Pt. Ravishankar Shukla University,
Raipur (C.G.), India 492010

CURRICULUM & Syllabus
(Based on CBCS & LOCF)

M. Pharm.- Pharmaceutical Biotechnology
(Semester System)

Semester: I-IV

Session: 2025-2027

टीपः– सत्र. 2024-2025 के पाठ्यक्रम को सत्र 2025-2026 के लिए यथावत प्रभावशील किया जाता है।

Approved by	:	
Board of Studies	:	Pharmacy
Dates	:	16-05-2025
Name of Chairman	:	Dr. S. J. Daharwal
Name of Member's	:	Dr. Preeti K. Suresh
		Dr. Manju Singh
		Dr. Amber Vyas
		Dr. Deependra Singh

M. Pharm in Pharmaceutical Biotechnology

Program Outcomes (POs)

PO-1: Knowledge
Gain deep knowledge in genetic engineering, bioprocessing, recombinant DNA technology, monoclonal antibody production, vaccines, and biopharmaceutical product development.

PO-2: Critical Thinking and Reasoning
Develop scientific reasoning and analytical thinking to design and evaluate biotechnological solutions for healthcare challenges.

PO-3: Problem Solving
Address complex issues in the development, expression, purification, and characterization of recombinant proteins and biotech-based drugs.

PO-4: Advanced Analytical and Computational Skills
Apply biotechnological tools and techniques such as PCR, ELISA, electrophoresis, cell culture, and bioinformatics for research and product development.

PO-5: Effective Communication
Communicate effectively in academic, industrial, and regulatory settings regarding biotechnological processes, biosafety, and biopharmaceutical research.

PO-6: Social/Interdisciplinary Interaction
Collaborate across disciplines such as microbiology, molecular biology, and immunology to develop innovative biotech-based pharmaceutical solutions.

PO-7: Self-directed and Life-long Learning
Foster a lifelong learning attitude to stay abreast with developments in biotechnology, genomics, proteomics, and emerging therapeutic platforms.

PO-8: Effective Citizenship: Leadership and Innovation
Lead and innovate in biopharmaceutical product development with focus on scalable production, cost-effectiveness, and global health impact.

PO-9: Ethics
Adhere to ethical standards in research involving genetic material, human subjects, and biosafety compliance, respecting bioethics and intellectual property rights.

PO-10: Further Education or Employment
Pursue doctoral research or take up roles in biotech industries, vaccine production units, R&D labs, and regulatory agencies.

PO-11: Global Perspective
Understand the global regulatory framework for biotech products (FDA, EMA, CDSCO), and the international trends in biosimilar and biologic drug development.

Program Specific Outcomes (PSOs)

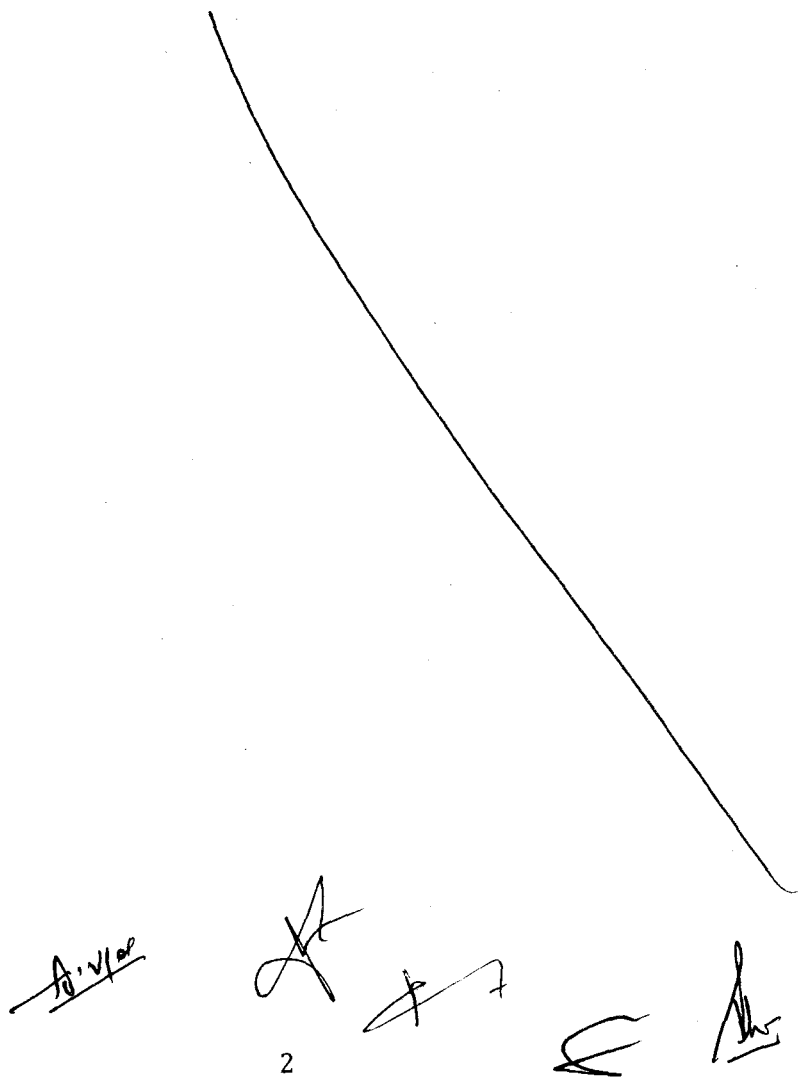
PSO-1: Biotechnological Process Mastery
Demonstrate proficiency in microbial and mammalian cell culture, fermentation technology, and downstream processing for biopharmaceutical production.

