfer (TT). Phases of TT — R&D, pilot plant, production, and commercialization. Key documentation: technology transfer protocol (TTP), master formula record (MFR), and batch manufacturing record (BMR), Roles and responsibilities of sending unit (SU) and receiving unit (RU).

UNIT-III:
Scale-Up of Dosage Forms
Scale-up considerations for: Solid dosage forms (blending, granulation, compression, coating). Semisolids (mixing, emulsification, homogenization), Liquid orals (solubilization, filtration, filling), Parenterals (sterilization, aseptic processing) In-process quality control and process validation.

UNIT-IV:
Equipment and Facility Considerations
Selection and design of pilot-plant equipment. Material of construction, cGMP layout, and environmental control. Instrumentation, automation, and process monitoring systems. Case studies on equipment scale-up (mixers, dryers, reactors).

UNIT-V:
Regulatory and Quality Aspects of Technology Transfer
Regulatory expectations for TT as per WHO, USFDA, EMA, and ICH. ICH Q8–Q12 guidelines related to technology transfer. Quality risk management, change control, and post-transfer validation. Examples of successful technology transfers in pharmaceutical industries.

Text Books:

1. Michael Levin, *Pharmaceutical Process Scale-Up*, 3rd Edition, CRC Press, 2011.
2. Tim Freeman, *Pharmaceutical Manufacturing Handbook: Production and Processes*, Wiley-Interscience, 2008.

Reference Books:

1. Sarfaraz K. Niazi, *Handbook of Pharmaceutical Manufacturing Formulations*, Vol. 1–6, CRC Press, 2019.
2. Robert A. Nash and Alfred H. Wachter, *Pharmaceutical Process Validation*, 3rd Edition, Marcel Dekker, 2003.

Web Links:

1. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations
2. https://www.ich.org/page/quality-guidelines
3. https://www.who.int/publications/i/item/WHO-TRS-961-annex-7

Principles of Drug Discovery

Course Code: 2517PY14

UNIT-I:
Basic Concepts of Drug Discovery
Definition, scope, and stages of drug discovery and development. Sources of new drugs: natural products, synthetic compounds, and biotechnological approaches. Historical evolution of drug discovery — from serendipity to rational design. Target identification and validation — enzymes, receptors, ion channels, and nucleic acids. Role of genomics and proteomics in modern drug discovery.

UNIT-II:
Lead Discovery and Optimization
Concept of lead compounds and lead optimization. Strategies for lead discovery — random screening, virtual screening, and high-throughput screening (HTS). Structure–Activity Relationship (SAR) and quantitative SAR (QSAR) approaches. Pharmacophore mapping, molecular docking, and fragment-based drug design.

UNIT-III:
Molecular Modeling and Computational Approaches
Introduction to computer-aided drug design (CADD). Ligand-based and structure-based design methods. Homology modeling, docking algorithms, and molecular dynamics simulations.

UNIT-IV:
Drug–Receptor Interactions and Mechanisms of Action
Types of drug–receptor interactions: ionic, hydrogen bonding, hydrophobic, and van der Waals forces. Agonists, antagonists, partial agonists, and inverse agonists. Signal transduction pathways — GPCR, ion channels, and enzyme-linked receptors.

UNIT-V:
Recent Trends and Regulatory Aspects
Drug discovery approaches in cancer, CNS, and infectious diseases. Introduction to biologics, biosimilars, and peptide-based drugs. Drug repurposing and repositioning strategies.

Text Books:

1. Thomas J. Hennekens, *Principles of Drug Discovery*, Academic Press, 2018.
2. Raymond G. Hill and Humphrey P. Rang, *Drug Discovery and Development: Technology in Transition*, 2nd Ed., Elsevier, 2013.

Reference Books:

1. Gareth Thomas, *Medicinal Chemistry: An Introduction*, 2nd Ed., Wiley, 2007.
2. Vogel H. G. and Maas J., *Drug Discovery and Evaluation: Pharmacological Assays*, 4th Ed., Springer, 2016.

Web Links:

1. https://www.fda.gov/drugs/development-approval-process-drugs
2. https://pubchem.ncbi.nlm.nih.gov
3. https://www.nature.com/subjects/drug-discovery

Artificial Intelligence in Drug Discovery and Development

Course Code: 2517PY15

UNIT-I:
Introduction to Artificial Intelligence in Drug Discovery
Overview of Artificial Intelligence (AI), Machine Learning (ML), and Deep Learning (DL). Applications of AI across the pharmaceutical R&D pipeline. Integration of AI with computational chemistry, bioinformatics, and pharmacology. Advantages, challenges, and limitations of AI in drug discovery and development. Case studies of AI-driven drug discovery success stories.

UNIT-II:
AI in Target Identification and Validation
Role of AI in omics data analysis (genomics, proteomics, and metabolomics). AI-based prediction of drug–target interactions and biomarker discovery. Machine learning algorithms for disease modeling and target prioritization. Use of network pharmacology

UNIT-III:
AI in Lead Discovery and Optimization
Virtual screening, molecular docking, and de novo molecule generation using AI. QSAR modeling, pharmacophore identification, and molecular property prediction. AI-driven retrosynthetic analysis and synthesis route prediction.

UNIT-IV:
AI in Preclinical and Clinical Development
Application of AI in ADMET prediction, toxicity assessment, and pharmacokinetics. Optimization of formulation and drug delivery using ML models. AI in clinical trial design — patient selection, adaptive trials, and predictive analytics.

UNIT-V:
Regulatory, Ethical, and Future Perspectives
Regulatory framework and guidance from FDA, EMA, and ICH for AI-based tools. Model validation, interpretability, and data transparency challenges. Ethical considerations bias, privacy, and accountability in AI systems. Emerging trends: generative AI, quantum computing, and AI in personalized medicine. AI-driven innovation in the global pharmaceutical ecosystem.

Text Books:

1. Nathan Brown, *Artificial Intelligence in Drug Discovery*, Royal Society of Chemistry, 2020.
2. Mark Chang, *Artificial Intelligence for Drug Development, Precision Medicine, and Healthcare*, CRC Press, 2020.

Reference Books:

1. Andreas Bender & Igor Tetko, *Computational Drug Discovery and Design*, Springer, 2021.

2. Jürgen Bajorath (Ed.), *Chemoinformatics and Computational Chemical Biology*, Humana Press, 2016.

Web Links:

1. https://www.nature.com/collections/ai-drug-discovery
2. https://pubs.acs.org/journal/acsjctc
3. https://www.fda.gov/science-research/science-and-research-special-topics/artificial-intelligence-and-machine-learning

Computer Aided Drug Design

Course Code: 2517PY16

UNIT-I:
Introduction to Computer Aided Drug Design (CADD)
Fundamentals of CADD — concepts, scope, and applications in modern drug discovery. Structure–Activity Relationship (SAR) and Quantitative SAR (QSAR). Overview of drug design strategies: ligand-based and structure-based approaches. Role of computational chemistry, cheminformatics, and molecular modeling. Advantages and limitations of CADD in pharmaceutical R&D.

UNIT-II:
Molecular Modeling and Energy Calculations
Concept of molecular mechanics and quantum mechanics in modeling. Force fields (AMBER, CHARMM, OPLS, MMFF) and energy minimization techniques. Conformational analysis and potential energy surface mapping. Molecular dynamics

UNIT-III:
Ligand-Based Drug Design (LBDD)
Pharmacophore modelling, definition, generation, and validation. 3D-QSAR methods: CoMFA and CoMSIA. Molecular alignment and descriptor calculation. Database searching and virtual screening techniques. Applications of machine learning and AI in LBDD.

UNIT-IV:
Structure-Based Drug Design (SBDD)
Protein structure preparation and active site identification. Molecular docking — types, algorithms (rigid, flexible), and scoring functions. De novo design of ligands using fragment-based and evolutionary algorithms. Validation of docking protocols and binding affinity prediction.

UNIT-V:
ADMET, Toxicity, and Regulatory Aspects
In-silico prediction of Absorption, Distribution, Metabolism, Excretion, and Toxicity (ADMET). Drug-likeness filters (Lipinski, Veber, Ghose rules). Prediction of physicochemical and pharmacokinetic properties.

Text Books:

1. Andrew R. Leach, *Molecular Modelling: Principles and Applications*, 2nd Ed., Pearson Education, 2001.
2. Patrick Walters & Matthew Repasky, *Practical Applications of CADD: Virtual Screening and Lead Optimization*, Springer, 2018.

Reference Books:

1. G. Patrick, *An Introduction to Medicinal Chemistry*, 6th Ed., Oxford University Press, 2017.
2. Johan Gasteiger & Thomas Engel, *Chemoinformatics: A Textbook*, Wiley-VCH, 2003.

Web Links:

1. https://www.rcsb.org
2. https://pubchem.ncbi.nlm.nih.gov
3. https://www.schrodinger.com/resources

Advanced Pharmaceutical Biotechnology

Course Code: 2517PY17

UNIT-I:
Fundamentals of Biotechnology in Drug Development
Overview and scope of biotechnology in pharmaceuticals. Recombinant DNA technology — tools, techniques, and applications. Cloning vectors, expression systems (bacterial, yeast, mammalian). Production of recombinant proteins and monoclonal antibodies. Regulatory perspectives on biotechnology-derived products.

UNIT-II:
Protein Engineering and Biopharmaceuticals
Principles and techniques of protein engineering and directed evolution. Design, modification, and optimization of therapeutic proteins. Production of biopharmaceuticals hormones, vaccines, cytokines, and growth factors. Biosimilars and biobetters development, characterization, and regulatory considerations.

UNIT-III:
Gene Therapy and Nucleic Acid-Based Therapeutics
Fundamentals of gene therapy — ex-vivo and in-vivo approaches. Viral and non-viral vectors for gene delivery. Antisense oligonucleotides, siRNA, miRNA, and CRISPR-Cas9 technologies. Design and development of mRNA-based vaccines and therapeutics. Ethical and biosafety considerations in gene therapy.

UNIT-IV:
Fermentation and Downstream Processing
Fermentation technology: types of bioreactors, scale-up, and process control. Upstream and downstream processing of recombinant products. Cell culture techniques media optimization, cell banking, and contamination control. Purification and recovery of proteins chromatography, filtration, and ultracentrifugation. Quality assurance and validation in bioprocessing.

UNIT-V:
Emerging Trends in Pharmaceutical Biotechnology
Tissue engineering and regenerative medicine. Stem cell technology and induced pluripotent stem cells (iPSCs). Current trends — AI in bioprocessing, personalized medicine, and 3D bioprinting.

Text Books:

1. Gary Walsh, *Pharmaceutical Biotechnology: Concepts and Applications*, 2nd Ed., Wiley, 2013.
2. B. R. Glick, J. J. Pasternak, & C. L. Patten, *Molecular Biotechnology: Principles and Applications of Recombinant DNA*, 5th Ed., ASM Press, 2017.

