Revised PhD Course Work Syllabus

(as per IGNTU notification IGNTU/RO/2021/43 dt. 27.04.2021)

Course Structure

Course Code	Name of the Course	No. of Hours per Week	Credit Points
Core Courses			
PH-01	Research Methodology	4	4
PH-02	Research Publication & Ethics	2	2
--	**Computer Applications***	4	4
Discipline Specific Elective (DSE-1) Courses (Opt Any One)			
PH-03	Advanced Drug Delivery Systems	4	4
PH-04	Advanced Drug Design Methodologies	4	4
PH-05	Advanced Pharmacology and Regulatory Toxicology	4	4
PH-06	Advanced Pharmacognosy and Phytochemistry	4	4
PH-07	Advanced Pharmaceutical Biotechnology	4	4
PH-08	Advanced Pharmaceutical Analysis	4	4
Discipline Specific Elective (DSE-2) Course			
PH-09	Experimental Pharmacology in Drug Research	2	2
Total		16	16

this core course is taught at University level

Scheme for Internal Assessments and End Semester Examination

Name of the Course	Continuous Mode	Sessional examination			End semester Examination		Total Marks
		Marks	Duration	Total	Marks	Duration	
Core Courses							
Research Methodology	10	30	1 Hr	40	60	3 Hrs	100
Computer Applications	10	30	1 Hr	40	60	3 Hrs	100
Research Publication and Ethics	5	15	1Hr	20	30	2 Hrs	50
DSE-1 (Any One)							
Advanced Drug Delivery Systems	10	30	1 Hr	40	60	3 Hrs	100
Advanced Drug Design Methodologies	10	30	1 Hr	40	60	3 Hrs	100
Advanced Pharmacology and Regulatory Toxicology	10	30	1 Hr	40	60	3 Hrs	100
Advanced Pharmacognosy and Phytochemistry	10	30	1 Hr	40	60	3 Hrs	100
Advanced Pharmaceutical Biotechnology	10	30	1 Hr	40	60	3 Hrs	100
Advanced Pharmaceutical Analysis	10	30	1 Hr	40	60	3 Hrs	100
DSE-2							
Experimental Pharmacology in Drug Research	5	15	1Hr	20	30	2 Hrs	50

इंदिरा गाँधी राष्ट्रीय जनजातीय विश्वविद्यालय, अमरकंटक
Indira Gandhi National Tribal University, Amarkantak
(A Central University established by an Act of Parliament)

Syllabus for Ph.D. Course Work

Department of Pharmacy

In accordance with the UGC [Minimum Standards & Procedure for Award of M.Phil/PhD Degree] Regulation 2016 as Adopted by Indira Gandhi National Tribal University, Amarkantak vide Ref. No IGNTU/990/2016 dt. 25.11.2016

&

In accordance with IGNTU Notification Ref. No. IGNTU/RO/2021/43 dt. 27.04.2021

Syllabus for Core Courses

RESEARCH METHODOLOGY (PH-01)

Credit: 4 **Hours: 60**

Scope: This subject is designed to guide the PhD students of Pharmacy towards achieving competence and proficiency in the theory of and practice to research.

Objective (s):

- This course will enable scholars to identify and apply appropriate research methodology in order to plan, conduct and evaluate basic research.
- The Course will enable scholars to distinguish between the scientific method and knowledge while laying the foundation for research skills at higher levels.
- This course will enable students to develop the subject of their research, encourage the formation of higher level of trained intellectual ability, critical analysis, rigour, and independence of thought, foster individual judgement, and skill in the application of research theory and methods, and develop skills required in writing research proposals, reports, and dissertation.

Course Content

Unit-I: Introduction to Research Methodology- Motivation and objectives of research, types of research, introduction to drug discovery & development research, objectives, Flow diagram for discovery to post-marketing research, overview of research methodology in various research areas in drug discovery and development.

Unit-II: Research formulation– Defining and formulating the research problem, selecting the problem, necessity of defining the problem, importance of literature review in defining a problem, Literature review - primary and secondary sources, reviews, monographs, patents, research databases, web as a source, searching the web, critical literature review, identifying gap areas from literature review and research databases, development of working hypothesis. Hypothesis: Types, Formulation of Hypothesis, Feasibility, Preparation and Presentation of Research Proposal, Testing of Hypothesis.

Unit-III: Research design – Basic principles, need of research design, features of good design, important concepts relating to research design, research databases, development of models, developing a research plan – exploration, description, diagnosis, and experimentation.

Design of Experiment: Basic Principal of Experimental Design, Randomized Block, Completely Randomized Block, Latin Square, Factorial Design.