PSO-2: Genetic Engineering and Molecular Biology
Apply molecular biology techniques for cloning, gene expression, and recombinant protein production.

PSO-3: Biopharmaceutical Formulation and Analysis
Design, develop, and analyze stable, effective biopharmaceutical dosage forms such as vaccines, monoclonal antibodies, and therapeutic proteins.

PSO-4: Regulatory and Quality Systems
Understand and implement GMP, biosafety, and regulatory guidelines related to biopharmaceuticals and biotechnological research.

PSO-5: Translational Research and Industry Interface
Translate lab-scale biotech innovations into industrial applications through collaborations and technology transfers, ensuring clinical and commercial viability.



M. Pharm. Pharmaceutical Biotechnology

Semester-I

Program	Subject	Year	Semester
M. Pharm.	Pharmaceutical Biotechnology	I	I
Course Code	Course Title		Course Type
MPB 101T	MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES		Core
Credit	Hours Per Week (L-T-P)		
	L	T	P
4	4	–	--

Maximum Marks	CIA	ESE
100	25	75

Learning Objective (LO):

After completion of course student is able to know about,

- Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

Course Outcomes (CO):

CO No.	Expected Course Outcomes At the end of the course, the students will be able to :	CL
1	Understand the significance of pharmacognosy in the herbal drug industry and explain the principles and practices of cultivation, collection, and conservation of medicinal plants, including regulatory and ethical guidelines.	Ap
2	Describe the techniques for isolation and purification of marine natural products, identify marine toxins, discuss recent advances, and analyze challenges and solutions in marine drug research.	Ap
3	Explain the classification, formulation, standardization, and regulatory guidelines of nutraceuticals; and evaluate the sources, chemical nature, and health benefits of commonly used nutraceutical ingredients.	U
4	Identify and classify important phytopharmaceuticals based on chemical nature, explain their isolation, and evaluate their pharmacological and health-related applications.	An
5	Understand and apply WHO and AYUSH guidelines for safety monitoring of natural medicines, and analyze biodrug interactions and reporting systems with appropriate examples.	U

CL: Cognitive Levels (**R**-Remember; **U**-Understanding; **Ap**-Apply; **An**-Analyze; **E**-Evaluate; **C**-Create).

CO-PO/PSO Mapping for the course:

PO / CO	POs											PSO				
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	3	2	3	1	2	3	3	2	3	2	2	3	1	2	3	2
CO2	3	3	3	3	1	1	3	1	2	3	2	2	3	2	1	2
CO3	3	3	2	3	2	2	2	2	2	3	3	3	3	2	2	3
CO4	3	2	3	3	2	1	3	2	2	3	2	3	3	3	2	2
CO5	3	3	2	1	3	2	3	1	3	2	3	2	2	2	2	3

"3" – Strong; "2" – Moderate; "1"- Low; "-" No Correlation

Detailed Syllabus:

Unit No.	Topics	No. of Lectures	CO No.
I	a) **UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. b) **IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy. c) **Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. d) Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.	10hrs	1
II	**NMR spectroscopy**: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.	10hrs	2
III	**Mass Spectroscopy**: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.	10hrs	3
IV	**Chromatography**: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: a. Thin Layer chromatography b. Thin Layer Chromatography c. Ion exchange chromatography d. Column chromatography e. Gas chromatography f. High Performance Liquid chromatography g. Affinity chromatography	10hrs	4
V	a. **Electrophoresis**: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone	10hrs	

	electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing b. **X ray Crystallography**: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction **Immunological assays :** RIA (Radio immuno assay), ELISA,Bioluminescence assays		
VI	**Potentiometry:** Principle, working, Ion selective Electrodes and Application of potentiometry. **Thermal Techniques**: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.	10hrs	

Books Recommended:

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

Semester-I

Program	Subject	Year	Semester
M. Pharm.	Pharmaceutical Biotechnology	1	I
Course Code	Course Title		Course Type
MPB 102T	**MICROBIAL AND CELLULAR BIOLOGY**		Core
Credit	Hours Per Week (L-T-P)		
	L	T	P
4	4	--	--

Maximum Marks	CIA	ESE
100	25	75

Learning Objective (LO):
This subject is designed to provide the advanced knowledge to the biotechnology students in invaluable areas of advanced microbiology which plays a crucial role in determining its future use and applications in medicine, drug discovery and in pharmaceutical industry.

Course Outcomes (CO):

CO No.	Expected Course Outcomes At the end of the course, the students will be able to :	CL
1	Understand the structural and functional characteristics of microorganisms, their classification, cultivation, and industrial relevance.	Ap
2	Explain the molecular mechanisms of gene expression, regulation, and mutagenesis including techniques such as gene mapping and phage genetics.	Ap
3	Describe cell structure, signalling, apoptosis, developmental biology, and the roles of cytoskeleton and oncogenes in cell function.	U
4	Demonstrate knowledge of microbial and animal cell culture techniques and their pharmaceutical applications, including in-vitro screening methods.	An
5	Identify and explain the mechanisms of microbial pathogenicity and antimicrobial action, along with current therapies for infections.	U

CL: Cognitive Levels (**R**-Remember; **U**-Understanding; **Ap**-Apply; **An**-Analyze; **E**-Evaluate; **C**-Create).

