Study Scheme & Syllabus of

PhD Course Work in Pharmaceutical Sciences

Batch 2025 Onward

By

Board of Study Pharmacy

Department of Academics

IK Gujral Punjab Technical University

Program Outcomes of Ph.D. Pharmacy Program

1. Pharmacy Knowledge: The scholastic educational module and research programs have been structured with refreshed information with the essential concentration to rudiments and developing fields of Pharmacy. Possess knowledge and comprehension of the advanced, core and basic knowledge associated with the profession of pharmacy, including biomedical sciences; pharmaceutical sciences; behavioural, social, and administrative pharmacy sciences; and manufacturing practices.
2. Pharmacy Research: Research regions in the division essentially centre around different pharmaceutical medication conveyance frameworks, novel medication conveyance frameworks, phytochemistry, institutionalization and quality control of home-grown medications, and other push regions of Pharmaceutical Research.
3. Planning Abilities: Demonstrate effective planning abilities including time management, resource management, delegation skills and organizational skills. Develop and implement plans and organize work to meet deadlines.
4. Problem analysis: Utilize the principles of scientific enquiry, thinking analytically, clearly and critically, while solving problems and making decisions during daily practice. Find, analyze, evaluate and apply information systematically and shall make defensible decisions.
5. Modern tool usage: Learn, select, and apply appropriate methods and procedures, resources, and modern pharmacy-related computing tools with an understanding of the limitations.
6. Leadership skills: Understand and consider the human reaction to change, motivation issues, leadership and team-building when planning changes required for fulfilment of practice, professional and societal responsibilities. Assume participatory roles as responsible citizens or leadership roles when appropriate to facilitate improvement in health and well- being.
7. Professional Identity: Understand, analyse and communicate the value of their professional roles in society (e.g. health care professionals, promoters of health, educators, managers, employers, employees).
8. Pharmaceutical Ethics: Honour personal values and apply ethical principles in professional and social contexts. Demonstrate behaviour that recognizes cultural and personal variability in values, communication and lifestyles. Use ethical frameworks;

apply ethical principles while making decisions and take responsibility for the outcomes associated with the decisions.

9. Communication: Communicate effectively with the pharmacy community and with society at large, such as, being able to comprehend and write effective reports, make effective presentations and documentation, and give and receive clear instructions.
10. The Pharmacist and society: Apply reasoning informed by the contextual knowledge to assess societal, health, safety and legal issues and the consequent responsibilities relevant to the professional pharmacy practice.
11. Environment and sustainability: Understand the impact of the professional pharmacy solutions in societal and environmental contexts, and demonstrate the knowledge of, and need for sustainable development.
12. Life-long learning: Recognize the need for, and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change. Self- assess and use feedback effectively from others to identify learning needs and to satisfy these needs on an ongoing basis.

Study Scheme

Course Code	Course Type	Course Name	Load			Marks			Credits
			L	T	P	Internal	External	Total	
PHP-101-25	Compulsory Course *(common to all branches/disciplines)*	Research Methodology	3	1	-	40	60	100	4
PHP-102-25		Research & Publication Ethics	2	-	-	20	30	50	2
PHP-201-25	Core Theory (Any One)	Pharmaceutics	3	1	-	40	60	100	4
PHP-202-25		Pharmaceutical Chemistry	3	1	-	40	60	100	
PHP-203-25		Pharmacology	3	1	-	40	60	100	
PHP-204-25		Pharmacognosy	3	1	-	40	60	100	
PHP-205-25		Modern Pharmaceutical Analytical Techniques	3	1	-	40	60	100	
PHP-206-25		Intellectual Property Rights	3	1	-	40	60	100	
PHP-207-25		Pharmacology & Toxicological Screening Methods	3	1	-	40	60	100	
PHP-208-25		Biochemical & Separation Techniques	3	1	-	40	60	100	
PHP-209-25		Bioprocess Technology	3	1	-	40	60	100	
PHP-210-25		Recombinant Biotechnology	3	1	-	40	60	100	
PHP-211-25		Plant Tissue Culture	3	1	-	40	60	100	
PHP-301-25	Interdisciplinary	*Seminar	-	-	8	100	-	100	4
		Total	**9**	**02**	**08**	**200**	**150**	**350**	**14**

** The evaluation of seminar shall be based on the submission of project report on the topic of research or relevant area followed by the evaluation through presentation.*
**Non-University Exam*

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
PHP-101-25	Research Methodology (Common to all branches)	3	1	-	40	60	1.5	3	4

Module 01 **15 Hrs**

Objectives and Types of Research
Meaning, Objectives, Motivation, Utility. Concept of theory, empiricism, deductive and inductive theory. Characteristics of scientific method – Understanding the language of research – Concept, Construct, Definition, Variable. Research Process, Research methods vs Methodology. Types of research – Descriptive vs. Analytical, Applied vs. Fundamental, Quantitative vs. Qualitative, Conceptual vs. Empirical

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, treatise, monographs-patents, various tool for search, Critical literature review–Identifying gap areas from literature review - Development of working hypothesis