Unit-IV: Data Analysis– Introduction, Analysis of parametric data, Analysis of non – parametric data, data collection and analysis: Aspects of method validation, observation, data processing and analysis strategies and tools.

Unit-V: Reporting and thesis writing: Structure and components of scientific reports, types of report, technical reports and thesis. Thesis writing – different steps and software tools (Word processing, etc) in the design and preparation of thesis, layout, structure (chapter plan) and language of typical reports, Illustrations and tables, bibliography, referencing and

footnotes. Oral presentation-planning, software tools, creating and making effective presentation, use of visual aids, importance of effective communication.

Practice [*This section is for continuous mode through tutorials/assignment/hands-on training only*]
Formulation of research proposal, presentation, and defense

Suggested Readings:

[1]. C.R. Kothari, Research Methodology Methods and Techniques (Second Revised Edition), New Age. International Publication.
[2]. R.Panneerselvam , Research Methodology, PHI
[3]. Ranjit Kumar, Research methodology: a step-by-step guide for beginners, SAGE Publication. Ltd.
[4]. Montgomery, Douglas C;(2007), 5/e, Design and Analysis of Experiments, Wiley India)
[5]. Montgomery, Douglas C. &Runger; George C. (2007), 3/e, Applied Statistics & Probability for Engineers (Wiley India)
[6]. Krishimswamy, K.N. Sivakumar, Appalyer and Mathirattian M. (2006), Management Research Methodology; Integration of Principles, Methods and Techniques (Pearson Education, New Delhi)

Research and Publication Ethics (PH-02)

Credit: 2 **Hours: 30**

Scope: To provide a guideline and training to research scholars and university faculty members to publish research in credible and scholarly publications and to prepare an authentic document on Publication Ethics. Indexing and citation databases, open access publications, research metrics (citations, h-index, impact factor, etc.) and plagiarism will be introduced in this course.

Objective (s):

This course focuses on basics of philosophy of science and ethics, research integrity, publication ethics. Hands-on-sessions are designed to identify research misconduct and predatory publications.

Course Content

THEORY

Unit-I: PHILOSOPHY AND ETHICS

1. Introduction to philosophy: definition, nature and scope, concept, branches
2. Ethics: definition, moral philosophy, nature of moral judgments and reactions, root causes of unethical practices

Unit-II: SCIENTIFIC CONDUCT

1. Ethics with respect to science and research
2. Intellectual honesty and research integrity
3. Scientific misconducts: Falsification, Fabrication, and Plagiarism (FFP)

4. Redundant publications: duplicate and overlapping publications, salami slicing
5. Selective reporting and misrepresentation of data

Unit-III: PUBLICATION ETHICS

1. Publication ethics: definition, introduction and importance
2. Best practices / standards setting initiatives and guidelines: COPE, WAME, etc.
3. Conflicts of interest
4. Publication misconduct: definition, concept, problems that lead to unethical behavior and vice versa, types
5. Violation of publication ethics, authorship and contributorship
6. Identification of publication misconduct, complaints and appeals
7. Predatory publishers and journals

PRACTICE

[*This section is for continuous mode through tutorials/assignment/hands-on training only*]

Unit-IV: OPEN ACCESS PUBLISHING

1. Open access publications and initiatives
2. SHERPA/RoMEO online resource to check publisher copyright and self-archiving policies
3. Software tool to identify predatory publications developed by SPPU
4. Journal finder/ journal suggestion tools viz. JANE, Elsevier Journal Finder, Springer Journal Suggester, etc.

Unit-V: PUBLICATION MISCONDUCT

A. Group Discussions

1. Subject specific ethical issues, FFP, authorship
2. Conflicts of interest
3. 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: DATABASES AND RESEARCH METRICS

A. Databases

1. Indexing databases
2. Citation databases: Web of Science, Scopus, etc.

B. Research Metrics

1. Impact Factor of journal as per Journal Citation Report, SNIP, SJR, IPP, Cite Score
2. Metrics: h-index, g-index, il0 index, altmetrics

Suggested readings:

[1] Bird, A. (2006). Philosophy of Science. Routledge.
[2] MacIntyre, Alasdair (1967) A Short History of Ethics. London.
[3] P. Chaddah, (2018) Ethics in Competitive Research: Do not get scooped; do not get plagiarized, ISBN:978- 9387480865
[4] National Academy of Sciences, National Academy of Engineering and Institute of Medicine. (2009). On Being a Scientist: A Guide to Responsible Conduct in Research: Third Edition. National Academies Press.