CO-PO/PSO Mapping for the course:

PO / CO	POs											PSO				
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	3	2	3	1	2	3	3	2	3	2	2	3	1	2	3	2
CO2	3	3	3	3	1	1	3	1	2	3	2	2	3	2	1	2
CO3	3	3	2	3	2	2	2	2	2	3	3	3	3	2	2	3
CO4	3	2	3	3	2	1	3	2	2	3	2	3	3	3	2	2
CO5	3	3	2	1	3	2	3	1	3	2	3	2	2	2	2	3

"3" – Strong; "2" – Moderate; "1"- Low; "-" No Correlation

Detailed Syllabus:

Unit No.	Topics	No. of Lectures	CO No.
I	**Microbiology:** Introduction – Prokaryotes and Eukaryotes. Bacteria, fungi, actionomycetes and virus - structure, chemistry and morphology, cultural, physiological and reproductive features. Methods of isolation, cultivation and maintenance of pure cultures. Industrially important microorganisms - examples and applications.	12	1
II	**Molecular Biology:** Structure of nucleus and chromosome, Nucleic acids and composition, structure and types of DNA and RNA. Central dogma of molecular biology: Replication, Transcription and translation. **Gene regulation:** Gene copy number, transcriptional control and translational control. **RNA processing** Modification and Maturation, RNA splicing, RNA editing, RNA amplification. Mutagenesis and repair mechanisms, types of mutants, application of mutagenesis in stain improvement, gene mapping of plasmids- types purification and application. Phage genetics, geneticorganization, phage mutation and lysogeny.	12	2
III	**Cell structure and function:** Cell organelles, cytoskeleton & cell movements, basic aspectsof cell regulation, bioenergetics and fuelling reactions of aerobics and anaerobics,secondary metabolism & its applications. Cell communication, cell cycle and apoptosis, mechanism of cell division. Celljunctions/adhesion and extra cellular matrix, germ cells and fertilization, histology – thelife and death of cells in tissues. **Cell Cycle and Cytoskeleton:** Cell Division and its Regulation, G-Protein Coupled Receptors, Kinases, Nuclear receptors, Cytoskeleton & cell movements, Intermediate Filaments. **Apoptosis and Oncogenes:** Programmed Cell Death, Tumor cells, carcinogens & repair. **Differentiation and Developmental Biology:** Fertilization, Events of Fertilization, *In vitro* Fertilization, Embryonic Germ Cells, Stem Cells and its Application.	12	3
IV	**Principles of microbial nutrition:** Physical and chemical environment for microbial growth, Stability and degeneration of microbial cultures. **Growth of animal cells in culture:** General procedure for cell culture, Nutrient composition, Primary, established and transformed cell cultures, applications of cell cultures in pharmaceutical industry and research. Growth of viruses in cell culture propagation and enumeration. *In-vitro* screening techniques- cytotoxicity, anti-tumor, anti-viral assays.	12	4
V	**Microbial pathology:** Identifying the features of pathogenic bacteria, fungi and viruses. Mechanism of microbial pathogenicity, etiology and pathology of common microbial diseases and currently recommended therapies for common bacterial, fungal & viral infections. Mechanism of action of antimicrobial agents and possible sites of chemotherapy.	12	5

Books Recommended:

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn, Industrial Microbiology, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. David Freifelder, Molecular Biology, 2nd edition, Narosa Publishing House.
5. R. Ian Freshney, Culture of animal cells – A manual of Basic techniques, 6th edition, Wileys publication house.
6. David Baltimore,Molecular cell biology, W H Freeman & Co publishers.
7. Cell biology vol-I,II,III by Julio E.Cells
8. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company.

Semester-I

Program	Subject	Year	Semester
M. Pharm.	Pharmaceutical Biotechnology	I	I

Course Code	Course Title	Course Type
MPB 103T	BIOPROCESS ENGINEERING AND TECHNOLOGY	Core

Credit	Hours Per Week (L-T-P)		
	L	T	P
4	4	--	--

Maximum Marks	CIA	ESE
100	25	75

Learning Objective (LO):

It will provide the knowledge to the biotechnology students in invaluable areas of bioprocess technology to develop skills to modify, design and operate different types of fermenters, to understand and implement various fermentation procedures, to train students in scale up fermentation operations.

Course Outcomes (CO):

CO No.	Expected Course Outcomes At the end of the course, the students will be able to :	CL
1	Understand the design, operation, and control of various bioreactors used in industrial fermentation.	Ap
2	Explain the principles of mass transfer, aeration, and rheology relevant to microbial and fermentation processes.	Ap
3	Describe scale-up and immobilization techniques in fermentation, including cultivation systems and enzyme engineering applications.	U
4	Understand scale-down methodologies, downstream processing, cell disruption, and methods for product recovery and strain improvement.	An
5	Discuss the industrial production of important microbial metabolites and regulatory aspects in bioprocessing and biosynthetic pathways.	U

CL: Cognitive Levels (**R**-Remember; **U**-Understanding; **Ap**-Apply; **An**-Analyze; **E**-Evaluate; **C**-Create).