Module 02 **10 Hrs**

Research Design and Methods
Research design- Basic Principles- Need of research design-Features of good design – Important concepts relating to research design – Observation and Facts, Laws and Theories, Prediction and explanation, Induction, Deduction, Development of Models. Developing a research plan-Exploration, Description, Diagnosis, Experimentation. Determining experimental and sample designs

Module 03 **15 Hrs**

Statistical Techniques and Tools
Introduction of statistics – Functions, Limitations, Measures of central tendency, Arithmetic mean, Median, Mode, Standard deviation, Co-efficient of variation, (Discrete serious and continuous serious), Correlation, Regression, Multiple Regression, Sampling distribution, Standard error, Concept of point and interval estimation, Level of significance, Degree of freedom, Analysis of variance, One way and two-way classified data- 'F'-test.

Module 04 **10 Hrs**

Reporting and Thesis Writing

Structure and components of scientific reports - Types of report – Technical reports and thesis – Significance – Different steps in the preparation – Layout, structure, and Language of typical reports – Illustrations and tables- Bibliography, referencing and footnotes - Oral presentation – Planning – Preparation –Practice – Making presentation – Use of visual aids - Importance of effective communication

Application of Results and Ethics

Environmental impacts - Ethical issues -ethical committees - Commercialisation – Copy right – royalty - Intellectual property rights and patent law – Trade Related aspects of Intellectual Property Rights-Reproduction of published material – Plagiarism - Citation and acknowledgement - Reproducibility and accountability.

Course Outcomes: Students will be able:

- CO1: Understand some basic concepts of research and its methodologies
- CO2: Define and apply appropriate parameters and research problems
- CO3: Develop skills to draft a research paper
- CO4: Utilize statistical tools and techniques for analysing pharmaceutical data
- CO5: Develop scientific writing skill of comprehensive reports and thesis writing.
- CO6: Analyse and comprehend the ethical practices in conducting research and dissemination of results in different forms

Suggested Readings/Recommended Books (Latest Editions)

1. Geoffrey R. Norman, David L. Streiner, Biostatistics: The Bare Essentials, PMPH USA
2. Beth Dawson, Robert G. Trapp, Basic & Clinical Biostatistics, McGraw-Hill
3. Marcello Pagano, Kimberlee Gauvreau, Principles of Biostatistics, CRC Press
4. Antonella Bacchieri, Giovanni Della Cioppa, Fundamentals of Clinical Research, Springer
5. Katsumi Kobayashi, K. Sadasivan Pillai, A Handbook of Applied Statistics in Pharmacology, CRC Press
6. Garg, B.L., Karadia, R., Agarwal, F. and Agarwal, U.K. An introduction to Research Methodology, RBSA Publishers.
7. Kothari, C.R. Research Methodology: Methods and Techniques. New Age International.
8. Sinha, S.C. and Dhiman, A.K. Research Methodology, Ess Ess Publications.
9. Trochim, W.M.K. Research Methods: the concise knowledge base, Atomic Dog Publishing.
10. Wadehra, B.L. Law relating to patents, trademarks, copyright designs and geographical indications. Universal Law Publishing.

Additional Reading

1. Anthony, M., Graziano, A.M. and Raulin, M.L. Research Methods: A Process of Inquiry, Allyn and Bacon.
2. Carlos, C.M. Intellectual property rights, the WTO and developing countries: the TRIPS agreement and policy options. Zed Books, New York.
3. Coley, S.M. and Scheinberg, C. A. Proposal Writing, Sage Publications.
4. Day, R.A. How to Write and Publish a Scientific Paper, Cambridge University Press.
5. Fink, A. Conducting Research Literature Reviews: From the Internet to Paper. Sage Publications.
6. Leedy, P.D. and Ormrod, J.E. Practical Research: Planning and Design, Prentice Hall.
7. Satarkar, S.V. Intellectual property rights and Copyright. Ess Ess Publications.

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
PHP-102-25	Research & Publication Ethics (Common to all branches)	2	-	-	20	30	1.5	3	4

Module 01 **05 Hrs**

Philosophy and Ethics

Introduction to philosophy: definition, nature and scope, concept, branches; Ethics: definition, moral philosophy, nature of moral judgments and reactions

Scientific Conduct

Ethics with respect to science and research, Intellectual honest and research integrity, Scientific misconducts: Falsification, Fabrication and Plagiarism (FFP), Redundant publication: duplicate and overlapping publications, salami slicing, Selective reporting and misrepresentation of data

Module 02 **05 Hrs**

Publication Ethics

Publications ethics: definition, introduction and importance, Best practices/standard setting initiative and guideline: COPE, WAME, etc., Conflicts of interest, Publication misconduct: definition, concepts, problems that lead to unethical behaviours and vice versa, types, Violation of publication ethics, authorship and contributor ship, Identification of publication misconduct, complaints and appeals, Predatory publisher and journals

Module 03 **05 Hrs**

Open Access Publishing

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

Publication Misconduct

Subject specific ethical issues, FFP, authorship, Conflicts of interest, Complaints and appeals: examples and fraud from India and abroad