[5] Resnik, D. B. (2011). What is ethics in research & why is it important. National Institute of Environmental Health Sciences, 1-10. Retrieved from https://www.niehs.nih.gov/research/resources/bioethics/whatis/index.cfm
[6] Beall, J. (2012). Predatory publishers are corrupting open access. Nature, 489(7415), 179- 179. https://doi.org/10.1038/489179a
[7] Indian National Science Academy (INSA), Ethics in Science Education, Research and Govemance(2019), ISBN:978-8 l-939482-1-7. http://www.insaindia.res.in/pdf/Ethics Book.pdf

Syllabus for Discipline Specific Elective (DSE-1)

ADVANCED DRUG DELIVERY SYSTEMS (PH-03)

Credit: 4 **Hours: 60**

Scope: This course is designed to impart knowledge and skills necessary to train the students in the area of drug delivery systems.

Objective (s): On completion of this course it is expected that students will be able to understand

- The need, concept, design and evaluation of various customized, sustained and controlled release dosage forms.
- To formulate and evaluate various novel drug delivery systems
- To apply pharmacokinetics in evaluating performance of drug delivery systems
- To get accustomed with the R& D and production facilities required for industrial scale-up of safe, stable, efficacious dosage forms

Course Content

Unit-I: Pre-formulation Studies: Pre-formulation parameters and its method of determination, Drug Excipient interactions -different analytical methods.

Unit-II: Drug Delivery Systems (DDS):

(a) Gastro-Retentive DDS: Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit.

(b) Buccal DDS: Principle of mucoadhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.

(c) Ocular DDS: Barriers of drug permeation, Methods to overcome barriers, design of ocular DDS.

(d) Transdermal DDS: Structure of skin and barriers, penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.

(e) Delivery of Macromolecules: Barriers for oral protein-peptide delivery, novel strategies to overcome these barriers, introduction to vaccines, mucosal and transdermal delivery of vaccines

(f) Tablets: Tablet excipients, Granulation technology, Physics of tablet compression, compression, consolidation, distribution of forces, compaction profiles, coating of tablets.

(g) Parenterals: Clean room, production facilities, formulation of injections, LVP and lyophilized products, quality control tests of parenteral products.

Unit-III: Herbal excipients for the design of drug delivery carriers, herbal formulations, herbal cosmetics, quality control of herbal formulations

Unit-IV: Nanocarriers: Concepts of targeted drug delivery, Events and biological process involved in drug targeting, tumor targeting, brain specific delivery. Preparation, evaluation and application of polymeric microparticles, polymeric nanoparticles, niosomes, liposomes, phytosomes, self-emulsifying carriers, nanoemulsion, nanosuspension.

Unit-V: Drug Product Performance: *In vitro&in vivo* drug product performance, concept of BA, BE, relative and absolute availability, methods for assessing bioavailability, bioequivalence studies-pharmacokinetic parameters, design and evaluation of bioequivalence studies, permeability studies, IVIVC, stability testing-ICH/ WHO guidelines

Suggested readings:

[1] Novel Drug Delivery System, Y.W. Chein, Vol 50, Marcel Dekker, NY.
[2] Controlled Drug Delivery Systems, Robinson, Vol 29, Marcel Dekker, NY.
[3] Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991
[4] Biopharmaceutics and Pharmacokinetics, A. Treatise, D.M. Brahmankar and Sunil B.Jaiswal., VallabPrakashan, Pitampura, Delhi
[5] Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY.
[6] Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
[7] Pharmaceutical dosage forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
[8] Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
[9] Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
[10] Modern Pharmaceutics by Banker, Vol 72, Marcel Dekker, NY.
[11] **COSMETICS : Formulation, manufacturing and Quality Control Fifth Ed., 2014** by P.P. Sharma
[12] The Complete Technology Book on Herbal Beauty Products with Formulations and Processes by H. Panda, ASIA PACIFIC BUSINESS PRESS Inc., 2005.

ADVANCED DRUG DESIGN METHODOLOGIES (PH-04)

Credit: 4 **Hours:** 60

Scope: This subject is designed to provide detailed knowledge of drug design methodologies for lead discovery to lead optimization and also to introduce students to the science of complex molecule synthesis.