Reference Books:

1. Peter J. Lachmann, *Biopharmaceuticals: Biochemistry and Biotechnology*, 2nd Ed., Wiley, 2003.

2. Janice M. Reichert, *Monoclonal Antibodies in Biotechnology: The Next Generation*, Springer, 2010.

Web Links:

1. https://www.fda.gov/vaccines-blood-biologics
2. https://www.ema.europa.eu/en/human-regulatory/research-development/advanced-therapy-medicinal-products
3. https://www.nature.com/subjects/biotechnology

Proteins and Protein Formulation

Course Code: 2517PY18

UNIT-I:
Fundamentals of Proteins in Pharmaceuticals
Introduction to proteins classification, structure, and physicochemical properties. Protein folding, denaturation, and aggregation mechanisms. Protein–protein and protein–solvent interactions. Therapeutic applications of proteins and peptides — enzymes, hormones, antibodies. Challenges in developing protein-based pharmaceuticals.

UNIT-II:
Protein Engineering and Characterization
Techniques of protein engineering — site-directed mutagenesis and recombinant expression. Analytical methods for protein characterization — electrophoresis, chromatography, circular dichroism, and mass spectrometry.

UNIT-III:
Formulation Design for Protein Drugs
Principles of protein formulation — stability, solubility, and compatibility. Formulation components: buffers, stabilizers, surfactants, cryoprotectants, and preservatives.

UNIT-IV:
Processing, Packaging, and Storage
Scale-up and processing of protein formulations — mixing, filtration, and aseptic filling. Container–closure compatibility and impact of materials on protein stability. Cold chain management and storage conditions. Shelf-life prediction and stability-indicating assay development.

UNIT-V:
Regulatory and Quality Considerations
Guidelines for protein-based therapeutics — FDA, EMA, and ICH. Process validation, biosimilar evaluation, and comparability studies.

Text Books:

1. Rodney J. Y. Ho & Milo Gibaldi, *Biotechnology and Biopharmaceuticals: Transforming Proteins and Genes into Drugs*, 2nd Ed., Wiley, 2013.
2. Steve J. Shire (Ed.), *Formulation and Delivery of Proteins and Peptides*, Informa Healthcare, 2007.

Reference Books:

1. Gary Walsh, *Pharmaceutical Biotechnology: Concepts and Applications*, 2nd Ed., Wiley, 2013.
2. Rodney Pearlman & Y. Wang, *Formulation, Characterization, and Stability of Protein Drugs*, Plenum Press, 2002.

Web Links:

1. https://www.fda.gov/vaccines-blood-biologics/biologics
2. https://www.ich.org/page/quality-guidelines
3. https://www.nature.com/subjects/protein-engineering

Biological Evaluation of Drug Therapy

Course Code: 2517PY19

UNIT-I:
Introduction to Biological Evaluation
Definition, scope, and importance of biological evaluation in drug development. Preclinical and clinical evaluation stages — objectives and methodologies. Principles of pharmacodynamics and pharmacokinetics in biological testing. Biomarkers in drug evaluation and validation. Ethical and regulatory considerations in biological research.

UNIT-II:
In-Vitro Evaluation Techniques
Cell culture techniques and cytotoxicity assays (MTT, LDH, and trypan blue). Enzyme inhibition and receptor-binding assays. High-throughput screening and bioassay development. Molecular biology tools for evaluating drug action PCR, Western blotting, ELISA. In-vitro models for ADME and toxicity studies.

UNIT-III:
In-Vivo Pharmacological Evaluation
Animal models for evaluating CNS, cardiovascular, anti-inflammatory, and anticancer drugs. Pharmacodynamic studies — dose–response relationships and efficacy testing. Behavioral and functional assays in pharmacology.

UNIT-IV:
Immunological and Biochemical Evaluation
Immunological assays — antigen–antibody interactions, immunogenicity testing, and hypersensitivity studies.

UNIT-V:
Regulatory and Translational Aspects
Regulatory guidelines for biological evaluation (FDA, EMA, CPCSEA, OECD). GLP and ethical considerations in animal and human studies. Translation of preclinical data to clinical application. Biostatistical tools in drug evaluation and data interpretation.

Text Books:

1. S. K. Kulkarni, *Handbook of Experimental Pharmacology*, Vallabh Prakashan, 2012.
2. M. N. Ghosh, *Fundamentals of Experimental Pharmacology*, 6th Ed., Hilton & Company, 2015.

Reference Books:

1. R. Vogel, *Drug Discovery and Evaluation: Pharmacological Assays*, 4th Ed., Springer, 2016.
2. J. N. Crawley, *What's Wrong with My Mouse? Behavioral Phenotyping of Transgenic and Knockout Mice*, Wiley-Liss, 2007.

Web Links:

1. https://www.oecd.org/chemicalsafety/testing/oecdguidelinesforthetestingofchemicals.htm
2. https://www.fda.gov/science-research/animal-testing
3. https://www.nature.com/subjects/pharmacology

Bioinformatics and Computer Technology

Course Code: 2517PY20

UNIT-I:
Introduction to Bioinformatics and Computer Applications
Definition, scope, and applications of bioinformatics in pharmaceutical sciences. Overview of biological databases primary, secondary, and composite databases (GenBank, EMBL, Swiss-Prot). Basic computer hardware, software, and operating systems. Data acquisition, storage, and retrieval methods. Introduction to computer networks, cloud storage, and data security in bioinformatics.

UNIT-II:
Biological Databases and Data Analysis Tools
Database searching techniques BLAST, FASTA, and sequence alignment (pairwise and multiple). Protein and nucleic acid sequence analysis tools. Genome browsers and database resources (NCBI, PDB, KEGG, UniProt). Data mining and text mining in biomedical research. Bioinformatics file formats — FASTA, PDB, GenBank.

UNIT-III:
Molecular Modeling and Simulation
Fundamentals of molecular mechanics and dynamics. Homology modeling and protein structure prediction. Molecular docking principles and tools (AutoDock, Glide, GOLD). Visualization software — PyMOL, Chimera, Discovery Studio. Applications of molecular simulation in drug design and protein engineering.

UNIT-IV:
Genomics, Proteomics, and Pharmacoinformatics
Genome sequencing and annotation techniques. Comparative genomics and evolutionary analysis. Proteomics — protein profiling, expression analysis, and interaction networks.

UNIT-V:
Computer Technology and Artificial Intelligence in Bioinformatics
Programming languages in bioinformatics (Python, R, Perl). Machine learning and AI applications in genomics and proteomics. Big data analytics and cloud computing in life sciences. Ethical, legal, and regulatory considerations in bioinformatics research.

Text Books:

1. Arthur M. Lesk, *Introduction to Bioinformatics*, 5th Ed., Oxford University Press, 2019.
2. Andreas D. Baxevanis & B. F. Francis Ouellette, *Bioinformatics: A Practical Guide to the Analysis of Genes and Proteins*, 3rd Ed., Wiley-Blackwell, 2005.

Reference Books:

1. David W. Mount, *Bioinformatics: Sequence and Genome Analysis*, 2nd Ed., Cold Spring Harbor Laboratory Press, 2004.
2. Jean-Michel Claverie & Cedric Notredame, *Bioinformatics for Dummies*, 2nd Ed., Wiley, 2010.

Web Links:

1. https://www.ncbi.nlm.nih.gov
2. https://www.uniprot.org
3. https://www.rcsb.org

Bioprocess Engineering and Technology

Course Code: 2517PY21

UNIT-I:
Fundamentals of Bioprocess Engineering
Introduction, scope, and importance of bioprocess engineering in pharmaceuticals. Concepts of cell growth kinetics, batch, fed-batch, and continuous fermentation. Stoichiometry of microbial growth and product formation.

UNIT-II:
Upstream Processing
Preparation and sterilization of culture media. Inoculum development and optimization of fermentation parameters. Scale-up of fermentation — geometric and dynamic similarity principles. Agitation, aeration, mass transfer, and oxygen uptake in bioreactors. Monitoring and control of pH, temperature, and dissolved oxygen.

UNIT-III:
Downstream Processing
Overview of product recovery and purification. Cell disruption methods mechanical and non-mechanical. Solid-liquid separation: filtration, centrifugation, and flocculation. Product concentration and purification — chromatography, precipitation, and ultrafiltration. Drying, crystallization, and formulation of bioproducts.

UNIT-IV:
Enzyme and Cell Immobilization Technology
Principles, methods, and carriers for enzyme immobilization. Applications of immobilized enzymes and cells in biocatalysis and drug synthesis. Kinetic and diffusion characteristics of immobilized systems. Reactor configurations for immobilized enzyme processes. Industrial case studies involving immobilized biocatalysts.

UNIT-V:
Applications and Regulatory Aspects
Industrial applications — antibiotics, vaccines, enzymes, and recombinant therapeutics. Bioprocessing of monoclonal antibodies and biosimilars. Regulatory guidelines for biopharmaceutical manufacturing (FDA, EMA, WHO). Process validation, quality assurance, and GMP compliance in bioprocess industries. Recent advances — single-use bioreactors, PAT, and continuous bioprocessing.

Text Books:

1. Shuler M. L. & Kargi F., *Bioprocess Engineering: Basic Concepts*, 3rd Ed., Prentice Hall, 2017.
2. Peter F. Stanbury, Allan Whitaker & Stephen J. Hall, *Principles of Fermentation Technology*, 3rd Ed., Butterworth-Heinemann, 2016.

Reference Books:

1. Pauline M. Doran, *Bioprocess Engineering Principles*, 2nd Ed., Academic Press, 2012.

2. Gary Walsh, *Biopharmaceuticals: Biochemistry and Biotechnology*, 2nd Ed., Wiley, 2003.

Web Links:

1. https://www.fda.gov/vaccines-blood-biologics
2. https://www.ich.org/page/quality-guidelines
3. https://www.nature.com/subjects/bioprocess-engineering

Microbial and Cellular Biology

Course Code: 2517PY22

UNIT-I:
Fundamentals of Microbial and Cellular Biology
Introduction to microbial and cellular biology scope and relevance in harmaceutical sciences. Structure, classification, and morphology of bacteria, fungi, viruses, and protozoa. Prokaryotic vs. eukaryotic cell organization. Microbial growth kinetics, culture techniques, and measurement of growth.

UNIT-II:
Microbial Genetics and Molecular Biology
Structure and function of DNA, RNA, and chromosomes. Gene organization, replication, transcription, and translation. Mutation, recombination, transformation, conjugation, and transduction. Plasmids, transposons, and bacteriophages — roles in gene transfer. Molecular tools in microbiology — PCR, cloning, and gel electrophoresis.

UNIT-III:
Cell Biology and Signaling Mechanisms
Structure and functions of cellular organelles — nucleus, mitochondria, ER, Golgi complex, lysosomes. Cell cycle and mechanisms of cell division (mitosis and meiosis). Cell communication and signaling pathways — GPCR, tyrosine kinase, MAPK, and JAK-STAT. Apoptosis, necrosis, and autophagy — molecular mechanisms and significance.