Module 04 **05 Hrs**

Software Tools

Use of plagiarism software like Turnitin, Urkund and other open-source software tools

Databases and Research Metrics

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

Research Metric

Impact Factor of journal as per Journal Citation Report, SNIP, SJR, IPP, Cite Score, Metrics: h-Index, g index, i10 index, altmetrics

Course Outcomes: Students will be able to:

- CO1: Understand value of publication and knowledge of Journal, Magazine etc.
- CO2: Be aware about the publication ethics and publication misconducts
- CO3: Understand the philosophy of science and ethics and research integrity
- CO4: Develop hands-on skills to identify research misconduct and predatory publications.
- CO5: Differentiate indexing and citation databases, open access publication and research metrics
- CO6: Use plagiarism tools

Suggested Readings/Recommended Books (Latest Editions)

1. C. Neal Stewart Jr., Research Ethics for Scientists: A Companion for Students, Wiley.
2. Loue, Sana, Textbook of Research Ethics, Springer.
3. Julie Scott-Jones, Research Ethics in Practice, Sage.
4. Ana Smith Iltis, Research Ethics, Taylor & Francis.

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
PHP-201-25	Pharmaceutics	3	1	-	40	60	1.5	3	4

Pre-formulation Studies **07 Hrs**
Introduction, pre-formulation testing criteria, regulatory requirements, testing systems, solid-state characterization, transport across biological membranes

Polymers **05 Hrs**
Polymer classification, physiochemical properties and polymer solutions, biodegradable and non-biodegradable polymers, application of polymers in controlled release of drugs, transport of small molecules in polymers, ionic polymers as drug carriers, polymer drug interactions

Controlled Drug Delivery **07 Hrs**
Introduction, basic concept, rationale of SR/CR drug delivery, physicochemical and biological factors influencing design and performance of CR products, therapeutic status of CDDS, targeting through nano-particles, monoclonal antibodies, vitreous body, colon targeting, lung targeting

Pharmaceutical Process Validation **08 Hrs**
Basic concept, regulatory basis of validation, benefits of validation, types of process validation related to prospective retrospective and concurrent process validation, re-validation of validation process and scale-up and post approval changes (SUPAC), analytical Validation

Optimization **05 Hrs**
Introduction to statistical methods and factorial design, quality by design

Bioequivalence Studies **07 Hrs**
Basic pharmacokinetic concepts, *in vitro* and *in vivo* methods in establishment of bioequivalence

Pharmaceutical Packaging **08 Hrs**
Introduction, quality control, paper and board-based packaging materials and their use in pack security systems, sterile products, closures and closure systems, sterile product and the role of rubber components, blister strip, child resistant, sachet packaging, present and future trends

Course Outcomes: Students will be able to:

- CO1: Understand concept of pre-formulation studies for development of various dosage forms.

- CO2: Study polymer classification, physiochemical properties and application of polymers in Dosage form design.
- CO3: Develop concept, rationale of SR/CR drug delivery, physicochemical and biological factors influencing design and performance.
- CO4: Study validation and optimization techniques
- CO5: Study packaging material

Suggested Reading/Reference Books (Latest Edition)

1. J.R. Robinson & V.H.L. Lee (Eds), Controlled Drug Delivery, Fundament and applications, Vol. 29&Vol. 31, Marcel Dekker, N.Y.
2. Y.W. Chien (Ed.), Transdermal Controlled Systemic Medications, Marcel Dekker, N.Y.
3. N.K. Jain, Controlled and novel drug delivery, CBs, New Delhi.
4. N.K. Jain, Advances in Controlled and novel drug delivery, CBS, New Delhi.
5. J.I. Wells, Pharmaceutical Preformulation: The Physicochemical Properties of Drug Substances, Ellis Horwood, Chiechester (UK)
6. S.P.Vyas and R.K.Khar, Controlled Drug Delivery, concept and advances
7. J.G. Wagner, Pharmacokinetics for the Pharmaceutical Scientist, Technomic, Pa
8. L. Shargel, and A. Yu, Applied Biopharmaceutics and Pharmacokinetics, Appleton and Large, Norwalk, CT.
9. M. Gibaldi and D. Perrier, Pharmacokinetics, J. Swarbrick, ed., Marcel Dekker, N.Y.

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
PHP-202-25	Pharmaceutical Chemistry	3	1	-	40	60	1.5	3	4

Stereochemistry **10 Hrs**

Optical isomerisim: chirality and molecular symmetry; stereochemical designation of chiral centre(s) (*R*& *S*); chiral axis; resolution of racemic mixture-techniques including chiral chromatography, geometric Isomerisim: *cis*, *trans*; *E, Z, conformational* analysis: boat-chair conformations; staggered, gauche, eclipsed conformations

Fundamentals of Medicinal Chemistry **05 Hrs**

Basics of drug action: covalent, ionic, ion-diople, hydrogen bonding, vander waals interactions, bio-isosterism, drug receptor interaction, constitution of cell membrane