Course Objective (s): The purpose of this course is to provide the student with an appreciation of Modern drug discovery methodologies and the area of complex molecule synthesis.
At the end of the course the student should be able to understand:

- Discovery of lead molecules through analog-based and structure-based drug design
- Application of computational tools for lead design and discovery
- Analysis of the synthetic problem and design of a reasonable synthetic solution based on known (or reasonable) chemical transformations.
- Have a good knowledge of some important modern synthetic methods, including their mechanisms and stereochemical implications

Course Content

Unit I: Analog based drug design.
Pharmacophore: Concept, Pharmacophore mapping, Methods of conformational search used in pharmacophore mapping,Structure-based pharmacophore analysis, 3D- QSAR approaches,Lead

discovery and lead optimization using ligand-based virtual screening, Case studies.***In silico* ADME Studies**: Modelling ADME properties, pattern recognition,regression, ANN, GA, etc.

Unit II: Structure based drug design.
Molecular docking and dynamics: Types of molecular docking, docking algorithms (FlexXAutodock, Dock, Glide etc.), Scoring functions,Limitations of molecular docking, Introduction to Molecular dynamics and Monte Carlo simulations and its applications in structure-based drug design. Lead discovery and lead optimization using structure based-virtual screening. Case studies for discovery of drug candidates / drugs (eg.) ABT 737 and application in discovery of protein-protein interaction inhibitors (eg.) p53-MDM2 interaction inhibitors.

Unit III: Retrosynthetic Approach: Retrosynthetic analysis, disconnections and reliability of reactions, synthons: Donor and acceptor, functional group interconversions, one group carbon-heteroatom and carbon–carbon disconnections, two group carbon-heteroatom and carbon-carbon disconnections, chemo-, regio- and stereo- selectivity considerations, natural reactivity and umpolung, 1,3 and 1,5–difunctional compounds.
Tutorial: Application of retrosynthetic strategies for the synthesis of any five recently approved small molecule active pharmaceutical ingredients.

Unit IV: Organometallic Chemistry: Formation of carbon-carbon bonds *via* organometallic reagents,Organolithium Reagents, Organomagnesium Reagents, Organotitanium Reagents, Organocerium Reagents, Organocopper Reagents, Organochromium Reagents, Organozinc Reagents, Organoboron Reagents, Organosilicon Reagents, Palladium-Catalyzed Coupling Reactions, Application of coupling reactions) in C-H activation and synthesis of pharmaceutically-relevant compounds; Importance in the drug discovery research.

Unit V: Introduction to Green Chemistry, Green chemistry metrics, Process safety, Safer solvents and auxiliaries, and alternative energy sources in chemistry.

Suggested Readings

[1] Alfred Burger, Donald J. Abraham - Burger's Medicinal Chemistry and Drug Discovery. Volume 1: Drug Discovery (6th edition) ,Publisher: Wiley-Interscience | 2003-01-17 | ISBN: 0471270903
[2] Leach, A. R. (2001). Molecular Modelling: Principles and Applications, Prentice Hall.
[3] Gasteiger, J. and T. Engel (2006). Chemoinformatics: A Textbook, Wiley.
[4] Bajorath, J. (2004). Chemoinformatics: Concepts, Methods, and Tools for Drug Discovery, Humana Press.
[5] Stuart Warren : Organic Synthesis – The Disconnection Approach , John Wiley & Sons publications.
[6] Zweifel, G. S., et al. (2017). Modern Organic Synthesis: An Introduction, Wiley.
[7] P. T. Anastas, J. C. Warner, “Green Chemistry. Theory and Practice”, Oxford University Press, 1998.
[8] M. Lancaster, “Green Chemistry. An Introductory Text”, 2nd Ed., RSC Publishing, 2010.
[9] P. Tundo, A. Perosa, F. Zecchini (Eds.), “Methods and Reagents for Green Chemistry. An introduction”, Wiley-Interscience, 2007.

Advanced Pharmacology and Regulatory Toxicology (PH-05)

Credit: 4 **Hours: 60**

Scope: This paper will provide the basic concepts and general principles of the receptor pharmacology, clinical pharmacology, regulatory toxicology as well as pre-clinical animal model development for various disease and applications of artificial intelligence (AI).

Objectives: Upon completion of this paper the students should be able to:

- Understand the concept of receptor and its signaling mechanism.
- Know about different regulatory guidelines for the toxicological evaluation of any substance.
- Learn the development and validation of preclinical animal model for toxicity studies.
- Identify various drug targets and preclinical evaluation of substances for the treatment of various diseases of CNS, CVS, metabolism, inflammation etc.
- Learn the applications of artificial intelligence in the diagnosis and treatment of disorders and in the development of pharmacovigilance (PV) system.
- Understand the basic concepts of Clinical Pharmacology, clinical phases of drug development and adverse drug reactions (ADRs) monitoring and reporting methods.
- Learn the design and organization of Clinical Trial studies (Phase-I to Phase-IV).
- Understand the Pharmacovigilance Program of India (PvPI) requirements for ADR reporting in India

Course Content

UNIT-I: Introduction to Pharmacology: Drug Receptors: Drug receptor interaction theories, Receptor occupation and response relationship, spare receptors, silent receptors, orphan receptors, pre-synaptic and postsynaptic receptors. Receptor characterization methods, receptor subtypes, IUPHAR nomenclature, clinical significance of receptor sub-classification. Receptor transduction mechanisms, second messengers (cAMP, cGMP, calcium), receptor down regulation and up-regulation, Dose response relationship and different types of antagonisms. Reverse Pharmacology.