UNIT-IV:
Immunology and Host–Pathogen Interactions
Overview of innate and adaptive immunity. Structure and function of immunoglobulins and antigens. Antigen–antibody reactions and diagnostic applications (ELISA, Western blot, immunofluorescence). Mechanisms of microbial pathogenesis and immune evasion. Vaccine development and monoclonal antibody production.

UNIT-V:
Applications and Recent Advances
Microbial production of pharmaceuticals — antibiotics, enzymes, and vaccines. Cell and tissue culture techniques for biopharmaceutical production. Genetic engineering of microbial and mammalian cells. Omics technologies — genomics, proteomics, and metabolomics.

Text Books:

1. Pelczar M. J., Chan E. C. S., & Krieg N. R., *Microbiology: Concepts and Applications*, McGraw-Hill, 1993.
2. Bruce Alberts et al., *Molecular Biology of the Cell*, 6th Ed., Garland Science, 2014.

Reference Books:

1. Prescott L. M., Harley J. P., & Klein D. A., *Microbiology*, 10th Ed., McGraw-Hill, 2019.
2. Karp G., *Cell and Molecular Biology: Concepts and Experiments*, 9th Ed., Wiley, 2021.

Web Links:

1. https://www.ncbi.nlm.nih.gov *(Genomic and microbial databases)*
2. https://www.nature.com/subjects/microbiology *(Microbial research articles)*
3. https://www.cell.com *(Journal – Cellular Biology and Biotechnology)*

Experimental Biotechnology

Course Code: 2517PY23

UNIT-I:
Fundamentals of Experimental Biotechnology
Introduction, scope, and significance of biotechnology in pharmaceutical and biomedical sciences. Basic principles of experimental design and biotechnological research. Good Laboratory Practices (GLP) and biosafety guidelines in biotechnology laboratories.

UNIT-II:
Cell and Tissue Culture Techniques
Fundamentals of cell culture — media composition, sterilization, and aseptic techniques. Establishment and maintenance of primary and continuous cell lines. Animal and plant tissue culture — applications and optimization.

UNIT-III:
Molecular Biology and Genetic Engineering
Isolation and purification of nucleic acids (DNA/RNA). Techniques of gene cloning restriction digestion, ligation, and transformation. Polymerase Chain Reaction (PCR) and its applications. Electrophoresis, blotting techniques, and sequencing methods.

UNIT-IV:
Protein Expression and Downstream Processing
Expression of recombinant proteins in microbial and mammalian systems. Protein extraction, purification, and characterization techniques. Chromatographic methods — affinity, ion-exchange, and gel filtration. SDS-PAGE, Western blotting, and enzyme assays.

UNIT-V:
Emerging Trends and Applications
Applications of biotechnology in drug discovery, diagnostics, and therapeutic development. Stem cell technology, regenerative medicine, and nano biotechnology. Biosensors, bioinformatics, and systems biology approaches.

Text Books:

1. B. D. Hames & N. M. Hooper, *Instant Notes in Biotechnology*, 2nd Ed., Garland Science, 2005.
2. T. A. Brown, *Gene Cloning and DNA Analysis: An Introduction*, 7th Ed., Wiley-Blackwell, 2016.

Reference Books:

1. R. K. Sharma & S. P. Singh, *Experimental Biotechnology*, 1st Ed., Campus Books International, 2010.
2. Bernard R. Glick & Jack J. Pasternak, *Molecular Biotechnology: Principles and Applications*, 5th Ed., ASM Press, 2017.

Web Links:
1. https://www.ncbi.nlm.nih.gov
2. https://www.thermofisher.com/in/en/home/life-science.html
3. https://www.nature.com/subjects/biotechnology

Immuno-Technology

Course Code: 2517PY24

UNIT-I:
Fundamentals of Immunology
Introduction to the immune system types, organs, and cells of immunity. Overview of innate and adaptive immune responses. Antigens, antibodies, and haptens properties, structure, and functions. Antigen–antibody interactions: precipitation, agglutination, and complement fixation. Theories of antibody production and immunological memory.

UNIT-II:
Immunological Techniques
Principles and applications of immunoassays — RIA, ELISA, and Western blotting. Immunofluorescence, immunoelectrophoresis, and flow cytometry. Hybridoma technology

UNIT-III:
Molecular Immunology
Genetic organization of immunoglobulin genes and antibody diversity. MHC molecules structure, function, and antigen presentation. Cytokines and chemokines — roles in immune regulation.

UNIT-IV:
Applied Immuno technology
Conventional, recombinant, and DNA-based vaccine development Adjuvants and delivery systems in immunization. Immunodiagnostics and immunotherapy in cancer, infectious, and autoimmune diseases.

UNIT-V:
Emerging Trends in Immuno technology
Advances in cellular immunotherapy — CAR-T cells and dendritic cell vaccines. Immuno informatics and computational vaccine design. Nanotechnology and biomaterials in immunotherapy.

Text Books:

1. Kuby J., *Immunology*, 8th Ed., W. H. Freeman and Company, 2018.
2. Roitt I. M., Brostoff J., & Male D., *Immunology*, 8th Ed., Mosby Elsevier, 2011.

Reference Books:

1. Abul K. Abbas, Andrew H. Lichtman & Shiv Pillai, *Cellular and Molecular Immunology*, 10th Ed., Elsevier, 2023.
2. Weir D. M. & Blackwell C., *Handbook of Experimental Immunology*, Blackwell Scientific Publications, 2010.

Web Links:
1. https://www.ncbi.nlm.nih.gov/books/NBK10757/
2. https://www.nature.com/subjects/immunology
3. https://www.who.int/teams/immunization-vaccines-and-biologicals

Modern Pharmaceutical Analytical Techniques

Course Code: 2517PY25

UNIT-I:
Introduction to Analytical Techniques
Significance of analytical chemistry in pharmaceuticals. Classification of analytical methods: chemical, instrumental, and hyphenated techniques.

UNIT-II:
UV–Visible and Infrared Spectroscopy
Principles and applications of UV–Visible spectroscopy. Instrumentation — sources, monochromators, detectors, and sample handling. Infrared spectroscopy, basic principles, instrumentation, sample preparation, and interpretation of spectra. Applications of IR in structural elucidation and functional group identification.

UNIT-III:
Chromatographic Techniques
Theory and classification of chromatography. Principles, instrumentation, and applications of HPLC, HPTLC, and GC. Method development, validation, and optimization in chromatographic systems. Ion-exchange, size-exclusion, and affinity chromatography.

UNIT-IV:
Nuclear Magnetic Resonance (NMR) and Mass Spectrometry
Principles of NMR spectroscopy — chemical shift, coupling constant, and spin–spin splitting. Instrumentation, 1H-NMR and 13C-NMR spectra interpretation, and 2D NMR techniques (COSY, NOESY, HSQC). Mass spectrometry — ionization methods (EI, CI, FAB, ESI, MALDI), mass analyzers, and fragmentation patterns. Applications of NMR and MS in structure elucidation and impurity profiling.

UNIT-V:
Thermal, Elemental, and Hyphenated Analytical Techniques
Principles and applications of thermal analysis — DSC, TGA, and DTA. X-ray diffraction (XRD) and its application in polymorphism and crystallinity studies. Flame photometry, atomic absorption spectroscopy (AAS), and inductively coupled plasma (ICP) analysis.

Text Books:

1. Beckett A. H. & Stenlake J. B., *Practical Pharmaceutical Chemistry*, Vol. I & II, CBS Publishers, 2005.
2. Pavia D. L., Lampman G. M., & Kriz G. S., *Introduction to Spectroscopy*, 5th Ed., Cengage Learning, 2015.

Reference Books:

1. Willard H. H., Merritt L. L., Dean J. A., & Settle F. A., *Instrumental Methods of Analysis*, 7th Ed., CBS Publishers, 1988.
2. K. Dong, *Modern HPLC for Practicing Scientists*, Wiley, 2006.

Web Links:

1. https://www.fda.gov/science-research/science-and-research-special-topics/analytical-procedures
2. https://www.ich.org/page/quality-guidelines
3. https://www.chromacademy.com

Food Analysis

Course Code: 2517PY26

UNIT-I:
Fundamentals of Food Analysis
Introduction and scope of food analysis. Food composition — water, carbohydrates, proteins, fats, vitamins, and minerals. Sampling techniques and sample preparation for analysis. Concepts of proximate composition and nutritional labeling. Regulatory aspects — FSSAI and Codex Alimentarius guidelines.

UNIT-II:
Physicochemical and Proximate Analysis
Determination of moisture, ash, fiber, fat, protein, and carbohydrate content. pH, acidity, and color measurements. Analysis of sugars, starches, and non-nutritive sweeteners. Analysis of fats and oils — saponification, iodine, and peroxide values.

UNIT-III:
Instrumental Methods in Food Analysis
Spectroscopic techniques : UV–Vis, IR, and Atomic Absorption. Chromatographic analysis — HPLC, GC, and TLC for food components. Determination of additives, preservatives, and colorants. Electrochemical and enzymatic methods in food testing.

UNIT-IV:
Microbiological and Contaminant Analysis
Detection of pathogens — E. coli, Salmonella, and Staphylococcus. Food spoilage indicators and microbial load estimation. Analysis of contaminants — pesticides, heavy metals, mycotoxins. Hygiene and safety standards in food testing laboratories.

UNIT-V:
Quality Standards and Recent Advances
Good Laboratory Practices (GLP) and validation of analytical methods. Food authenticity and adulteration testing. Application of biosensors, NIR spectroscopy, and rapid detection kits.

Text Books:

1. Nielsen S. S., Food Analysis, 5th Ed., Springer, 2017.
2. Pomeranz Y. & Meloan C. E., Food Analysis: Theory and Practice, CBS, 2008.

Reference Books:

1. AOAC International, Official Methods of Analysis, 21st Ed., 2019.
2. Ranganna S., Handbook of Analysis and Quality Control for Fruit and Vegetable Products, Tata McGraw Hill, 2011.

Weblinks:

1. https://www.fssai.gov.in
2. https://www.aoac.org
3. https://www.sciencedirect.com/topics/food-science

Advanced Instrumental Analysis (MPA 102T)

Course Code: 2517PY27

UNIT-I:
Fundamentals of Instrumental Methods
Principles, advantages, and classification of instrumental analysis. Calibration, validation, and maintenance of analytical instruments.

UNIT-II:
Spectroscopic Techniques
Advanced UV–Vis, IR, Fluorescence, and Raman spectroscopy. Atomic absorption and emission spectroscopy.

UNIT-III:
Chromatographic and Hyphenated Techniques
Principles and applications of HPLC, UPLC, and GC. Hyphenated systems — LC-MS, GC-MS, C-NMR, CE-MS.

UNIT-IV:
Thermal and Electro analytical Methods
DSC, TGA, and DTA in pharmaceutical characterization. Potentiometry, conductometry, and cyclic voltammetry applications.