Drug Design **12 Hrs**

Analogue synthesis versus rational drug design, discovery of lead compounds, pharmacophore identification, structure modifications of lead compound (prototype), physicochemical alterations, pro-drug approach, quantitative structure activity relationship, computer aided drug design, molecular modelling, combinatorial chemistry and high throughput screening

Natural Products **14 Hrs**

Drugs of natural origin: from plants, micro-organisms, animal source, marine products, biosynthesis of natural products, approaches of structure elucidation: degradation and synthetic approaches; spectral analysis (UV, IR, NMR, Mass), hyphenated techniques: GC-MS, LC-MS, chemical modifications of natural products; opiod analgesics, anti-neoplastic agents, anti-malarials

Techniques of Quantitative Estimation of Drugs for Determination of Purity **06 Hrs**

Course Outcomes: Students will be able to:

- CO1: Study of Stereochemistry
- CO2: Fundamental study of covalent, ionic, ion-dipole, hydrogen bonding, Vander Waals interactions, bioisosterism, drug receptor interaction, constitution of cell membrane
- CO3: Understanding of analogue synthesis versus rational drug design, discovery of lead compounds, pharmacophore identification, structure modifications of lead compound
- CO4: Spectral analysis (UV, IR, NMR, Mass), hyphenated techniques: GC-MS, LC-MS, chemical modifications of natural products

- CO5: Study of techniques of Quantitative Estimation of Drugs for Determination of Purity

Suggested Reading/Reference Books (Latest Edition)

1. Ernest EI and Samuel H. Stereochemistry of Organic Compounds. John Wiley and Sons, New York.
2. Lehr RE and Marchand AP. Orbital Symmetry: A Problem-Solving Approach. Academic Press, New York.
3. March J. Advanced Organic Chemistry: Reactions, Mechanisms and Structures. John Wiley and Sons, New York.
4. Lehr RE and Marchand AP. Orbital Symmetry: A problem-solving approach. Academic Press, New York.
5. Mitscher LA and Baker WR. Wiley and Sons
6. A Search for Novel Chemotherapy Against Tuberculosis Amongst Natural Products. Pure and Applied Chemistry (1998), Vol. 70, No.2, pp 365-371.
7. Wermuth CG. The Practice of Medicinal Chemistry. Academic Press, Jordon Hill, Oxford.

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
PHP-203-25	Pharmacology	3	1	-	40	60	1.5	3	4

Molecular Aspects of Drug Action **07 Hrs**
Receptor occupancy, types of drug targets, main families of receptors and ion channels, signal transduction mechanisms coupling receptors to cellular function

Cellular Mechanisms of Drug Action **08 Hrs**
Short-term regulation of cellular function (excitation, contraction and secretion), slower mechanisms of cell response (cell proliferation, apoptosis) and their pathophysiological significance

Inflammation and Immune Reactions **04 Hrs**
Acute inflammatory reaction, mediators of inflammation and immune response, therapies based on manipulation of immune response

Antioxidants **02 Hrs**
Reactive oxygen intermediates, antioxidants and their therapeutic implications

Toxicity Studies **06 Hrs**
Acute, sub-acute, sub-chronic, chronic toxicity

Advances in Transgenic Animals **02 Hrs**
Regulatory Guidelines **06 Hrs**
Guidelines for maintenance and experimentation using laboratory animals **(**CPCSEA, OECD, ICH, ICMR, Schedule Y)

***In-vitro* Experimentation Techniques** **06 Hrs**
Animal cell lines and their uses, radioligand binding assay, patch clamp, ELISA

Molecular Techniques **06 Hrs**
PCR, blotting, immunostaining, cloning, RIA

Course Outcomes: Students will be able to:

- CO1: Understand basics of receptor occupancy, types of drug targets, main families of receptors and ion channels
- CO2: Understand cellular mechanisms of drug action, acute inflammatory reaction, mediators of inflammation and immune response
- CO3: Knowledge of antioxidants and toxicity
- CO4: Study guidelines for maintenance and experimentation using laboratory animal

- CO5: Understanding techniques PCR, blotting, immunostaining, cloning, RIA

Suggested Reading/Reference Books (Latest Edition)

1. BG Katzung AJ Trevor, Basic and Clinical Pharmacology, Mc Graw-Hill.
2. HP Rang, MM Dale, JM Ritter, RJ Flower, G Henderson, Rang & Dale's Pharmacology, Elsevier.
3. PN Bennett, MJ Brown and P Sharma, Clinical Pharmacology, Churchill Livingstone Elsevier.
4. KD Tripathi, Essentials of Medical Pharmacology, Jay Pee Medical.