UNIT-II: Introduction to Regulatory Toxicology: Drug discovery and development process, GLP, Drug Laws, FDA, OECD and ICH guidelines, Schedule Y. Methods in toxicity testing and factors affecting toxicity studies, dose-response characterization, Drug discovery and registration: Regulatory affairs, WTO, patent regime, accreditation and harmonization process, Regulations of human pharmaceuticals: Preclinical development, Environmental impact: Regulation for biological products, Influence of new technologies: Discovery development gap, future of drug safety. Flow chart for development of preclinical testing, Data evaluation and regulatory requirements, Preclinical toxicological evaluation of Nanopharmaceuticals: Requirements, Methods, Regulatory guidelines, Animal models, Challenges.

UNIT-III: Pharmacology in Drug Discovery and Drug Development: Introduction to laboratory animals, handling, care and techniques used in the animals, general principles of pharmacological screening, correlations between various animal models and human situations. Pathophysiology, drug targets and pharmacology of drugs for the inflammation, pain, diabetes, and brain diseases. Neurohumoral Transmission in CNS, CNS drug discovery and challenges,

Neurotransmitters. Pharmacological screening models for therapeutic areas such as cerebral ischemia, neuropathic pain, epilepsy, depression, Parkinson's disease, Alzheimer's disease, diabetes, anxiety, autism spectrum disorders, inflammation, rheumatoid arthritis, stroke, cognitive impairments and neglected tropical diseases, role of Gut-Brain Axis in the neurological disorders. Artificial intelligence (AI) utility in the diagnosis, management and treatment of various diseases.

UNIT-IV: Clinical Pharmacology: Introduction to clinical pharmacology: Importance of clinical pharmacokinetics, therapeutic monitoring of important drugs. Drug-drug interactions: Drug-food interactions; Drug-pollutant interaction, Good Clinical Practices (GCP). Pharmacovigilance (PV): Introduction, Pharmacovigilance methods, Process of adverse drug reactions (ADRs) monitoring and reporting with reference to India and foreign countries, Artificial intelligence and Pharmacovigilance system. Design and organization of phase-I to phase-IV clinical studies, Epidemiological studies of the common diseases: design, methods and challenges. Drug abuse, addiction and dependence: Diagnosis, Prevention and treatment approaches.

UNIT-V: Bioethics: Ethics, moral and laws related to animals. Social pressure and friendly use of animals in higher research, Approval process for use of animals in experiments, Precautions in biological experiments, Labeling: Identification, cage cards, Handling of experimental animals, Disposal of dead animals after experiments.

Suggested readings:

[1] The Pharmacological Basis of Therapeutics by Goodman and Gilman's.
[2] Basic and Clinical Pharmacology by Katzung
[3] ICH Guidelines (https://www.ich.org/page/ich-guidelines)
[4] Schedule Y (https://rgcb.res.in/documents/Schedule-Y.pdf)
[5] OECD Guidelines (https://www.oecd.org/env/ehs/testing/oecdguidelinesforthetestingofchemicals.htm)
[6] USFDA Guidelines (https://www.fda.gov/regulatory-information/search-fda-guidance-documents)
[7] Regulatory Toxicology by Shayne C. Gad Taylor & Francis Principles and Methods of Toxicology by A. Wallace Hayes
[8] Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers
[9] Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle, Wiley Publishers.
[10] An Introduction to Pharmacovigilance: Patrick Waller,Wiley Publishers.
[11] Cobert's Manual of Drug Safet y and Pharmacovigilance: Barton Cobert, Jones & Bartlett Publishers.

ADVANCED PHARMACOGNOSY& PHYTOCHEMISTRY (PH-06)

Credit: 4 **Hours: 60**

Scope: At the end of the course the scholar will be able to (i) identify, isolate and characterize the active constituents from medicinal plants and (ii) apply pharmacovigilance in herbal therapy and establish authentic standards.