CO-PO/PSO Mapping for the course:

PO / CO	POs											PSO				
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	3	3	3	2	2	1	3	2	2	3	2	3	3	2	1	2
3	2	3	3	2	2	3	2	3	3	2	3	2	3	3	3	3
3	3	3	3	2	2	3	2	3	3	2	3	2	2	2	2	2
3	3	3	3	2	2	3	2	2	3	3	3	3	3	3	3	2
3	3	3	3	2	2	3	2	3	3	3	3	3	2	3	3	3
3	3	3	3	3	2	3	2	3	3	3	3	3	3	3	3	3

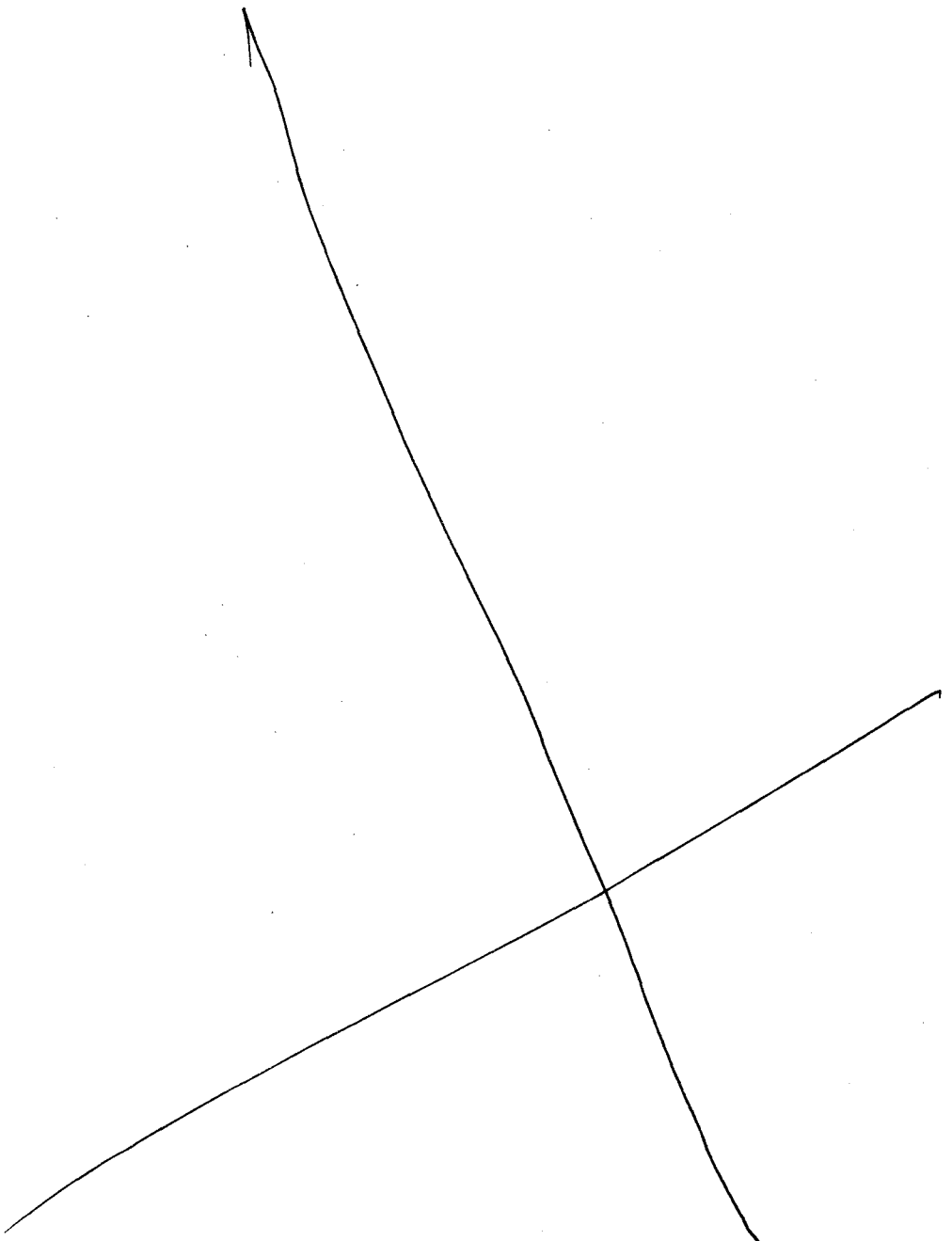
"3" – Strong; "2" – Moderate; "1"- Low; "-" No Correlation

Detailed Syllabus:

Unit No.	Topics	No. of Lectures	CO No.
I	**Introduction to fermentation technology:** Basic principles of fermentation **Study of the design and operation of bioreactor:** Ancillary parts and function, impeller design and agitation, power requirements on measurements and control of dissolved oxygen, carbon dioxide, temperature, pH and foam. **Types of bioreactors:** CSTR, tower, airlift, bubble column, packed glass bead, hollow fiber, configuration and application **Computer control of fermentation process:** System configuration and application	12	1
II	**Mass transfer:** Theory, diffusional resistance to oxygen requirements of microorganisms, measurements of mass transfer co- efficient and factor affecting them, effects of aeration and agitation on mass transfer, supply of air, air compressing, cleaning and sterilization of air and plenum ventilation, air sampling and testing standards for air purity. **Rheology:** Rheological properties of fermentation system and their importance in bioprocessing	12	2
III	**Scale up of fermentation process:** Principles, theoretical considerations, techniques used, media for fermentation, HTST sterilization, advantage and disadvantage, liquid sterilization. **Cultivation and immobilized culture system:** Cultivation system - batch culture, continuous culture, synchronous cultures, fed batch culture. Graphical plot representing the above systems. **Introduction to immobilization:** Techniques, immobilization of whole cell, immobilized culture system to prepare fine chemicals. Immobilization of enzymes and their applications in the industry. Reactors for immobilized systems and perspective of enzyme engineering.	12	3
IV	**Scale down of fermentation process:** Theory, equipment design and operation, methods of filtration, solvent extraction, chromatographic separation, crystallization turbidity analysis and cell yield determination, metabolic response assay, enzymatic assay, bioautographic techniques and disruption of cells for product recovery. **Isolation and screening:** Primary and secondary, maintenance of stockculture, strain improvement for increased yield.	12	4
V	Bioprocessing of the industrially important microbial metabolites a) Organic solvents – Alcohol and Glycerol b) Organic acids - Citric acids, Lactic acids, c) Amino acids - Glutamic acids, Lysine, Cyclic AMP and GMP d) Antibiotics - Penicillin, Streptomycin, Griseofulvin, e) Vitamins - B12, Riboflavin and Vitamin C Biosynthetic pathways for some secondary metabolites, microbial transformation of steroids and alkaloids Regulation governing the manufacturing of biological products .	12	5

Books Recommended:

1. Peter Stanbury, Allan Whitaker, Stephen Hall, Principles of Fermentation technology, Elsevier stores.
2. L.E. Casida, Industrial Microbiology, John Wiley & sons Inc.
3. F.M. Asubel, Current protocols in molecular biology, volume I and II, John Wiley Publishers.
4. Biotol Board, Bioreactor design and product yield, Butterworth and Helhemann Publishers.
5. H. Patel, Industrial microbiology, Macmillan India Limited.



Semester-I

Program	Subject	Year	Semester
M. Pharm.	**Pharmaceutical Biotechnology**	I	I
Course Code	Course Title		Course Type
MPB 104T	ADVANCED PHARMACEUTICAL BIOTECHNOLOGY		Core
Credit	Hours Per Week (L-T-P)		
	L	T	P
4	4	--	--

Maximum Marks	CIA	ESE
100	25	75

Learning Objective (LO):

The course is designed to provide the knowledge to the students to develop skills of advanced techniques of isolation and purification of enzymes, to enrich students with current status of development of vaccines and economic importance of biotechnology products. The students will gain an understanding of advanced biotechnology techniques used in drug and vaccine development, genetic engineering, and pharmacogenomics. They will also learn about enzyme sources, gene manipulation, and the regulatory approval process for drugs and biologics.

Course Outcomes (CO):

CO No.	Expected Course Outcomes At the end of the course, the students will be able to :	CL
1	Understand enzyme classification, sources, purification, and applications in pharmaceutical and industrial settings.	Ap
2	Apply genetic engineering tools such as cloning, site-directed mutagenesis, and recombinant expression for therapeutic biomolecule production.	Ap
3	Explain therapeutic peptide delivery, transgenic animal technology, gene therapy, and chromosomal studies including human genome analysis.	U
4	Describe cellular signal transduction pathways, oncogenes, and their roles in health and disease.	An
5	Evaluate microbial biotransformation, biodegradation, and biosensor applications in drug synthesis, waste management, and diagnostics.	U

CL: Cognitive Levels (**R**-Remember; **U**-Understanding; **Ap**-Apply; **An**-Analyze; **E**-Evaluate; **C**-Create).

CO-PO/PSO Mapping for the course:

PO / CO	POs											PSO				
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	3	3	3	2	2	1	3	2	2	3	2	3	3	2	1	2
CO2	2	3	3	2	2	3	2	3	3	2	3	2	3	3	3	3
CO3	3	3	3	2	2	3	2	3	3	2	3	2	2	2	2	2
CO4	3	3	3	2	2	3	2	2	3	3	3	3	3	3	3	2
CO5	3	3	3	2	2	3	2	3	3	3	3	3	2	3	3	3

"3" – Strong; "2" – Moderate; "1"- Low; "-" No Correlation

Detailed Syllabus:

Unit No.	Topics	No. of Lectures	CO No.
I	**Enzyme Technology:** Classification, general properties of enzymes, dynamics of enzymatic activity,sources of enzymes, extraction and purification, pharmaceutical,therapeutic and clinical application. Production of amyloglucosidase, glucose isomerase,amylase and trypsin.	12	1
II	**Genetic Engineering:** Techniques of gene manipulation, cloning strategies,procedures, cloning vectors expression vectors, recombinant selection andscreening, expression in E.coli and yeast. Site directed mutagenesis, polymerase chain reaction, and analysis of DNAsequences. Gene library and cDNA Applications of the above technique in the production of, • Regulatory proteins - Interferon, Interleukins • Blood products - Erythropoietin • Vaccines - Hepatitis-B • Hormones - Insulin	12	2
III	**Therapeutic peptides:** Study on controlled and site specified delivery of therapeutic peptides and proteins through various routes of administration. **Transgenic animals:** Production of useful proteins in transgenic animals and gene therapy. **Human Genome:** The human genome project-a brief study. Human chromosome – Structure and classification, chromosomal abnormalities – Syndromes	12	3
IV	**Signal transduction:** Introduction, cell signaling pathways, Ion channels, Sensors and effectors, ON and OFF mechanisms, Spatial and temporal aspects of signaling, cellular process, development, cell cycle and proliferation, neuronal signaling, cell stress, inflammatory responses and cell death, signaling defects and diseases. **Oncogenes:** Introduction, definition, various oncogenes and their proteins.	12	4
V	**Microbial Biotransformation:** Biotransformation for the synthesis of chiral drugs and steroids. **Microbial Biodegradation:** Biodegradation of xenobiotics, chemical and industrial wastes, Production of single-cell protein, Applications of microbes in environmental monitoring. **Biosensors:** Definition, characteristics of ideal biosensors, types of biosensors, biological recognition elements, transducers, application of biosensors.	12	5