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
PHP-204-25	Pharmacognosy	3	1	-	40	60	1.5	3	4

Organoleptic Evaluation of Plant Drugs **08 Hrs**
Gross morphology, detection of foreign matter, quantitative microscopy: vein islet number, vein termination number, stomatal number, stomatal index, palisade ratio, micrometry: measurement of fibers, trichomes, starch grains, calcium oxalate crystals, lycopodium spore analysis, fluorescence analysis, determination of moisture content, ash values, extractive values, swelling index, refractive index, optical rotation

Primary and Secondary Plant Metabolites **05 Hrs**
Classification of secondary metabolites (e.g. alkaloids, glycosides, terpenoids, saponins, flavonoids, coumarins, phenolics, etc.), biogenetic theories

Extraction Techniques **04 Hrs**
Maceration, percolation, sonication, soxhlet assisted extraction, ultrasound assisted extraction, super critical fluid extraction, microwave assisted extraction, enzyme assisted extraction

Isolation of Plant Constituents **10 Hrs**
Column Chromatography (adsorbents, eleutropic series of solvents), paper chromatography, TLC, HPLC, HPTLC, GLC, preparative chromatography

Phytoconstituent Characterization **10 Hrs**
Basic concepts of spectroscopy (UV, IR, NMR and Mass), interpretation of spectral data

Cultivation of Medicinal Plants and Harvesting **01 Hrs**

WHO Guidelines for Assessment of Crude Drugs **02 Hrs**
Evaluation of identity, purity, quality of crude drugs, determination of pesticide residue, determination of microorganisms, aflotoxins, determination of arsenic and heavy metals (Hg, Pb, Cd)

Herbal Drug Standardization **06 Hrs**
Phytochemical reference standards (PRS), botanical reference standards (BRS), TLC fingerprint profile along with PRS, quantitative estination of biomarker by HPTLC or GC, GC-MS, LC-MS

Nutraceuticals **01 Hrs**

Course Outcomes: Students will be able to:

- CO1: Study organoleptic evaluation of plant drugs
- CO2: Classification of secondary metabolites & biogenetic theories
- CO3: Understanding and application of extraction and isolation techniques

- CO4: Basic concepts of spectroscopy (UV, IR, NMR and Mass)
- CO5: Knowledge of herbal drug standardization and WHO guidelines for assessment of crude drugs

Suggested Reading/Reference Books (Latest Edition)

1. W.C.Evans, Trease and Evans Pharmacognosy, 15th edition, W.B. Sounders & Co., London.
2. Egon Stahl, Thin Layer chromatography -A laboratory handbook, Springer-Verlag, Berlin.
3. M.J. Cupp, Toxicology and Clinical Pharmacology of Herbal Products, Humana Press New-Jersy.

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
PHP-205-25	Modern Pharmaceutical Analytical Techniques	3	1	-	40	60	1.5	3	4

Spectral Techniques **10 Hrs**
Spectral interpretation of FTIR, ^{1}H-NMR, ^{13}C-NMR and Mass fragmentation and its rules of organic molecules of different classes

Chromatographic Techniques **08 Hrs**
Applications and data interpretation of thin layer chromatography, ion exchange chromatography, column chromatography, high performance liquid chromatography, ultra-high performance liquid chromatography, flash chromatography, gas chromatography, affinity chromatography, gel chromatography, and electrophoresis

Hyphenated Techniques **10 Hrs**
Principle, instrumentation, and applications of the following techniques: LC-MS/MS, GC-MS, MS-MS, LC-NMR, LC-AAS

X ray Crystallography **05 Hrs**
Production of X rays, Bragg's law, rotating crystal technique, X ray powder technique, types of crystals, interpretation and applications of X-ray diffraction

Thermal Techniques **08 Hrs**
Principle, application and interpretation of thermal analysis curves of Differential Scanning Calorimetry (DSC), Differential Thermal Analysis (DTA), Thermogravimetric analysis (TGA)

Immunological Assays **04 Hrs**
Principle and application of Radio Immunoassay (RIA) and Enzyme Linked Immunosorbent Assay (ELISA)

Course Outcomes: Students will be able to:

- CO1: Understand the basic knowledge on assay of single and multiple component pharmaceuticals by using various analytical instruments.
- CO2: Develop the theoretical knowledge on various instrumental techniques available for analysis of organic substances by using analytical instruments.
- CO3: Improve skills in selecting the suitable techniques for analysis of drugs and pharmaceuticals.
- CO4: Interpret spectra of UV-visible, IR, NMR and Mass to identity the given compound.

- CO5: Describe the general methods for separation and purification of components from a mixture and their application to pharmaceutical industry

Suggested Reading/Reference Books (Latest Edition)

1. Robert M Silverstein, Spectrometric Identification of Organic Compounds, John Wiley & Sons.
2. Doglas A Skoog, F. James Holler, Timothy A. Nieman, Principles of Instrumental Analysis Eastern press, Bangalore.
3. Willards Instrumental methods of analysis, CBS Publishers.
4. Beckett and Stenlake, Practical Pharmaceutical Chemistry, CBS Publishers, New Delhi.
5. William Kemp, Organic Spectroscopy, ELBS.
6. P D Sethi, Quantitative Analysis of Drugs in Pharmaceutical formulation, CBS Publishers, New Delhi.
7. J W Munson, Pharmaceutical Analysis- Modern methods – Part B, Volume 11, Marcel Dekker Series.
8. P.S. Kalsi, Spectroscopy of Organic Compounds, Wiley Eastern Ltd., Delhi.
9. K. A. Connors, Textbook of Pharmaceutical Analysis, John Wiley & Sons.
10. P D Sethi, Quantitative Analysis of Drugs in Pharmaceutical formulation, CBS Publishers, New Delhi.
11. J W Munson, Pharmaceutical Analysis- Modern Methods, Marcel Dekker Series.