UNIT-V:
Emerging Analytical Tools
NMR, XRD, ICP-MS, MALDI-TOF, and capillary electrophoresis. Automation and miniaturization in analytical instrumentation.

Text Books:

1. Willard H. H. et al., Instrumental Methods of Analysis, CBS, 1988.
2. Skoog D. A. et al., Principles of Instrumental Analysis, 7th Ed., Cengage, 2017.

Reference Books:

1. K. Dong, Modern HPLC for Practicing Scientists, Wiley, 2006.
2. Pavia D. L., Introduction to Spectroscopy, Cengage, 2015.

Web Links:

1. https://www.chromacademy.com
2. https://www.fda.gov/science-research
3. https://www.ich.org

Herbal and Cosmetic Analysis (MPA 103T)

Course Code: 2517PY28

UNIT-I:
Fundamentals of Herbal Analysis
Importance and scope of herbal drug standardization. WHO guidelines for herbal medicines and Ayurvedic Pharmacopoeia standards.

UNIT-II:
Analytical Techniques for Herbal Drugs
Chromatographic (HPTLC, HPLC) and spectroscopic (UV, IR, MS) techniques. Phytochemical screening — alkaloids, glycosides, flavonoids, and tannins.

UNIT-III:
Herbal Formulation Analysis
Evaluation of tablets, capsules, syrups, and extracts of herbal origin. Stability testing and marker-based standardization.

UNIT-IV:
Cosmetic Analysis
Classification of cosmetics and their ingredients. Evaluation of creams, lotions, shampoos, and toothpastes.

UNIT-V:
Regulatory and Safety Aspects
Toxicity testing, microbial contamination, and labeling regulations. Regulatory perspectives (FDA, EU, AYUSH).

Text Books:

1. Handa S. S. et al., Pharmacognosy and Phytochemistry, CBS, 2008.
2. P. P. Sharma, Cosmetic Formulation, Manufacturing and Quality Control, Vandana Publications, 2018.

Reference Books:

1. Kokate C. K. et al., Pharmacognosy, Nirali Prakashan, 2016.
2. Trease & Evans, Pharmacognosy, Elsevier, 2009.

Web Links:

1. https://www.ayush.gov.in
2. https://www.fda.gov/cosmetics
3. https://www.phytochemicalreference.com

Quality Control and Quality Assurance

Course Code: 2517PY29

UNIT-I:
Introduction to Quality Concepts
Overview, scope, and objectives of Quality Control (QC) and Quality Assurance (QA) in the pharmaceutical industry. Concepts of quality — Quality by Design (QbD), Total Quality Management (TQM), and Quality Risk Management (QRM). Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP), and Good Documentation Practice (GDP). Quality systems and their role in ensuring product consistency and safety.

UNIT-II:
Quality Management Systems and Documentation
Components of pharmaceutical quality systems — organizational structure, responsibilities, and management review. Documentation — Master Formula Record (MFR), Batch Manufacturing Record (BMR), Standard Operating Procedures (SOPs). Change control, deviation, out-of-specification (OOS), and corrective & preventive actions (CAPA). Good Automated Manufacturing Practice (GAMP) and data integrity (ALCOA principles).

UNIT-III:
Validation and Qualification
Validation concepts — analytical, process, cleaning, and computer system validation. Qualification stages — Design (DQ), Installation (IQ), Operational (OQ), and Performance Qualification (PQ). Calibration and maintenance of analytical instruments. Periodic review, revalidation, and validation documentation requirements.

UNIT-IV:
Audits, Inspections, and Regulatory Compliance
Types of audits — internal, external, supplier, and regulatory inspections. Audit preparation, conduct, and follow-up. FDA, EMA, MHRA, and WHO guidelines for inspection and quality assurance. Handling non-conformances and implementing preventive measures.

UNIT-V:
ICH Guidelines and Quality Risk Management
ICH Q8, Q9, Q10, and Q12 — pharmaceutical development, risk management, and quality systems. Continuous improvement and product lifecycle management. Role of statistical process control (SPC) in QA. Case studies of successful quality management implementations in the pharmaceutical industry.

Text Books:

1. Willig S. H., Tuckerman M. M., & Hitchings W. S., *Good Manufacturing Practices for Pharmaceuticals*, 6th Ed., CRC Press, 2011.
2. Michael Levin, *Pharmaceutical Process Scale-Up*, 3rd Ed., CRC Press, 2011.

Reference Books:

1. Guarino R. A., *New Drug Approval Process: The Global Challenge*, 5th Ed., CRC Press, 2010.
2. Niazi S. K., *Handbook of Pharmaceutical Manufacturing Formulations*, Vol. 1–6, CRC Press, 2019.

Web Links:

1. https://www.fda.gov/drugs/guidances-drugs
2. https://www.ich.org/page/quality-guidelines
3. https://www.who.int/teams/health-product-and-policy-standards/standards-and-specifications

Modern Bio-Analytical Techniques

Course Code: 2517PY30

UNIT-I:
Introduction to Bioanalytical Techniques
Scope, importance, and applications of bioanalysis in drug development. Principles of bioanalytical method development and validation. GLP and regulatory perspectives as per FDA, EMA, and ICH guidelines. Parameters in validation — accuracy, precision, selectivity, sensitivity, linearity, LOD, and LOQ. Handling of biological matrices and sample stability studies.

UNIT-II:
Chromatographic Techniques
Principles and applications of HPLC, UPLC, and LC–MS/MS in bioanalysis. Sample preparation — protein precipitation, liquid–liquid extraction (LLE), and solid-phase extraction (SPE). Quantification of drugs and metabolites in biological fluids. Method optimization, matrix effect evaluation, and recovery studies. Troubleshooting and maintenance of chromatographic systems.

UNIT-III:
Spectroscopic and Immunoanalytical Methods
Spectroscopic techniques — UV, fluorescence, and atomic absorption spectroscopy. Immunoassays — principles and types (RIA, ELISA, ECLIA). Biosensors and microfluidic analytical systems. Applications of immunoassays in therapeutic drug monitoring and biomarker detection.

UNIT-IV:
Bioanalytical Data Handling and Validation
Pharmacokinetic and pharmacodynamic correlation through bioanalysis. Calibration curve preparation, accuracy, precision, and recovery assessment. Incurred sample reanalysis (ISR) and partial validation concepts. Data acquisition, processing, and documentation for regulatory submission. Case studies of bioanalytical validation and troubleshooting.

UNIT-V:
Advanced and Emerging Bioanalytical Tools
Proteomic and metabolomic analytical techniques — LC-MS, MALDI-TOF, CE-MS. Automation, robotics, and AI-based bioanalytical systems. Microarray and nanoparticle-based analytical approaches. Integration of bioinformatics in biomarker discovery. Recent trends — real-time bioanalysis and miniaturized devices.

Text Books:

1. Dominique Massart et al., *Handbook of Chemometrics and Qualimetrics*, Elsevier, 1997.
2. P. B. L. Meijering, *Bioanalytical Chemistry*, Springer, 2019.

Reference Books:

1. Shah V. P. & Midha K. K., *Principles and Practices of Bioanalytical Method Validation*, AAPS Press, 2012.
2. Skoog D. A., Holler F. J., & Crouch S. R., *Fundamentals of Analytical Chemistry*, 9th Ed., Cengage, 2014.

Web Links:

1. https://www.fda.gov/media/70858/download *(FDA Bioanalytical Method Validation)*
2. https://www.ema.europa.eu/en/documents/scientific-guideline/bioanalytical-method-validation_en.pdf *(EMA Guideline)*
3. https://pubs.acs.org/journal/ancham *(Analytical Chemistry Journal)*

Advanced Spectral Analysis

Course Code: 2517PY31

UNIT-I:
Fundamentals of Spectroscopy
Introduction to molecular spectroscopy — electromagnetic spectrum and its interaction with matter. Basic principles, selection rules, and types of electronic, vibrational, and rotational transitions. Instrumentation and components of spectroscopic systems — sources, monochromators, detectors, and sample handling. Spectral resolution, signal-to-noise ratio, and data interpretation.

UNIT-II:
Ultraviolet–Visible and Infrared Spectroscopy
Principles of UV–Visible spectroscopy — absorption laws, chromophores, and auxochromes. Quantitative analysis using Beer–Lambert's law and derivative spectrophotometry. Infrared (IR) and Fourier-transform infrared (FTIR) spectroscopy — theory, instrumentation, and sample preparation. Interpretation of IR spectra — identification of functional groups and characteristic frequencies. Applications in drug identification and impurity profiling.

UNIT-III:
Nuclear Magnetic Resonance (NMR) Spectroscopy
Fundamentals of NMR — nuclear spin, resonance condition, relaxation processes. 1H and 13C NMR spectroscopy — chemical shifts, spin–spin coupling, integration, and multiplicity. Advanced NMR techniques — DEPT, COSY, NOESY, HSQC, and HMBC. Applications of NMR in structural elucidation of organic molecules. Quantitative NMR (qNMR) and its use in pharmaceutical analysis.

UNIT-IV:
Mass Spectrometry and Hyphenated Techniques
Basic principles — ionization methods (EI, CI, ESI, MALDI, FAB) and types of mass analyzers. Interpretation of fragmentation patterns and isotopic peaks. Applications of MS in molecular weight determination and impurity analysis. Hyphenated techniques — LC–MS, GC–MS, LC–NMR, and CE–MS. Case studies of spectral interpretation using combined spectral data (UV, IR, NMR, MS).

UNIT-V:
Advanced and Emerging Spectroscopic Techniques
Raman spectroscopy — principle, instrumentation, and applications in polymorphic studies. Fluorescence and phosphorescence spectroscopy — concepts and pharmaceutical relevance. X-ray diffraction (XRD) and its role in crystal structure determination. Thermal analysis and differential scanning calorimetry (DSC) for complementary spectral data. Recent advances — NIR, terahertz spectroscopy, and chemometric spectral data analysis.

Text Books:

1. Pavia D. L., Lampman G. M., & Kriz G. S., *Introduction to Spectroscopy*, 5th Ed., Cengage Learning, 2015.
2. Silverstein R. M., Webster F. X., & Kiemle D. J., *Spectrometric Identification of Organic Compounds*, 8th Ed., Wiley, 2014.

Reference Books:

1. Skoog D. A., Holler F. J., & Nieman T. A., *Principles of Instrumental Analysis*, 7th Ed., Cengage, 2017.
2. Kalsi P. S., *Spectroscopy of Organic Compounds*, 6th Ed., New Age International, 2017.

Web Links:

1. https://www.sciencedirect.com/topics/chemistry/spectroscopy
2. https://pubs.acs.org/journal/ancham
3. https://www.nature.com/subjects/spectroscopy

Interpretative Molecular Spectroscopy

Course Code: 2517PY32

UNIT-I:
Fundamentals of Molecular Spectroscopy
Introduction to spectroscopy and electromagnetic radiation. Regions of the spectrum and their analytical significance. Molecular energy levels — rotational, vibrational, and electronic transitions. Selection rules, transition moments, and intensity of spectral lines. Molecular symmetry and its influence on spectral interpretation.