Books Recommended:

1. Biotechnology-The biological principles: MD Trevan, S Boffey, KH Goulding and P.F. Stanbury.
2. Immobilization of cells and enzymes: Hosevear Kennady cabral & Bicker staff
3. Principles of Gene Manipulating: RW Old and S.B.Primrose.
4. Molecular Cell Biology: Harvey Lodish, David Baltimore, Arnold Berk, S LawenceZipursky, Paul Matsudaira, James Darnell.
5. Modern Biotechnology: S.B Primrose
6. Gene transfer and expression protocols-methods in Molecular Biology, vol. VII, Edit E.T. Murray
7. Current protocols in Molecular Biology, Vo1.I & II:F.M. Asubel, John wiley Publishers
8. Current protocols in cellular biology, Vo1.1 & II John wiley publishers.
9. Principles of human genetics; by Curt Stern, published by W.H. Freeman.

Semester-I

Program	Subject	Year	Semester
M. Pharm.	**Pharmaceutical Biotechnology**	1	I
Course Code	Course Title		Course Type
MPB 105P	PHARMACEUTICAL BIOTECHNOLOGY PRACTICAL - I		Core
Credit	Hours Per Week (L-T-P)		
	L	T	P
06	-	--	12

Maximum Marks	CIA	ESE
150	50	100

Learning Objective (LO):

By the end of this practical course, students will be able to:

Students will gain hands-on experience in various analytical techniques such as UV-Vis spectrophotometry, HPLC, and gas chromatography for drug and compound analysis.

They will also learn microbial isolation, cell culturing, fermentation processes, and genetic techniques including DNA/RNA isolation, PCR, and electrophoresis.

Additionally, students will apply knowledge in microbiology, biochemistry, and biotechnology to conduct experiments related to antimicrobial testing, cell growth, and protein analysis.

Course Outcomes (CO):

CO No.	Expected Course Outcomes At the end of the course, the students will be able to :	CL
1	Demonstrate the ability to use advanced instrumental techniques like UV-Vis spectrophotometry, HPLC, Gas Chromatography, and fluorimetry for qualitative and quantitative analysis of pharmaceutical compounds and formulations.	Ap
2	Apply microbial techniques to isolate and purify microorganisms, assess water contamination, perform sterility tests, and determine Minimum Inhibitory Concentrations (MIC) using gradient plate and dilution. methods.	Ap
3	Gain hands-on experience in molecular biology techniques including DNA/RNA isolation, plasmid extraction, agarose gel electrophoresis, and Polymerase Chain Reaction (PCR) for genetic analysis and manipulation.	U
4	Understand and conduct fermentation processes for the production of alcohol, wine, vitamins, and antibiotics, and apply knowledge of whole-cell immobilization engineering for biotechnological applications.	An
5	Perform sub-culturing of cells, cytotoxicity assays, and growth curve construction, enabling students to evaluate cell growth, specific growth rates, doubling times, and cellular responses to various substances in a laboratory setting.	U

CL: Cognitive Levels (**R**-Remember; **U**-Understanding; **Ap**-Apply; **An**-Analyze; **E**-Evaluate; **C**-Create).

CO-PO/PSO Mapping for the course:

PO / CO	POs											PSO				
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	3	2	3	2	2	3	3	3	2	3	2	3	2	2	2	3
CO2	3	3	3	2	2	2	3	2	3	3	3	3	2	2	2	3
CO3	3	2	3	3	2	1	3	1	2	3	2	3	3	3	2	3
CO4	3	2	3	3	2	1	3	1	2	3	2	3	3	2	2	2
CO5	3	2	3	3	2	1	3	1	2	3	2	3	3	3	2	3

"3" – Strong; "2" – Moderate; "1"- Low; "-" No Correlation

Detailed Syllabus:

LIST OF PRACTICALS

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. Isolation and Purification of microorganism from the soil
8. Microbial contamination of Water and biochemical parameters.
9. Determination of Minimum Inhibitory concentration by gradient plate technique and serial dilution method.
10. UV- survival curve and Dark repair
11. Sterility test for pharmaceutical preparations
12. Sub culturing of cells and cytotoxicity assays.
13. Construction of growth curve and determination of specific growth rate and doubling time
14. Fermentation process of alcohol and wine production
15. Fermentation of vitamins and antibiotics
16. Whole cell immobilization engineering
17. Thermal death kinetics of bacteria
18. Replica plating
19. Bio-autography.
20. Isolation and estimation of DNA
21. Isolation and estimation of RNA
22. Isolation of plasmids
23. Agarose gel electrophoresis.
24. Transformation techniques
25. SDS – polyacrylamide gel electrophoresis for proteins
26. Polymerase chain reaction technique.