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
PHP-206-25	Intellectual Property Rights	3	1	-	40	60	1.5	3	4

Definition, need for patenting, types of patents, conditions to be satisfied by an invention to be patentable, introduction to patent search. **10 Hrs**

Parts of patents, filling of patents, the essential elements of patent, guidelines for preparation of laboratory note book, non-obviousness in patent **10 Hrs**

Role of GATT, TRIPS, and WIPO **05 Hrs**

Brief introduction to trademark protection and WHO Patents, IPR's and its types, major bodies regulating Indian pharmaceutical sector **07 Hrs**

Brief introduction to CDSCO, WHO, USFDA, EMEA, TGA, MHRA, MCC, ANVISA **08 Hrs**

Regulatory requirements for contract research organization, regulations for biosimilar **07 Hrs**

Course Outcomes: Students will be able to:

- CO1: Study different types of Intellectual Properties (IPs), the right of ownership, scope of protection as well as the ways to create and to extract value from IP
- CO2: Identify activities and constitute IP infringements and the remedies available to the IP owner and describe
- CO3: Understanding of Intellectual Property Management (IPM) and various approaches for IPM and conducting IP and IPM auditing and explain
- CO4: Identify, apply and assess ownership rights and marketing protection under intellectual property law
- CO5: Application of IPR

Suggested Reading/Reference Books (Latest Edition)

1. Ira R. Berry and Robert A. Nash, Pharmaceutical Process Validation, CRC Press
2. Willing S.H. Marcel and Dekker, GMP for pharmaceuticals, Marcel Dekker Inc
3. Parikshit Bansal, IPR Handbook for Pharma Students and Researchers, BSP Books Private Limited
4. Josef Drexl, Nari Lee, Pharmaceutical Innovation, Competition and Patent Law: A Trilateral Perspective, Edward Elgar

5. Rashmi Aggarwal and Rajinder Kaur, Patent Law and Intellectual Property in the Medical Field, IGI Global
6. Arthur Miller and Michael Davis, Intellectual Property, Patents, Trademarks, and Copyright in a Nutshell (Nutshells), West Academic Publishing

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
PHP-207-25	Pharmacology & Toxicological Screening Methods	3	1	-	40	60	1.5	3	4

Laboratory Animals **07 Hrs**

Common lab animals: description, handling and applications of different species and strains of animals; transgenic animals: production, maintenance and applications; anaesthesia and euthanasia of experimental animals; maintenance and breeding of laboratory animals; CPCSEA guidelines to conduct experiments on animals; good laboratory practice

Preclinical Screening of New Substances for the Pharmacological Activity **22 Hrs**

General principles of preclinical screening; CNS pharmacology: behavioural and muscle coordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti-epileptics and nootropics; drugs for neurodegenerative diseases like parkinsonism, alzheimers and multiple sclerosis; drugs acting on autonomic nervous system; respiratory pharmacology: anti-asthmatics, drugs for COPD and anti-allergic; reproductive pharmacology: aphrodisiacs and anti-fertility agents; analgesics, anti-inflammatory and antipyretic agents; gastrointestinal drugs: anti-ulcer, anti-emetic, anti-diarrheal and laxatives; cardiovascular pharmacology: anti-hypertensives, anti-arrythmics, anti-anginal, anti-atherosclerotic agents and diuretics; drugs for metabolic disorders like anti-diabetic, anti-hyperlipidemic, and agents; anti-cancer agents; immunosuppressants and immunomodulators

Limitations of Animal Experimentation and Alternate Animal Experiments **04 Hrs**

Extrapolation of in vitro Data to Preclinical and Preclinical to Humans **02 Hrs**

Regulatory Guidelines for Conducting Toxicity Studies **12 Hrs**

OECD, ICH, EPA, Schedule Y, OECD principles of Good laboratory practice (GLP)

Course Outcomes: Students will be able to:

- CO1: Description, handling and applications of different species and strains of animals
- CO2: Study of General principles of preclinical screening; CNS pharmacology.
- CO3: Knowledge of limitations of Animal Experimentation and Alternate animal Experiments
- CO4: Study of regulatory Guidelines for Conducting Toxicity Studies)
- CO5: Understanding of OECD, ICH, EPA, Schedule Y, OECD principles of Good laboratory practice (GLP).