Objectives: At the end of the course student should be able

- To know the exhaustive list of plants having active constituents, which are effective against diseases like cancer, Alzheimers and viral diseases.
- To know the phytochemistry & phytopharmacology of the drugs.
- To understand the concept of Ethnopharmacognosy, Ethnomedicine.

Course Content

UNIT-I: Drug Discovery from Natural Products: a) Introduction, recent developments, different methods of extraction like soxhlet extraction, microwave extraction, supercritical fluid extraction, solid phase extraction, Column chromatography, Flash chromatography b) study on flora and fauna of local biodiversity; c) Isolation and characterization studies of different class of phytoconstituents like Alkaloids, Glycosides, Steroids, Tannins, Resins, Saponins, Iridoids

UNIT-II: Characterization of Plant Constituents: General methods of characterization of plant constituents –Melting point, boiling point, optical rotation, spectroscopy (UV, IR, NMR and Mass) and XRD – Interpretation of spectroscopic data and X-ray crystallography.

UNIT-III: WHO Guidelines for Assessment of Crude Drugs: WHO Guidelines for the evaluation of identity, purity and quality of crude drugs, determination of pesticide residue, micro-organisms content and estimation of arsenic and heavy metals. Standardization of herbal drugs by conventional and modern techniques, markers based study.

UNIT-IV: Methods of Biological Evaluation of Plant Drugs: (a) Antidiabetic (b) Hepatoprotective (c) Antioxidant (d) Antineoplastic (e) Antiviral (f) Antiseptic (g) Anti-inflammatory (h) Analgesic (i) Antialzhemier

UNIT-V: Alternatives to Animal Experimentation: a) Animal cell lines and their uses b) Radio ligand binding assay c) Patch clamp and ELISA d) Stem cell research.

Suggested readings:

[1] W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Sounders &Co., London, 2009.
[2] Tyler, V.E., Brady, L.R. and Robbers, J.E., Pharmacognosy, 9th Edn., Lea and Febiger, Philadelphia, 1988.
[3] Text Book of Pharmacognosy by T.E. Wallis
[4] Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers, New Delhi.

[5] Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
[6] Herbal drug industry by R.D. Choudhary (1996), IstEdn, Eastern Publisher, New Delhi.
[7] Pharmacognosy & Pharmacobiotechnology. James Bobbers, Marilyn KS, VE Tylor.
[8] Text Book of Biotechnology by Vyas and Dixit.
[9] Text Book of Biotechnology by R.C. Dubey.
[10] Textbook of Pharmacognosy and Phytochemistry by Biren Shah., 1st Edition, Elsevier, India.

ADVANCED PHARMACEUTICAL BIOTECHNOLOGY (PH-07)

Credit: 4 **Hours: 60**

Scope: The syllabus includes the fundamentals and applications of diverse topics in the area of pharmaceutical biotechnology. By reading these topics, student will be able to understand molecular biology and biotechnology and tissue culture techniques. The students will also learn about nano-biotechnology, nanomedicine and advanced molecular medicine.

Objectives:

- To learn the fundamentals of pharmaceutical biotechnology
- To be familiar with advanced biotechnological methods and its applications

Course Content

Unit-I: Molecular Biotechnology: Basic terminology of molecular biology and immunology, Immunology - Cellular basis of Immune response, Immunity to Viruses, Bacteria and fungi, Immunodeficiency diseases, autoimmune diseases, Vaccine technology: Conventional vaccines, novel methods for vaccine production, anti- idiotype vaccine, DNA vaccine, genetically engineered vaccine, ISCOMS, synthetic peptides.
Hybridoma techniques – Fusion methods for myeloma cells and B-Lymphocytes, selection and screening techniques. Production and purification of monoclonal antibodies and their applications in clinical diagnosis and immunotherapy.

Unit-II: Biomolecular methods and Immunodiagnostics techniques: Purification and separation techniques of biomolecules, Electrophoresis, Blotting techniques, Polymerase Chain Reaction, Immunoassay, radio immunoassay, fluorescence immunoassay-types, principle, working and its applications, diagnostic kits-development and applications.

Unit-III: Tissue Culture Technology: Cell culture – Basic and types, Primary and secondary cell culture, Nutrient Media, Plant cell and animal cell culture, applications of cell culture technique in plant propagation, medicinal and food value/yield enrichment and production, new

drug discovery and pharmaceutical screening of compounds and formulations, Understanding cellular and molecular dynamics and kinetics of tissue/organs, advanced tissue regeneration.

Unit-IV: Nanobiotechnology: Nano-biosensors, Nano-biochips and biomicroarray, Nano-diagnostics, Physical model of the cell as a machine smart nano system /device for tissue & bone engineering, cosmeceutics, molecular pharmaceutics and biomedical applications, New therapeutics and targeted drug/siRNA delivery vehicles.