Semester-II

Program	Subject	Year	Semester
M. Pharm.	**Pharmaceutical Biotechnology**	I	II
Course Code	Course Title		Course Type
MPB 201T	PROTEINS AND PROTEIN FORMULATIONS		Core
Credit	Hours Per Week (L-T-P)		
	L	T	P
4	4	–	--

Maximum Marks	CIA	ESE
100	25	75

Learning Objective (LO):

To explore fundamental aspects of proteins and their formulations is a part of drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of information for protein formulation and design are provided to help the students to clarify the various biological concepts of protein.

Course Outcomes (CO):

CO No.	Expected Course Outcomes At the end of the course, the students will be able to :	CL
1	Understand and apply the concepts and methods of protein engineering including gene shuffling and directed evolution.	Ap
2	Explain peptidomimetics, their design principles, and applications in rational drug development and computer-aided drug design (CADD).	Ap
3	Apply proteomics techniques for protein identification and characterization including isotope labeling and 2D-gel electrophoresis.	U
4	Describe strategies for protein/DNA formulation, stability enhancement, and characterization using modern biophysical techniques.	An
5	Understand various protein sequencing and mapping techniques used in proteomic and biochemical analysis.	U

CL: Cognitive Levels (**R**-Remember; **U**-Understanding; **Ap**-Apply; **An**-Analyze; **E**-Evaluate; **C**-Create).

CO-PO/PSO Mapping for the course:

PO / CO	POs											PSO				
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	3	3	3	3	2	2	3	2	3	3	3	3	3	3	3	3
CO2	3	3	2	3	2	2	2	2	2	2	2	2	2	3	3	3
CO3	3	3	3	3	2	2	3	2	2	3	2	2	3	3	2	2
CO4	3	3	3	3	3	2	3	2	2	3	2	2	3	3	3	3
CO5	3	3	3	3	2	2	3	2	2	3	2	2	3	3	3	2

"3" – Strong; "2" – Moderate; "1"- Low; "-" No Correlation

Detailed Syllabus:

Unit No.	Topics	No. of Lectures	CO No.
I	**Protein engineering:** Concepts for protein engineering. Isolation and purification of proteins, Stability and activity-based approaches of protein engineering, Chemical and Physical Considerations in Protein and Peptide Stability, Different methods for protein engineering, gene shuffling, and direct evolution.	12	1
II	**Peptidomimetics:** Classification; Conformationally restricted peptides, design, pseudopeptides, peptidomimetics and transition state analogs; Biologically active template; Amino acid replacements; Peptidomimetics and rational drug design; CADD techniques in peptidomimetics; Development of non peptide peptidomimetics.	12	2
III	**Proteomics:** Protein identification and characterization: Methods/strategies, protein identification, de novo protein characterization, Isotope labelling, N- and C-terminal tags. **2-Dimensional gel electrophoresis:** Methods including immobilized pH gradients (IPGs), resolution, reproducibility and image analysis, future developments	12	3
IV	**Protein formulation:** Different strategies used in the formulation of DNA and proteins, Analytical and biophysical parameters of proteins and DNA in pre-formulation, Liposomes, Neon-spears, Neon-particulate system, PEGylation, Biological Activity, Biophysical Characterization Techniques, Forced degradation studies of protein.	12	4
V	**Methods of protein sequencing**: Various methods of protein sequencing, characterisation, Edman degradation, Tryptic and/or Chymotryptic Peptide Mapping.	12	5

Books Recommended:

1. H. Lodhishet. Al. Molecular Cell Biology, W. H. Freeman and Company
2. Protein Purification – Hand Book, Amersham pharmacia biotech
3. EngelbertBuxbaum, Fundamentals of Protein Structure and Function, Springer Science
4. Sheldon J. Park, Jennifer R. Cochran, Protein Engineering and Design, CRC press.
5. Robert K. Skopes. Protein purification, principle and practice, springer link.
6. David Whitford, Proteins-Structure and Function, John Wiley & Sons Ltd.
7. James Swarbrick, Protein Formulation and Delivery Informa Healthcare USA,Inc.
8. Rodney Pearlman, Y. John Wang Formulation, Characterization, and Stability of Protein Drugs, Kluwer Academic Publishers.

Semester-II

Program	Subject	Year	Semester
M. Pharm.	**Pharmaceutical Biotechnology**	I	II
Course Code	Course Title		Course Type
MPB 202T	**IMMUNOTECHNOLOGY**		Core
Credit	Hours Per Week (L-T-P)		
	L	T	P
4	4	--	--

Maximum Marks	CIA	ESE
100	25	75

Learning Objective (LO):

To know and understand production and engineering of antibodies, the application of antigens, the design of (recombinant) vaccines, strategies for immune intervention, etc. The Immunotechnology - based techniques will be used for therapeutics and diagnostics, industries in the production, quality control and quality assurance, and in R&D.