UNIT-II:
Infrared and Raman Spectroscopy
Theory and instrumentation of IR and Raman spectroscopy. Group frequency correlations and identification of functional groups. Fourier Transform Infrared (FTIR) spectroscopy and sample handling techniques. Complementarity of IR and Raman spectra in structural elucidation. Quantitative analysis and molecular conformation studies using IR and Raman.

UNIT-III:
Ultraviolet–Visible and Electronic Spectroscopy
Electronic transitions in UV–Visible spectroscopy — $\sigma \rightarrow \sigma^*$, $n \rightarrow \sigma^*$, $\pi \rightarrow \pi^*$, $n \rightarrow \pi^*$. Chromophores, auxochromes, and solvent effects. Woodward–Fieser rules for conjugated dienes and enones. Interpretation of UV spectra in aromatic and heteroaromatic systems. Applications in determining conjugation, tautomerism, and electronic environment.

UNIT-IV:
Nuclear Magnetic Resonance (NMR) Spectroscopy
Principles of ^{1}H and ^{13}C NMR — chemical shift, coupling constants, multiplicity, and integration. Correlation of NMR data with molecular structure. Advanced NMR techniques — DEPT, COSY, HSQC, and HMBC. Interpretation of spectra for aliphatic, aromatic, and heterocyclic compounds.

UNIT-V:
Mass Spectrometry and Combined Spectral Interpretation
Principles and instrumentation of mass spectrometry. Ionization techniques — EI, CI, ESI, and MALDI. Fragmentation patterns, isotopic peaks, and molecular ion determination. Interpretation of spectra using combined MS, IR, UV, and NMR data. Applications in structural elucidation, impurity profiling, and metabolite identification.

Text Books:

1. Robert M. Silverstein, Francis X. Webster, & David Kiemle, *Spectrometric Identification of Organic Compounds*, 8th Ed., Wiley, 2014.
2. P. S. Kalsi, *Spectroscopy of Organic Compounds*, 6th Ed., New Age International, 2017.

Reference Books:

1. Pavia D. L., Lampman G. M., & Kriz G. S., *Introduction to Spectroscopy*, 5th Ed., Cengage Learning, 2015.
2. Holler F. J., Skoog D. A., & Crouch S. R., *Principles of Instrumental Analysis*, 7th Ed., Cengage, 2017.

Web Links:

1. https://pubs.acs.org/journal/ancham
2. https://www.sciencedirect.com/topics/chemistry/molecular-spectroscopy
3. https://www.nature.com/subjects/spectroscopy

Clinical Research

Course Code: 2517PY33

UNIT-I:
Fundamentals of Clinical Research
Introduction, scope, and importance of clinical research in drug development. Phases of clinical trials — Phase I to Phase IV. Historical perspectives and evolution of clinical trial regulations. Good Clinical Practice (GCP) guidelines and ethical principles.

UNIT-II:
Clinical Trial Design and Methodology
Types of clinical trial designs — randomized, double-blind, crossover, and adaptive trials. Elements of protocol design — objectives, endpoints, inclusion/exclusion criteria. Randomization techniques and blinding methods. Sample size determination and statistical considerations.

UNIT-III:
Clinical Data Management and Documentation
Process of data collection, case report forms (CRFs), and electronic data capture (EDC). Data validation, query management, and database lock procedures. Adverse event (AE) and serious adverse event (SAE) reporting. Pharmacovigilance, signal detection, and risk management. Quality control in data management and documentation standards.

UNIT-IV:
Regulatory and Ethical Aspects
Regulatory requirements for clinical trials — ICH-GCP, USFDA, EMA, and CDSCO. Institutional Review Boards (IRB)/Ethics Committees (EC) — composition, role, and function. Informed consent process and subject confidentiality. Compassionate use, post-marketing surveillance, and investigator responsibilities. Clinical research compliance and audit preparation.

UNIT-V:
Current Trends and Future Directions
Patient-centric and decentralized clinical trials. Use of AI, big data, and real-world evidence (RWE) in clinical research. Biomarkers and personalized medicine. Adaptive design and virtual clinical trials.

Text Books:

1. Stuart J. Pocock, *Clinical Trials: A Practical Approach*, Wiley, 2008.
2. Lawrence M. Friedman et al., *Fundamentals of Clinical Trials*, 5th Ed., Springer, 2015.

Reference Books:

1. P. Kumar & G. S. Bhat, *Clinical Research and Pharmacovigilance*, PharmaMed Press, 2012.
2. S. K. Gupta, *Basic Principles of Clinical Research and Methodology*, Jaypee Brothers, 2021.

Web Links:

1. https://www.ich.org/page/efficacy-guidelines
2. https://clinicaltrials.gov
3. https://cdsco.gov.in

Clinical Pharmacokinetics and Therapeutic Drug Monitoring

Course Code: 2517PY34

UNIT-I:
Fundamentals of Clinical Pharmacokinetics
Introduction, scope, and significance of clinical pharmacokinetics (CPK). Basic pharmacokinetic parameters — absorption, distribution, metabolism, and excretion (ADME).Compartmental and non-compartmental models. Pharmacokinetic variability — genetic, physiological, pathological, and environmental factors. Therapeutic relevance of pharmacokinetic parameters in clinical settings.

UNIT-II:
Drug Absorption and Bioavailability
Factors affecting drug absorption and bioavailability. Bioequivalence studies and assessment parameters (Cmax, Tmax, AUC). Role of formulation and route of administration in pharmacokinetics. Assessment of first-pass metabolism and presystemic elimination. Clinical implications of altered absorption and bioavailability.

UNIT-III:
Drug Distribution, Metabolism, and Excretion
Plasma protein binding and tissue distribution — clinical significance. Volume of distribution, clearance, and elimination half-life. Hepatic and renal clearance mechanisms. Drug interactions affecting distribution and elimination.

UNIT-IV:
Therapeutic Drug Monitoring (TDM)
Concept, need, and importance of TDM in clinical practice. Criteria for drug selection for TDM (narrow therapeutic index drugs). Sampling procedures, specimen handling, and timing considerations.

UNIT-V:
Clinical Applications and Population Pharmacokinetics
Pharmacokinetics in special populations — pediatrics, geriatrics, pregnancy, hepatic and renal impairment. Population pharmacokinetics and Bayesian forecasting.

Text Books:

1. Rowland M. & Tozer T. N., *Clinical Pharmacokinetics and Pharmacodynamics: Concepts and Applications*, 4th Ed., Wolters Kluwer, 2010.
2. Burton M. E., Shaw L. M., Schentag J. J., & Evans W. E., *Applied Pharmacokinetics and Pharmacodynamics*, 4th Ed., Lippincott Williams & Wilkins, 2006.

Reference Books:

1. Shargel L. & Yu A. B. C., *Applied Biopharmaceutics and Pharmacokinetics*, 8th Ed., McGraw Hill, 2022.
2. Gibaldi M. & Perrier D., *Pharmacokinetics*, 2nd Ed., Marcel Dekker, 2006.

Web Links:

1. https://www.fda.gov/drugs/science-and-research-drugs/pharmacokinetics
2. https://pubmed.ncbi.nlm.nih.gov
3. https://www.clinicalpharmacology.com

Pharmacoepidemiology & Pharmacoeconomics

Course Code: 2517PY35

UNIT I:
Introduction to Pharmacoepidemiology
Definition, Scope, Need, Aims, and Applications of Pharmacoepidemiology. Outcome Measurement: Outcome measures, Drug use measures, Monetary units, Number of prescriptions, Units of drug dispensed, Defined daily doses (DDD), Prescribed daily doses (PDD), Diagnosis and Therapy surveys, Prevalence, Incidence rate, Medication adherence measurements, Concept of Risk: Measurement of risk, Attributable risk, Relative risk, Time-risk relationship, Odds ratio.

UNIT II:
Pharmacoepidemiological Methods
Qualitative Models: Drug Utilization Review (DUR), Quantitative Models: Case reports, Case series, Cross-sectional studies, Cohort and Case-control studies, Calculation of Odds Ratio, Meta-analysis models, Drug Effects Study in Populations

Unit III:
Introduction to Pharmacoeconomics
Definition, History, and Evolution of Pharmacoeconomics, Need for Pharmacoeconomic studies in the Indian healthcare system, Cost Categorization and Resources for Cost Estimation: Direct, Indirect, and Intangible costs, Outcomes and Measurements in Pharmacoeconomics: Clinical, Economic, and Humanistic outcomes, Health Outcome Measures.

Unit IV:
Pharmacoeconomic Evaluations
Definition, Steps involved, Applications, Advantages, and Disadvantages of: Cost Minimization Analysis (CMA), Cost Benefit Analysis (CBA), Cost Effectiveness Analysis (CEA), Cost Utility Analysis (CUA), Cost of Illness (COI), Cost Consequence Analysis (COA),Role of pharmacoeconomic evaluations in healthcare policy and resource allocation.

Unit V:
Advanced Pharmacoeconomic Methods and Quality of Life Assessment
Health-Related Quality of Life (HRQOL): Definition, Need for HRQOL measurement, Common HRQOL tools and measures. Decision Analysis and Modeling: Definition, Steps involved, Applications of Decision Analysis and Decision Trees, Sensitivity Analysis and Markov Modeling. Software and Applications in Pharmacoeconomic Analysis

Text Books

1. Rascati K. L. *Essentials of Pharmacoeconomics*, Wolters Kluwer, Lippincott Williams & Wilkins, Philadelphia.
2. Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien, and Greg Stoddart. *Methods for the Economic Evaluation of Health Care Programmes*, Oxford University Press, London.

Reference Books

1. Andrew Briggs, Karl Claxton, and Mark Sculpher. *Decision Modelling for Health Economic Evaluation*, Oxford University Press, London.
2. Thomas E. Getzen. *Health Economics: Fundamentals and Flow of Funds*, John Wiley & Sons, USA.

Web Links

1. https://www.ispor.org/
2. https://www.cdc.gov/csels/dsepd/ss1978/lesson1/section8.html
3. https://www.who.int/health-topics/pharmacoeconomics

Cellular and Molecular Pharmacology

Course Code: 2517PY36

UNIT I:
Cell Biology
Structure and functions of cell and its organelles, Genome organization, gene expression, and its regulation, Importance of siRNA and microRNA, gene mapping, and gene sequencing, Cell cycle and its regulation, Cell death mechanisms: events, regulators, intrinsic and extrinsic pathways of apoptosis, Necrosis and autophagy.

UNIT II:
Cell Signaling
Intercellular and intracellular signaling pathways, Classification and molecular structure of receptor families: Ligand-gated ion channels, G-protein coupled receptors (GPCRs), Tyrosine kinase receptors, Nuclear receptors. Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate (IP_3), nitric oxide (NO), and diacylglycerol (DAG). Detailed study of intracellular signaling pathways: Cyclic AMP signaling pathway, Mitogen-Activated Protein Kinase (MAPK) pathway, Janus Kinase (JAK)/Signal Transducer and Activator of Transcription (STAT) pathway.