Suggested Reading/Reference Books (Latest Edition)

1. J.H. Burn D.J. Finney and I.G. Goodwin, Biological standardization, Oxford University Press, New York
2. Robert A. Turner, Screening methods in Pharmacology, Academic Press
3. Laurence and Bachrach, Evaluation of Drugs Activities: Pharmacometrics, Academic Press
4. Arnold Schwartz, Methods in Pharmacology, Springer
5. M. N. Ghosh, Fundamentals of experimental Pharmacology, Hilton Company
6. L. J. McLeod, Pharmacological experiment on intact preparations, Churchill Livingstone
7. Vogel H.G., Drug discovery and Evaluation by, Springer
8. Hand book on GLP, Quality practices for regulated non-clinical research and development (http://www.who.int/tdr/publications/documents/glp-handbook.pdf)
9. Schedule Y Guideline: drugs and cosmetics (second amendment) rules, 2005, ministry of health and family welfare (department of health) New Delhi
10. Rick N.G., Drugs from discovery to approval by, Wiley-Blackwell.
11. Shayne C. Gad, Animal Models in Toxicology, CRC Press
12. OECD test guidelines.
13. Karen E. Stine, Thomas M. Brown, Principles of toxicology by, CRC Press
14. Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf)

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
PHP-208-25	Biochemical & Separation Techniques	3	1	-	40	60	1.5	3	4

Chromatography **12Hrs**
Introduction, Principles, Types- paper, two dimensional, HPLC, Ion exchange chromatography, Uses, Advantages and Limitations

Spectroscopy **12 Hrs**
UV/Visible spectroscopy, spectrophotofluorimeter, scope, basic principle and uses in biotechnology of different types of spectrometry (NMR, Magnetic resonance spectroscopy)

Radioisotopy **05 Hrs**
Use of radioisotope, detection and measurement of radioactivity, specific activity, applications in biological system, autoradiography

Microscopy **06 Hrs**
Brief introduction, types of microscopes and role in microbiology, structure and function of microscopes (compound microscope, dissecting microscope, phase contrast microscope, scanning electron microscopy)

Filtration **02 Hrs**
Theory and application

Centrifugation **02 Hrs**
Theory and application

Electrophoresis **02 Hrs**
Different methods for proteins and nucleic acids

Molecular Diagnostic Techniques **06 Hrs**
PCR, southern, nothern, western blotting, microarray

Course Outcomes: Students will be able to:

- CO1: Understand various techniques of chromatography and application.
- CO2: Study of spectroscopy and radioisotrpy techniques.
- CO3: Understanding of filtration and centrifugation.
- CO4: Knowledge of different methods for proteins and nucleic acids
- CO5: Understanding of PCR, southern, northern, western blotting, microarray

Suggested Reading/Reference Books (Latest Edition)

1. Keith Wilson and John Walker, Principles and Techniques of Biochemistry and Molecular Biology, Cambridge University Press
2. P.C. van der Vliet and S. Pillai, Laboratory Techniques in Biochemistry and Molecular Biology, Elsevier

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
PHP-209-25	Bioprocess Technology	3	1	-	40	60	1.5	3	4

Microbial Growth Kinetics **10Hrs**
Batch culture, continuous culture, fed-batch culture, biomass productivity, metabolite productivity, kinetics of microbial growth

Enzymes **07 Hrs**
Classification, uses, methods for immobilization

Fermentation **10 Hrs**
Raw materials used as media for industrial fermentations, development of inocula for industrial fermentations, isolation and preservation of industrially important microorganisms

Design of a Fermenter **10 Hrs**
Aseptic operation and containment, construction materials, temperature control, aeration and agitation, sterilization of the fermenter, air supply and exhaust gas from a fermenter

Recovery and Purification of Fermentation Products **10 Hrs**
Centrifugation, cell disruption, chromatography, ultra-filtration, drying

Course Outcomes: Students will be able to:

- CO1: Understand of microbial growth kinetics.
- CO2: Classification, uses, methods for immobilization.
- CO3: Study of industrial fermentations, isolation and preservation of industrially important microorganisms.
- CO4: Knowledge of Plant Transformation for Productivity and Performance
- CO5: Understanding of centrifugation, cell disruption, chromatography, ultra-filtration, drying

Suggested Reading/Reference Books (Latest Edition)

1. Stanbury, Whitaker & Hall, Principles of fermentation technology, Butterworth Heinemann
2. Shuler M. L. and Kargi F, Bioprocess Engineering,Pearson
3. Pelczar, Chan & Krieg, Microbiology, McGraw-Hill Inc., US
4. Prescott, Harley & Klein, Microbiology, McGraw Hill Education
5. Nduka Okafor, Modern Industrial Microbiology & Biotechnology, CRC Press

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
PHP-210-25	Recombinant Biotechnology	3	1	-	40	60	1.5	3	4

Tools of Genetic Engineering **10Hrs**

Cloning vehicles, modifying enzymes, DNA ligase, DNA polymerase, polynucleotide kinase, T4 DNA ligase, nick translation system, terminal deoxynucleotidy1 transferase, reverse transcriptase, restriction endonucleases Type I & II. etc.