Unit-V: Nanomedicine and Advanced Molecular Medicine: Nanomedicine and its applications in drug delivery, protein and peptide delivery, vaccine delivery, gene delivery and miscellaneous biopharmaceuticals, Impact and applications of nanotechnology in enzymatic bio-processing, Safety of nanomaterials/ nanosystems, quality control and regulatory aspects of nanomedicine, scale-up feasibilities and tech transfer of nanomedicine, individualized//personalized medicine, Biosimilars.

Suggested Readings:

[1]. Molecular Biotechnology- Principles and Applications of Recombinant DNA, Bernard R. Glick, Jack J. Pasternak, Cheryl N. Patten 5th Edition.

[2]. Pharmaceutical Biotechnology, S.P. Vyas and V.K. Dixit.

[3]. Kuby Immunology, J Punt, S Stranford, P Jones, JA Owen, 8th Edition, Freeman Publication.

[4]. Molecular cell Biology, H Lodish, A Berk, S Lawrence, 4th Edition, Freeman publication.

[5]. Molecular Biotechnology, S.B. Primrose, 2nd Edition, Blackwell Scientific Publication.

[6]. Animal Cell culture- Essential Methods, J Davis, Wiley- Blackwell Publisher.

[7]. Molecular Biology and Biotechnology, JM. Walker and E.B. Gingold: Royal Society of Chemistry

ADVANCED PHARMACEUTICAL ANALYSIS (PH-08)

Credit: 4 **Hours: 60**

Scope: To produce scholars with advanced knowledge and skills of Pharmaceutical Analysis along with professional ethics that are relevant in the evolving Pharmacy sectors both in national and global level. To enhance the ability of researchers to think rigorously and work independently to meet the higher level expectations of pharmaceutical industry, academics and research.

Objective (s): The objectives of this course are to enable the scholar to:

- Appraise the latest advances in the field of Pharmaceutical Analysis

- Discuss the principles of different analytical techniques and apply them in professional practice
- Proficiently use various analytical instruments for analysis of drugs and pharmaceuticals
- Demonstrate critical, analytical, problem solving and research skills in the domain of Pharmaceutical Analysis

Course Content

Unit-I: Analysis of Drug Substances: Solid state analysis of drug substance including related substances, and impurities present in drugs and their effect on drug stability and therapeutic action, Applications of various analytical techniques in preformulation analysis and its importance, Analysis of solid oral dosage form, Analysis of injectable dosage form, Compendial testing, Automated analysis, Compendia methods for evaluation of crude drug and herbal formulation, Regulatory requirement in pharmaceutical analysis-US-FDA, ICH.

Unit-II: Instrumental Methods of Drug Analysis: A detailed study of principle and procedures involved in various physicochemical methods of analysis including instrumental methods of analysis of Pharmaceutical dosage forms containing the following classes of drugs: a). Sulphonamides, b) Barbiturates: Barbituric acid derivatives and Xanthine derivatives, c). Steroids such as Adrenocortical steroids, Progesterone, Androgens and Cholesterol. d). Vitamins like Vitamin A, BI, B2, B12, C and E, e) Antibiotics like Chloramphenicol, Erythromycin, Penicillin and Streptomycin. f. Alkaloids of Cinchona, Ergot, Opium and Rauwolfia, g). Glycosides such as Digitoxin, Digoxin and Strophanthin.

Unit-III: Colorimetric Reagents for Drug Analysis: Principles and procedures involved in the use of the following reagents in Pharmaceutical analysis: a) N-(1-Naphthyl) ethylenediaminedihydrochloride, b) *p*-Dimethylaminobenzaldehyde (PDAB), c) 2,6-Dichloroquinone-4-chloroimide, d) 1,2-Naphthoquinone-4-sulfonic acid sodium salt e) 2,3,5 triphenyltetrazolium salt reagent f) Ninhydrin g. FolinCiocalteureagent, h) *p*-dimethyl amino cinnamaldehyde, i) 3-Methyl-2-benzothiazolinone hydrazone hydrochloride (MBTH), j) 2,4-dinitrophyenylhydrazine.

Unit-IV: Mass Spectrometry: Basic principles and instrumentation, ion formation and types, fragmentation processes and fragmentation pattern, Chemical Ionization Mass Spectroscopy (CIMS), Electrospray Ionization Mass Spectrometry (ESI-MS),Field Ionization Mass Spectrometry (FIMS), Fast Atom Bombardment MS (FAB MS), Matrix Assisted Laser Desorption / Ionization MS (MALDI-MS), interpretation of spectra and applications in Pharmacy.