UNIT III:
Principles and Applications of Genomic and Proteomic Tools
Molecular Biology Techniques: DNA electrophoresis, PCR (reverse transcription and real-time), gene sequencing, microarray technique, SDS-PAGE, ELISA, and Western blotting. Recombinant DNA Technology and Gene Therapy: Basic principles of recombinant DNA technology – restriction enzymes and vectors, Applications of recombinant DNA technology, Gene therapy – various types of gene transfer techniques, clinical applications, and recent advances.

UNIT IV:
Pharmacogenomics and Immunotherapeutics
Gene mapping and cloning of disease-related genes, Genetic variations and their role in health and pharmacology, Polymorphisms affecting drug metabolism, drug transporters, and G-protein coupled receptors, Applications of omics sciences: genomics, proteomics, metabolomics, functionomics, and nutrigenomics. Immunotherapeutics: Types of immunotherapeutics, Humanized antibody therapy, Applications of immunotherapeutics in clinical practice.

UNIT V:
Cell Culture Techniques and Biosimilars
Cell Culture Techniques: Basic equipment used in cell culture laboratories, Cell culture media, various types of cell cultures, General procedures: cell isolation, subculture, cryopreservation, and characterization, Applications of cell cultures. Assays and Analytical Techniques: Principles and applications of cell viability assays, glucose uptake assays, calcium influx assays, Principles and applications of flow cytometry. Biosimilars: Introduction, development, and applications of biosimilars in therapeutics.

Text Books

1. Geoffrey M. Cooper. *The Cell: A Molecular Approach.*
2. John Dickenson et al. *Molecular Pharmacology: From DNA to Drug Discovery.*

Reference Books

1. Ralph A. Bradshaw et al. *Handbook of Cell Signaling* (Second Edition).
2. J. Licinio and M.-L. Wong (Eds.). *Pharmacogenomics: The Search for Individualized Therapies.*

Web Links

1. https://www.ncbi.nlm.nih.gov/books/NBK21054/
2. https://www.cell.com
3. https://www.genome.gov/

Advanced Pharmacology and Therapeutics

Course Code: 2517PY37

UNIT I:
General Pharmacology
a. Pharmacokinetics:
Dynamics of drug absorption, distribution, biotransformation, and elimination. Concepts of linear and non-linear compartment models. Significance of protein binding in drug disposition and action.
b. Pharmacodynamics:
Mechanism of drug action and the relationship between drug concentration and effect. Drug receptors: structural and functional classification. Quantitation of drug–receptor interactions and elicited effects.

UNIT II:
Neurotransmission
General aspects and steps involved in neurotransmission. Neurohumoral transmission in the autonomic nervous system – detailed study of neurotransmitters: *Adrenaline and Acetylcholine.* Neurohumoral transmission in the central nervous system – detailed study of neurotransmitters: *Histamine, Serotonin, Dopamine, GABA, Glutamate, and Glycine.* Non-adrenergic, non-cholinergic (NANC) transmission and co-transmission mechanisms.

UNIT III:
Central Nervous System Pharmacology
A detailed study of the pathophysiology, mechanisms of drug action, pharmacology, and toxicology of existing and novel agents used in: General and local anesthesia, Sedatives and hypnotics, Drugs used for anxiety, depression, psychosis, and mania, Antiepileptics and drugs used in neurodegenerative diseases, Narcotic and non-narcotic analgesics.

UNIT IV:
Cardiovascular Pharmacology
Detailed study on the pharmacology, mechanism of action, and therapeutic use of drugs used in: Diuretics and antihypertensives, Anti-ischemic and antiarrhythmic drugs, Drugs for heart failure and hyperlipidemia, Hematinics, coagulants, anticoagulants, fibrinolytics, and antiplatelet agents.

UNIT V:
Autocoid Pharmacology
Physiological and pathological roles of autocoids: *Histamine, Serotonin, Kinins, Prostaglandins, and Opioids,* Pharmacology of antihistamines and 5-HT antagonists, Therapeutic applications and emerging trends in autocoid modulation.

Text Books

1. Goodman & Gilman's *The Pharmacological Basis of Therapeutics*, McGraw Hill Education.
2. B.G. Katzung. *Basic and Clinical Pharmacology*, McGraw Hill Education.

Reference Books

1. David E. Golan et al. *Principles of Pharmacology: The Pathophysiologic Basis of Drug Therapy*, Wolters Kluwer – Lippincott Williams & Wilkins.
2. K.D. Tripathi. *Essentials of Medical Pharmacology*, Jaypee Brothers Medical Publishers.

Web Links

1. https://pubchem.ncbi.nlm.nih.gov/
2. https://www.pharmacologyeducation.org/
3. https://www.drugs.com/

Pharmacological and Toxicological Screening Methods

Course Code: 2517PY38

UNIT I:
Laboratory Animals and Bioassay Principles
Common laboratory animals: Description, handling, and applications of different species and strains. Transgenic animals: Production, maintenance, and applications. Anesthesia and euthanasia of experimental animals. Maintenance, breeding, and housing of laboratory animals. CPCSEA guidelines for conducting animal experiments. Good Laboratory Practices (GLP) in animal experimentation. Bioassay: Principles, scope, limitations, and various methods.

UNIT II:
Preclinical Screening: Central and Autonomic Nervous System
General Principles of Preclinical Screening: Selection of animal species, dose translation, and ethical considerations. CNS Pharmacology Screening Models: Behavioral and muscle coordination studies. Screening of CNS stimulants and depressants. Evaluation of anxiolytics, antipsychotics, antiepileptics, and nootropics. Screening models for neurodegenerative diseases such as Parkinson's, Alzheimer's, and multiple sclerosis. ANS Pharmacology**:** Drugs acting on the autonomic nervous system.

UNIT III:
Preclinical Screening: Respiratory, Reproductive, Analgesic, and Gastrointestinal Systems
Respiratory Pharmacology: Screening models for anti-asthmatics, anti-allergics, and drugs for chronic obstructive pulmonary disease (COPD). Reproductive Pharmacology: Screening for aphrodisiacs and antifertility agents. Analgesic, Anti-inflammatory, and Antipyretic Agents: In vivo and in vitro models for evaluating pain, inflammation, and fever. Gastrointestinal Pharmacology: Screening methods for anti-ulcer, anti-emetic, antidiarrheal, and laxative drugs.

UNIT IV:
Preclinical Screening: Cardiovascular, Metabolic, and Hepatic Systems
Cardiovascular Pharmacology: Screening models for antihypertensives, antiarrhythmics, antianginal, antiatherosclerotic agents, and diuretics. Metabolic Disorders: Screening models for antidiabetic and antidyslipidemic agents. Anticancer Agents: Evaluation of potential anticancer compounds. Hepatoprotective Agents**:** Screening models for hepatoprotective activity and hepatotoxicity assessment.

UNIT V:
Immunopharmacology, Immunoassay Techniques, and Alternatives to Animal Testing
Immunopharmacology: Screening of immunomodulators, immunosuppressants, and immunostimulants. Immunoassay Techniques: Theoretical basis, optimization, and types: heterogeneous and homogeneous immunoassay systems. Protocols and evaluation of immunoassays (e.g., digoxin and insulin assays). Limitations and Alternatives: Limitations of animal experimentation. Use of alternative animal models and in vitro systems. Data Extrapolation: Translating in vitro data to preclinical and preclinical data to clinical settings.

Text Books

1. M.N. Ghosh. *Fundamentals of Experimental Pharmacology.*
2. H.G. Vogel. *Drug Discovery and Evaluation: Pharmacological Assays.*

Reference Books

1. Robert A. Turner. *Screening Methods in Pharmacology.*
2. S.K. Kulkarni. *Handbook of Experimental Pharmacology.*

Web Links

1. https://www.cpcsea.nic.in/
2. https://www.nc3rs.org.uk/
3. https://www.nature.com/subjects/pharmacology

Neurobiology

Course Code: 2517PY39

UNIT-I:
Introduction to Neurobiology
Overview and history of neuroscience; evolution of the nervous system. Organization of the brain central and peripheral nervous systems. Methods and tools in neurobiology electrophysiology, imaging, and molecular approaches. bStructure and function of neurons and glial cells. bMembrane potentials, conductance, capacitance, and equilibrium potentials.

UNIT-II:
Neuronal Excitability and Synaptic Transmission
Ion channels and the generation of action potentials. Synapses, electrical and chemical; neurotransmitter synthesis, release, and receptors. Synaptic integration, summation, and plasticity. Neurotransmission defects and associated neurological disorders. Pharmacological modulation of synaptic transmission.

UNIT-III:
Neural Circuits and Sensory Systems
Organization of neural circuits and their role in information processing. Mechanisms of sensory perception visual, auditory, olfactory, and somatosensory systems. Tuning curves and neural coding of sensory information. Reflex arcs and signal transduction pathways in sensory neurons. Comparative neurobiology and animal models for neural studies.

UNIT-IV:
Motor Systems and Higher Brain Functions
Neural control of movement and motor coordination. Role of basal ganglia, cerebellum, and motor cortex. Memory, learning, and cognition synaptic and molecular mechanisms. Emotion, motivation, and neural basis of behavior. Neuroplasticity and neurogenesis in brain repair and adaptation.

UNIT-V:
Applied and Clinical Neurobiology
Neurodegenerative diseases — Alzheimer's, Parkinson's, and Huntington's disease. Neural networks and computational neuroscience. Brain–computer interfaces and artificial intelligence applications. Techniques in neuropharmacology and neuroimaging.

Text Books:

1. Eric R. Kandel et al., *Principles of Neural Science*, 6th Ed., McGraw-Hill, 2021.
2. S. M. Kandel & J. H. Schwartz, *Essentials of Neural Science and Behavior*, McGraw-Hill, 1995.

Reference Books:

1. Purves D. et al., *Neuroscience*, 6th Ed., Oxford University Press, 2018.
2. Bear M. F., Connors B. W., & Paradiso M. A., *Neuroscience: Exploring the Brain*, 4th Ed., Wolters Kluwer, 2015.

Web Links:

1. https://onlinecourses.nptel.ac.in/noc23_bt65/preview
2. https://www.nature.com/subjects/neuroscience
3. https://www.ncbi.nlm.nih.gov/books/NBK10867/

Cancer Biology

Course Code: 2517PY40

UNIT-I:
Fundamentals of Cancer Biology
Definition, classification, and nomenclature of cancer. Theories of carcinogenesis and molecular basis of malignant transformation. Hallmarks of cancer and mechanisms of tumor initiation and progression. Oncogenes, proto-oncogenes, and tumor suppressor genes. Aberrations in signaling pathways and cell cycle regulation.