Cloning Vectors **04 Hrs**

Plasmids, lambda phage, phagemids, cosmids, artificial chromosomes, yeast vectors, shuttle vectors, virus-based vectors

Methods of Gene Transfer **05 Hrs**

Transformation, transduction, particle gun, electroporation, liposome mediated, microinjection, Agrobacterium mediated gene transfer

Preparation and Application of Molecular Probes **06 Hrs**

DNA probes, RNA probes, radioactive labelling, non-radioactive labelling, use of molecular probes, DNA fingerprinting

Analysis and Expression of Cloned Gene in Host Cells **10 Hrs**

Expression vectors, restriction enzyme analysis, southern blotting, northern blotting, western blotting, in-*situ* hybridization, colony and plaque hybridization, factors affecting expression of cloned genes, reporter genes, fusion proteins

Gene Libraries **04 Hrs**

cDNA synthesis, genomic DNA libraries, amplification of gene libraries, identifying the products of cDNA clones

Isolation, Sequencing and Synthesis of Gene **04 Hrs**

Different methods of gene isolation, techniques of DNA sequencing, artificial DNA synthesis

Applications of r-DNA Technology **04 Hrs**

Gene cloning in medicine (Insulin, Blood clotting factor VIII), high level expression of proteins in different host systems (*E. coli*, yeast, Insect, mammalian cells), limitation and advantages and novel technologies generation of transgenic animals, applications of PCR (DNA finger printing)

Course Outcomes: Students will be able to:

- CO1: Study basic concept of Biotechnology
- CO2: Understanding the importance of immobilized enzymes in pharmaceutical industries and knowledge of fermentation methods.

- CO3: Understanding about genetic engineering and its applications in pharmaceutical production.
- CO4: Knowledge about human immunity, blotting techniques, monoclonal bodies and immunization products.
- CO5: Understanding of various technique and knowledge about genetic organization of eukaryotes, prokaryotes and Microbial genetics'

Suggested Reading/Reference Books (Latest Edition)

1. R.W. Old and S.B. Primrose, Principles of Gene Manipulation, Blackwell Scientific Publication
2. B. Lewin Genes VIII, Benjamin Cummings; United States
3. E. L. Winnecker, From Genes to Clones, Vch Pub
4. T.A. Brown, Gene Cloning, Wiley
5. Glick B., Pasternak J., Molecular Biotechnology: Principles and Applications of Recombinant DNA, ASM Press.

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
PHP-211-25	Plant Tissue Culture	3	1	-	40	60	1.5	3	4

Introduction to Cell and Tissue Culture **06 Hrs**

Conventional plant breeding, tissue culture as technique to produce novel plants and hybrids, tissue culture media (composition and preparation), initiation and maintenance of callus and suspension cultures, single cell clones

Organogenesis: Somatic Embryogenesis **06 Hrs**

Transfer and establishment of whole plants in soil, shoot tip culture, rapid clonal propagation, embryo culture and embryo rescue

Protoplast **08 Hrs**

Isolation, culture and fusion, selection of hybrid cell and regeneration of hybrid plants, symmetric and asymmetric hybrids, cybrids, cryopreservation, slow growth and DNA banking for germplasm conservation

Plant Transformation Technology **06 Hrs**

Basis of tumor formation, hairy root, features of TI and RI plasmids, mechanism of DNA transfer, role of virulence genes, use of TI and RI as vectors, binary vectors, genetic markers, use of reporter genes, reporter gene with intron, methods of nuclear transformation, viral vectors and their application, multiple gene transfer, vectorless or direct DNA transfer (particle bombardment, elctroporation, microinjection), transformation of monocots, transgene stability and gene silencing

Application of Plant Transformation for Productivity and Performance **07 Hrs**

Herbicide resistance (phosphoinothricin, glyphosphate, sulfonyl urea, atrazine), insect resitance (Bt genes, non-Bt like protease inhibitors, alpha amylase inhibitor), virus resistance (coat protein mediated, nucleocapsid gene),disease resistance (chitinase, 1-3 beta glucanase, RIP, antifungal proteins, thionins,PR proteins), nematode resistance, abiotic stress, post-harvest losses, use of ACC synthase (polygalactrouranase, ACC oxidase), male sterile lines, bar and barnase systems, carbohydrate composition and storage, ADP glucose pyrophosphatase, biosafety and ethical issues associated with transgenic plants

Chloroplast Transformation **04 Hrs**

Advantages, vectors, success with tobacoo and potato

Metabolic Engineering and Industrial Products **06 Hrs**

Plant secondary metabolites, role of bioreactors for scaling up, biotransformation, biodegradable plastics, polyhydroxybutyrate

Molecular Pharming in Plants **04 Hrs**

Production of therapeutic proteins, edible vaccines antibodies, purification strategies

Course Outcomes: Students will be able to:

CO1: Understand of basic concept of Cell and Tissue Culture.

CO2: Study of Organogenesis: Somatic Embryogenesis and Protoplast.

CO3: Study of tumour formation, hairy root, features of TI and RI plasmids, mechanism of DNA transfer

CO4: Knowledge of fermenter and applications.

CO5: Understanding of Chloroplast Transformation and Molecular Pharming in Plants

Suggested Reading/Reference Books (Latest Edition)

1. H.S Chawla, Biotechnology in Crop Improvement, CRC Press
2. J. Hammond, R. McGravey and V. Yusibov, Plant Biotechnology, Springer
3. P.K Gupta, Elements of Biotechnology, Rastogi Publications
4. R.J Henry, Practical application of Plant Molecular Biology, CRC Press