Unit-V: Chromatographic Techniques: Principle, instrumentation and applications of HPLC, UPLC, HPTLC, LC-MS and GC-MS

Suggested Readings:

[1] Harry G Brittain, Spectroscopy of Pharmaceutical Solids, Drugs and Pharmaceutical Science Series, Vol. 160, Taylor and Francis, 2006 N.Y.
[2] S. Ahuja, Modem Pharmaceutical Analysis
[3] Lena Ohannesian and Anthony J. Stricter, Hand Book of Pharmaceutical Analysis, Vol. 117, Marcel Dekker Inc., NY.
[4] Peptide and Protein Drug Analysis, by Reid, (Mamel Dekker).
[5] Classification of cosmetics raw materials and adjuncts IS 3958 of Indian Standards Institution (BIS).
[6] Cosmetic and toilet goods — methods of sampling lS 3958 of Indian Standards Institution (BIS).
[7] Methods of sampling and test for various cosmetics as laid down by Indian Standard Institution (BIS)
[8] Indian Pharmacopoeia, Vol. I and Vol. 11 - 1996. The Controller of Publications; New Delhi, Govt. of India,
[9] The International Pharmacopoeia Vol 1,2,3,4, 3rd Edition General Methods of analysis and quality specifications for pharmaceutical substances, excipients, dosage forms.
[10] Quality Assurance of Pharmaceuticals — A compendium of guidelines and related materials Vol.1 and Volt, WHO, (1999)
[11] Basic tests for pharmaceutical substances — WHO (1988)
[12] Basic tests for pharmaceutical dosage forms — WHO (1991)
[13] Phytochemical Methods by J.B. Haroborne.

Discipline Specific Elective-2 (DSE-2)

EXPERIMENTAL PHARMACOLOGY IN DRUG RESEARCH (PH-09)

Credit: 2 **Hours: 30**

Scope: This course is framed to impart the basic knowledge of preclinical studies in experimental animals including design, conduct and interpretations of results.

Objective (s): The objectives of this course are to enable the scholar to:

- Understand the applications of various commonly used laboratory animals.
- Appreciate and demonstrate the various screening methods used in preclinical research
- Appreciate and demonstrate the importance of data collection and representation
- Design and execute a research hypothesis independently

Course Content

Unit-I: Common laboratory animals and their physiological parameters, breeding types, inbred strains, F1 hybrids; Random breeding, selective breeding, breeding methods, factors affecting the nature and degree of pharmacological responses; Handling and care of different animals; Bleeding and different routes of administration and chemical euthanasia.

Unit-II: Animal handling, route of administration of drugs, dose calculation, dose response relationship, acute and chronic toxicity, estimation of protein and haematological parameters. General principles of screening, correlations between various animal models and human situations, animal ethics.

Unit-III: Aseptic handling, cell counting and cell viability assays, Western, northern, southern blot hybridization and PCR techniques, Microbiological Assay Techniques.

Unit-IV: Correlation between *in-vitro* and *in-vivo* screens; Special emphasis on cell based assay, biochemical assay, radioligand binding assay, high through put screening, high through put pharmacokinetic analysis, specific use of reference drugs and interpretation of results.

Unit-V: Data collection: Data reduction, data representation, cumulative and noncumulative dose, response curves, transformation of data logit, probit, pA scale, pD scale.

Suggested Readings

1. Pavia, Donald L, Gary M. Lampman, and George S. Kriz. Introduction to Spectroscopy: A Guide for Students of Organic Chemistry. Philadelphia: W.B. Saunders Co, 2015.
2. Kemp, W. (1991). Organic Spectroscopy, Palgrave Macmillan.
3. Struve, W. S. (1989). Fundamentals of Molecular Spectroscopy, Wiley.
4. Hollas, J. M. (2004). Modern Spectroscopy, Wiley.
5. Silverstein, R. M., et al. (2014). Spectrometric Identification of Organic Compounds, Wiley.
6. H.G. Vogel (ed), Drug Discovery and Evaluation-Pharmacological Assays, 2nd edition, Springer Verlag, Berlin, Germany, 2002. 2.
7. M.N. Ghosh, Fundamentals of Experimental Pharmacology, 2nd edition, Scientific Book Agency, Calcutta, India, 1984.
8. D.R. Laurence and A.L. Bacharach (eds), Evaluation of Drug Activities: Pharmacometerics, Vol. 1 and Academic Press, London, U.K., 1964.