UNIT-II:
Molecular Mechanisms of Tumorigenesis
Self-sufficiency in growth signals and insensitivity to inhibitory signals. DNA repair defects and genomic instability in cancer cells. Evasion of apoptosis and mechanisms of cell immortality. Epigenetic alterations and dysregulation of cancer-associated genes. Role of microRNAs in tumor initiation and progression.

UNIT-III:
Angiogenesis, Invasion, and Metastasis
Mechanisms of tumor angiogenesis and vascular development. Epithelial–mesenchymal transition (EMT) and metastatic cascade. Molecular genetics of metastasis and tumor microenvironment. Extracellular matrix remodeling and cell adhesion molecules. Hypoxia and metabolic reprogramming in cancer cells.

UNIT-IV:
Tumor Immunology and Cancer Therapy
Host immune response to tumors and immune evasion mechanisms. Immune checkpoint inhibitors and monoclonal antibody therapy. Principles of chemotherapy, radiotherapy, and targeted therapy. Molecularly targeted therapies and drug resistance mechanisms. Tumor vaccines and gene therapy approaches.

UNIT-V:
Advances and Emerging Concepts in Oncology
Molecular diagnostics and biomarkers for cancer detection. Role of bioinformatics and omics technologies in cancer research. Cancer stem cells and personalized medicine. Recent advances in nanomedicine and immuno-oncology. Ethical and regulatory considerations in clinical cancer research.

Text Books:

1. Weinberg R. A., *The Biology of Cancer*, 3rd Ed., Garland Science, 2023.
2. King R. J. B. & Robins M. W., *Cancer Biology*, 5th Ed., Pearson Education, 2010.

Reference Books:

1. DeVita V. T. et al., *Cancer: Principles & Practice of Oncology*, 12th Ed., Lippincott Williams & Wilkins, 2023.
2. Vogelstein B. & Kinzler K. W., *The Genetic Basis of Human Cancer*, McGraw-Hill, 2002.

Web Links:

1. https://nptel.ac.in/courses/102106652
2. https://www.cell.com/cancer-cell
3. https://www.nature.com/subjects/cancer-biology

Indian System of Medicine

Course Code: 2517PY41

UNIT-I:
Introduction to Indian Systems of Medicine (ISM)
History, philosophy, and development of Indian systems of medicine. Overview of Ayurveda, Siddha, Unani, Yoga, Naturopathy, and Homeopathy. Fundamental principles of Ayurveda: Tridosha, Panchamahabhuta, Dhatu, and Agni. Concepts of health, disease, and prevention in Indian medicine. Role of AYUSH and the integration of traditional systems with modern healthcare.

UNIT-II:
Ayurvedic Pharmacology and Formulations
Classification of drugs (Dravyaguna Vijnana) — Rasa, Guna, Virya, Vipaka, and Prabhava. Sources of Ayurvedic drugs — plant, mineral, and animal origins. Formulation types: Asava, Arishta, Churna, Guggulu, Vati, and Taila. Standardization, quality control, and authentication of raw materials. Phytochemical and pharmacological evaluation of Ayurvedic preparations.

UNIT-III:
Siddha and Unani Systems of Medicine
Basic principles of Siddha system: Mukkuttram theory and Udal Thathukkal. Formulations: Chendooram, Mezhugu, Parpam, and Kattu. Unani medicine : Mizaj (temperament) and Asbab-e-Sitta Zarooriya (six essentials of life). Dosage forms: Arq, Majoon, Khamira, Jawarish, and Lauq. Standardization and pharmacopoeial aspects of Siddha and Unani formulations.

UNIT-IV:
Homeopathy and Naturopathy
Principles of Homeopathy — "Like cures like" and minimum dose concept. Preparation and potentization of homeopathic remedies. Classification and evaluation of mother tinctures. Concept and philosophy of Naturopathy — diet, hydrotherapy, and yoga therapy. Integrative approaches for disease prevention and wellness.

UNIT-V:
Regulatory and Contemporary Developments
Regulatory frameworks — Drugs and Cosmetics Act, 1940 (ISM provisions). Role of Pharmacopoeia Commission for Indian Medicine and Homoeopathy (PCIM&H). AYUSH guidelines for safety, efficacy, and quality evaluation.

Text Books:

1. Sharma P. V., *Dravyaguna Vijnana*, Vol. I–III, Chaukhambha Bharati Academy, Varanasi, 2013.
2. Nadkarni K. M., *Indian Materia Medica*, Vol. I & II, Popular Prakashan, 2010.

Reference Books:

1. Panda H., *Handbook on Ayurvedic Medicines with Formulae, Processes, and Their Uses*, National Institute of Industrial Research, 2002.

2. K. Nishteswar & R. Vidyanath, *Textbook of Dravyaguna Vijnana*, Chaukhambha Surbharati Prakashan, 2018.

Web Links:

1. https://www.ayush.gov.in
2. https://www.ccras.nic.in
3. https://www.who.int/health-topics/traditional-medicine

Industrial Pharmacognostical Technology

Course Code: 2517PY42

UNIT-I:
Introduction to Industrial Pharmacognosy
Scope and significance of industrial pharmacognosy in natural product research. Sources of crude drugs — cultivation, collection, processing, and storage. Factors affecting the quality of crude drugs — genetic, environmental, and processing parameters. Good Agricultural and Collection Practices (GACP) and post-harvest management. Industrial importance of medicinal and aromatic plants in pharmaceuticals and cosmetics.

UNIT-II:
Extraction and Isolation Techniques
Principles and industrial methods of extraction — maceration, percolation, Soxhlet, and supercritical fluid extraction. Solvent selection, extraction efficiency, and scale-up considerations. Isolation, purification, and concentration of phytoconstituents.

UNIT-III:
Standardization and Quality Control of Herbal Drugs
Concepts of standardization and quality assurance in herbal industries. Phytochemical screening, identification tests, and marker-based standardization. Physicochemical parameters — moisture, ash values, extractive values, and volatile oil content.

UNIT-IV:
Formulation and Product Development
Formulation of herbal dosage forms — tablets, capsules, syrups, ointments, and cosmetics. Stabilization, preservation, and packaging of herbal products. Role of excipients and compatibility studies in herbal formulations.

UNIT-V:
Industrial Production and Regulatory Aspects
Good Manufacturing Practices (GMP) for herbal and traditional medicines. Industrial layout, material flow, and process validation in pharmacognostic industries. Documentation and record-keeping in herbal manufacturing. Intellectual Property Rights (IPR) and patents related to natural products.

Text Books:

1. Kokate C. K., Purohit A. P., & Gokhale S. B., *Pharmacognosy*, 56th Ed., Nirali Prakashan, 2019.
2. Handa S. S. et al., *Pharmacognosy and Phytochemistry*, CBS Publishers, 2008.

Reference Books:

1. Trease G. E. & Evans W. C., *Pharmacognosy*, 16th Ed., Saunders, 2009.
2. Mukherjee P. K., *Quality Control of Herbal Drugs*, 2nd Ed., Business Horizons, 2019.

Web Links:

1. https://www.ayush.gov.in
2. https://www.who.int/publications/i/item/good-agricultural-and-collection-practices-(gacp)-for-medicinal-plants
3. https://pharmacognosy-magazine.com

Medicinal Plant Biotechnology

Course Code: 2517PY43

UNIT-I:
Introduction to Medicinal Plant Biotechnology
Scope and importance of biotechnology in medicinal plant research. Overview of plant tissue culture and its applications in secondary metabolite production. Totipotency, differentiation, and organogenesis. Culture media composition — macro/micronutrients, growth regulators, and additives. Good Laboratory Practices (GLP) and aseptic techniques in plant tissue culture.

UNIT-II:
Plant Tissue Culture Techniques
Callus culture, suspension culture, and organ culture methodologies. Micropropagation — stages, advantages, and industrial applications. Somatic embryogenesis and synthetic seed production. Protoplast isolation, culture, and fusion techniques. Cryopreservation and germplasm conservation.

UNIT-III:
Secondary Metabolite Production
Biotechnological approaches for enhanced secondary metabolite synthesis. Elicitation, precursor feeding, and immobilization of plant cells. Scale-up of plant cell cultures for commercial metabolite production. Hairy root cultures using *Agrobacterium rhizogenes* and their significance.

UNIT-IV:
Genetic Engineering in Medicinal Plants
Introduction to recombinant DNA technology and gene transfer methods. Agrobacterium-mediated and direct gene delivery techniques. Metabolic pathway engineering for enhanced phytochemical yield. Production of transgenic plants with improved therapeutic properties. Molecular markers (RAPD, AFLP, SSR) in identification and authentication of medicinal plants.

UNIT-V:
Industrial and Regulatory Aspects
Biotechnological production of plant-derived drugs — case studies (e.g., paclitaxel, artemisinin).
Good Manufacturing Practices (GMP) for biotech-derived herbal products. Regulatory requirements — DBT, GEAC, and WHO guidelines.
Intellectual Property Rights (IPR) and patenting issues in plant biotechnology.

Text Books:

1. J. Hammond, P. McGarvey & V. Yusibov, *Plant Biotechnology: New Products and Applications*, Springer, 2000.
2. Bhojwani S. S. & Razdan M. K., *Plant Tissue Culture: Theory and Practice*, Elsevier, 1996.

Reference Books:

1. Dixon R. A. & Gonzales R. A., *Plant Cell Culture: A Practical Approach*, Oxford University Press, 2014.
2. Neumann K. H. & Kumar A., *Plant Cell and Tissue Culture – A Tool in Biotechnology*, Springer, 2020.

Web Links:

1. https://dbtindia.gov.in
2. https://www.who.int/health-topics/medicinal-plants
3. https://www.sciencedirect.com/topics/agricultural-and-biological-sciences/plant-biotechnology

Herbal Cosmetics

Course Code: 2517PY44

UNIT-I:
Introduction to Herbal Cosmetics
Definition, scope, and classification of cosmetics. Historical development and importance of herbal cosmetics in modern healthcare. Concepts of cosmeceuticals and nutracosmetics. Advantages of herbal ingredients over synthetic products. Regulatory overview — Drugs and Cosmetics Act (India) and global cosmetic regulations (FDA, EU).

UNIT-II:
Raw Materials and Ingredients
Sources and characteristics of herbal ingredients used in cosmetics. Natural colorants, fragrances, oils, waxes, gums, and resins. Extraction, purification, and standardization of cosmetic herbs. Evaluation of raw materials — physicochemical and microbiological tests. Quality control and Good Manufacturing Practices (GMP) for cosmetic raw materials.

UNIT-III:
Formulation of Herbal Cosmetic Products
Formulation principles for herbal skin and hair care products. Preparation and evaluation of creams, lotions, shampoos, conditioners, and face packs. Formulation of herbal oral hygiene, nail, and eye cosmetics. Stabilizers, emulsifiers, preservatives, and natural antioxidants. Pilot-scale production, packaging, and shelf-life studies.

UNIT-IV:
Evaluation and Quality Control of Herbal Cosmetics
Evaluation parameters — physicochemical, rheological, and sensory properties. In-vitro and in-vivo methods for assessing safety and efficacy. Microbial contamination and preservative efficacy testing. Stability testing and accelerated aging studies. Pharmacopoeial standards and labeling requirements for herbal cosmetics.

UNIT-V:
Trends, Marketing, and Regulatory Aspects
Herbal cosmetic industry — current status and future prospects. Regulatory guidelines for herbal cosmetics (AYUSH, BIS, WHO). Intellectual Property Rights (IPR) and patenting of cosmetic formulations. Recent trends — nanocosmetics, green cosmetics, and biocosmetics. Case studies on successful herbal cosmetic formulations in the Indian market.

Text Books:

1. Sharma P. P., *Cosmetic Formulation, Manufacturing and Quality Control*, 5th Ed., Vandana Publications, 2018.
2. Handa S. S., *Pharmacognosy and Phytochemistry*, CBS Publishers, 2008.

Reference Books:

1. Draelos Z. D., *Cosmetic Dermatology: Products and Procedures*, 3rd Ed., Wiley-Blackwell, 2022.
2. Harry R. G., *Harry's Cosmeticology*, 9th Ed., Chemical Publishing Co., 2015.

Web Links:

1. https://www.ayush.gov.in
2. https://www.fda.gov/cosmetics
3. https://www.cosmeticsandtoiletries.com

Advanced Pharmacognosy

Course Code: 2517PY45

UNIT-I:
Introduction to Advanced Pharmacognosy
Scope, importance, and recent developments in pharmacognosy. Role of natural products in modern drug discovery and development. Phytochemistry of secondary metabolites — alkaloids, glycosides, flavonoids, terpenoids, and tannins. Chemotaxonomy and molecular systematics of medicinal plants. Advances in plant metabolomics and chemoinformatics.

UNIT-II:
Advanced Techniques in Phytochemical Investigation
Extraction and isolation of phytoconstituents using modern techniques — supercritical fluid extraction, microwave-assisted extraction, and pressurized liquid extraction. Hyphenated techniques and fingerprint profiling of herbal drugs. Quantitative evaluation and marker-based standardization.

UNIT-III:
Biosynthesis and Biotransformation of Natural Products
Biosynthetic pathways acetate, shikimate, mevalonate, and mixed pathways. Biotransformation and bioconversion using plant and microbial cultures. Tissue culture methods for production of bioactive secondary metabolites. Metabolic engineering and pathway modification for enhanced yield.

UNIT-IV:
Pharmacognosy in Drug Development
Screening of natural products for pharmacological activity. Bioassay-guided fractionation and structure–activity relationship (SAR). Drug discovery approaches — ethnopharmacology, reverse pharmacology, and high-throughput screening. Natural product-derived leads in anticancer, antimicrobial, and neuroactive drug discovery. Regulatory perspectives in herbal drug research and development.

UNIT-V:
Quality Control and Regulatory Aspects of Herbal Drugs
Quality assurance and standardization parameters for herbal formulations. Good Agricultural and Collection Practices (GACP) and Good Manufacturing Practices (GMP). WHO and AYUSH guidelines for herbal medicine quality evaluation.

Text Books:

1. Trease G. E. & Evans W. C., *Pharmacognosy*, 16th Ed., Saunders, 2009.
2. Kokate C. K., Purohit A. P., & Gokhale S. B., *Pharmacognosy*, 56th Ed., Nirali Prakashan, 2019.

Reference Books:

1. Mukherjee P. K., *Quality Control of Herbal Drugs*, 2nd Ed., Business Horizons, 2019.
2. Handa S. S., Kaul M. K., *Supplement to Cultivation and Utilization of Medicinal Plants*, RRL Jammu, 2008.

Web Link:

1. https://www.ayush.gov.in
2. https://www.sciencedirect.com/topics/pharmacognosy
3. https://pharmacognosy-magazine.com

Regulatory Aspects of Herbal and Biologicals

Course Code: 2517PY46

UNIT-I:
Introduction to Herbal and Biological Regulations
Overview and need for regulation of herbal and biological products. Classification, development, and commercialization pathways for herbal and biologicals. Comparative overview of global regulatory systems — India (AYUSH & CDSCO), USA (FDA), and EU (EMA). International Harmonization — WHO, ICH, and PIC/S guidelines. Regulatory definitions — herbal medicines, phytopharmaceuticals, biosimilars, and biologics.

UNIT-II:
Regulatory Requirements for Herbal Medicines
Regulatory approval process for herbal formulations in India and abroad. Documentation requirements — quality, safety, and efficacy data. Pharmacopoeial standards Indian Herbal Pharmacopoeia, Ayurvedic Pharmacopoeia, and WHO monographs. Good Agricultural and Collection Practices (GACP) and Good Manufacturing Practices (GMP) for herbal medicines. Quality assurance, standardization, and stability testing of herbal products.

UNIT-III:
Regulation of Biological Products and Biosimilars
Definition and classification of biological products — vaccines, monoclonal antibodies, recombinant proteins, and enzymes. Regulatory framework for biologicals development, approval, and post-marketing surveillance. Comparability and interchangeability of biosimilars with reference products. Guidelines for preclinical and clinical evaluation of biosimilars (CDSCO, EMA, USFDA).

UNIT-IV:
Intellectual Property Rights and Licensing
Patenting issues in herbal and biological product development. Traditional Knowledge Digital Library (TKDL) and prevention of biopiracy. Regulatory protection — patents, trademarks, and data exclusivity. Licensing procedures and technology transfer in herbal and biopharmaceutical sectors.

UNIT-V:
Pharmacovigilance and Post-Market Regulatory Compliance
Pharmacovigilance system for herbal and biological products. Reporting of adverse drug reactions (ADRs) and signal detection. Labeling, packaging, and product recall procedures.

Text Books:

1. Grampurohit N. D. & Baheti D. G., *Regulatory Affairs for Herbal and Biological Products*, PharmaMed Press, 2018.
2. Mehrotra R. & Vikas Sharma, *Pharmaceutical Regulatory Management and Compliance*, CBS Publishers, 2019.

Reference Books:

1. WHO, *Guidelines for the Assessment of Herbal Medicines*, Geneva, 1991.
2. EMA & USFDA, *Guidelines on Biosimilar Medicinal Products*, 2020.

Web Links:

1. https://cdsco.gov.in
2. https://www.ema.europa.eu
3. https://www.fda.gov/vaccines-blood-biologics

Phytochemistry

Course Code: 2517PY47

UNIT-I:
Fundamentals of Phytochemistry
Introduction, scope, and significance of phytochemistry in natural product research. Classification of secondary metabolites — alkaloids, glycosides, flavonoids, tannins, terpenoids, and steroids.

UNIT-II:
Extraction and Isolation Techniques
Selection of plant materials and methods of extraction maceration, percolation, Soxhlet, and modern techniques (SFE, MAE, PLE). Solvent selection and optimization for targeted phytoconstituents. Fractionation, purification, and crystallization of plant metabolites. Use of chromatographic techniques — HPTLC, HPLC, GC, LC–MS. Spectroscopic identification — UV, IR, NMR, and Mass spectrometry.

UNIT-III:
Chemical Tests and Structural Elucidation
Preliminary phytochemical screening of plant extracts. Color reactions and chemical identification tests for major metabolite classes. Structure elucidation of selected natural products using spectroscopic methods. Structure–activity relationships (SAR) in natural molecules.

UNIT-IV:
Biosynthesis and Biotransformation
Enzymatic and non-enzymatic biotransformation of plant metabolites. In-vitro and microbial systems for biosynthesis and modification of natural products. Isotopic labeling and precursor feeding studies. Production of secondary metabolites through plant cell and hairy root cultures. Metabolic engineering for enhanced yield and novel compound synthesis.

UNIT-V:
Application and Recent Advances
Natural products as pharmaceuticals, nutraceuticals, and cosmeceuticals. Chemotaxonomy and metabolomics in drug discovery. High-throughput screening of phytochemicals. Patent and regulatory aspects in phytochemical research. Recent advances — green extraction, dereplication, and metabolite profiling.

Text Books:

1. Harborne J. B., *Phytochemical Methods: A Guide to Modern Techniques of Plant Analysis*, 3rd Ed., Springer, 1998.
2. Rohit K. Sharma, *Phytochemistry: Theory and Practice*, Campus Books, 2011.

Reference Books:

1. Trease G. E. & Evans W. C., *Pharmacognosy*, 16th Ed., Saunders, 2009.
2. Dewick P. M., *Medicinal Natural Products: A Biosynthetic Approach*, 3rd Ed., Wiley, 2009.

Web Links:

1. https://www.sciencedirect.com/topics/chemistry/phytochemistry
2. https://pubs.acs.org/journal/npmdax *(ACS Natural Product Reports)*
3. https://www.pharmacognosy.com

Pharmacognosy and Metabolic Engineering

Course Code: 2517PY48

UNIT-I:
Introduction to Pharmacognosy and Metabolic Engineering
Concept of metabolic engineering and its importance in natural product biosynthesis. Plant secondary metabolism: types, localization, and regulation. Tools and techniques for studying plant metabolism.

UNIT-II:
Biosynthetic Pathways of Secondary Metabolites
Detailed study of biosynthetic pathways shikimic acid, acetate–malonate, and mevalonate routes. Enzymes and cofactors involved in secondary metabolite synthesis. Gene clusters and transcriptional regulation of metabolic pathways. Metabolic flux analysis and control mechanisms.

UNIT-III:
Genetic and Metabolic Manipulation
Recombinant DNA technology in secondary metabolite enhancement. Overexpression, gene silencing, and CRISPR/Cas-mediated genome editing. Elicitation and precursor feeding for pathway modification. Engineering of rate-limiting enzymes and transcription factors.

UNIT-IV:
Biotechnological Production of Phytochemicals
In-vitro culture systems — callus, suspension, and hairy root cultures. Optimization of media, elicitors, and bioreactor design for metabolite production. Scale-up and downstream processing of plant-based metabolites.

UNIT-V:
Industrial and Regulatory Perspectives
Industrial applications of metabolic engineering in pharmaceuticals and nutraceuticals. Patenting issues and intellectual property rights (IPR) in natural product biotechnology. Regulatory frameworks for plant-derived bioproducts (DBT, AYUSH, WHO). Good Manufacturing Practices (GMP) for biotechnological production.

Text Books:

1. Verpoorte R., Alfermann A. W., *Metabolic Engineering of Plant Secondary Metabolism*, Springer, 2000.
2. Dixon R. A., *Plant Cell Culture: A Practical Approach*, Oxford University Press, 2014.

Reference Books:

1. Dutta A. C., *Pharmacognosy*, Oxford University Press, 2019.
2. Neumann K. H. & Kumar A., *Plant Cell and Tissue Culture – A Tool in Biotechnology*, Springer, 2020.

Web Links:

1. https://dbtindia.gov.in
2. https://www.nature.com/subjects/metabolic-engineering
3. https://www.frontiersin.org/journals/plant-science