Course Outcomes (CO):

CO No.	Expected Course Outcomes At the end of the course, the students will be able to :	CL
1	Explain the structure and function of the immune system including organs, cells, antibodies, and immune responses (innate and adaptive).	Ap
2	Understand immune regulation, cytokine function, and the basis and treatment of hypersensitivity and autoimmune diseases.	Ap
3	Describe vaccine types, advanced vaccine technologies, and the application of stem cells in immunology	U
4	Demonstrate knowledge of hybridoma technology and the production and application of monoclonal antibodies.	An
5	Apply immunological techniques in diagnosis and understand immunological disorders, their mechanisms, and treatment approaches.	U

CL: Cognitive Levels (**R**-Remember; **U**-Understanding; **Ap**-Apply; **An**-Analyze; **E**-Evaluate; **C**-Create).

CO-PO/PSO Mapping for the course:

PO / CO	POs											PSO				
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	3	3	3	2	2	3	2	1	3	2	2	3	2	2	2	1
CO2	3	3	3	2	2	3	2	1	3	2	2	2	2	2	2	1
CO3	3	3	3	3	3	2	3	2	2	3	3	2	3	3	3	3
CO4	3	2	3	3	3	2	3	2	3	3	2	2	3	3	3	3
CO5	3	3	3	3	3	2	3	2	3	3	3	2	3	3	3	2

"3" – Strong; "2" – Moderate; "1"- Low; "-" No Correlation

Detailed Syllabus:

Unit No.	Topics	No. of Lectures	CO No.
I	**Fundamental aspects of immunology:** Introduction, cells and organs of the immune system, cellular basis of Immune response, primary and secondary lymphoid organs, antigen antibody and their structure. Types of immune responses, anatomy of immune response. Overview of innate and adaptive Immunity. **Humoral Immunity:** B – Lymphocytes and their activation. Structure and function of immunoglobulins, idiotypes and anti idiotypic antibodies. **Cell mediated Immunity:** Thymus derived lymphocytes (T cells) – their ontogeny and types, MHC complex, antigen presenting cells (APC), mechanisms of T cell activation, macrophages, dendritic cells, langerhans cells, mechanism of phagocytosis	12	1
II	**Immune Regulation and Tolerance:** Complement activation and types and their biological functions, cytokines and their role in immune response. **Hypersensitivity:** Hypersensitivity Types I-IV, Hypersensitivity reactions and treatment **Autoimmune diseases:** vaccine production, antiidiotype vaccine, DNA vaccine, genetically engineered vaccine, iscoms, synthetic peptides, and immunodiagnostics. Stem cell technology: Stem cell technology and applications to immunology	12	2
III	**Vaccine technology:** Vaccine and their types, conventional vaccines, novel methods for vaccine production, antiidiotype vaccine, DNA vaccine, genetically engineered vaccine, iscoms, synthetic peptides, and immunodiagnostics. **Stem cell technology:** Stem cell technology and applications to immunology	12	3
IV	**Hybridoma Technology:** Hybridoma techniques – fusion methods for myeloma cells and B- Lymphocytes, selection and screening techniques. Production and purification of monoclonal antibodies and their applications in Pharmaceutical industry.	12	4
V	**Immunological Disorder:** Autoimmune disorders and types, pathogenic mechanisms, treatment, experimental models of auto immune diseases, primary and secondary immunodeficiency disorders. **Immunodiagnosis:** Antigen antibody interaction – Precipitation reaction, Agglutination reactions, Principles and applications of ELISA, Radio Immuno Assay, Western blot analysis, immune-electrophoresis, immuno fluorescence, chemiluminescence assay, complement fixation reaction.	12	5

Books Recommended:

1. J. Kubey, Immunology – an Introduction.
2. S.C. Rastogi, Immunodiagonstics, New Age International.
3. Ashim Chakravarthy, Immunology and Immunotechnology, Oxford University Press.
4. E. Benjamini, Molecular Immunology.

Semester-II

Program	Subject	Year	Semester
M. Pharm.	**Pharmaceutical Biotechnology**	I	II
Course Code	Course Title		Course Type
MPB 203T	BIOINFORMATICS AND COMPUTATIONAL BIOTECHNOLOGY		Core
Credit	Hours Per Week (L-T-P)		
	L	T	P
4	4	–	--

Maximum Marks	CIA	ESE
100	25	75

Learning Objective (LO):

To make the students understand the role of computers in drug development and bioinformatics, including protein diversity and gene finding methods. They will gain skills in searching biological databases and targeting specific molecules for drug design. Additionally, students will explore various drug designing methods and their applications in modern biotechnology.

Course Outcomes (CO):

CO No.	Expected Course Outcomes At the end of the course, the students will be able to :	CL
1	Understand the basics of bioinformatics, biological databases, data mining, and their applications in pharmaceutical sciences.	Ap
2	Apply sequence alignment and protein informatics tools for analyzing biological macromolecules.	Ap
3	Predict protein structures using computational tools and docking techniques for drug discovery applications.	U
4	Analyze genome diversity, gene prediction, genome mapping, and perform phylogenetic analysis using bioinformatics approaches.	An
5	Apply bioinformatics tools for target identification, drug design, and validation of drug-like molecules using in-silico techniques.	U

CL: Cognitive Levels (**R**-Remember; **U**-Understanding; **Ap**-Apply; **An**-Analyze; **E**-Evaluate; **C**-Create).

CO-PO/PSO Mapping for the course:

PO / CO	POs											PSO				
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	3	2	3	2	2	2	2	1	2	2	1	3	2	2	2	1
CO2	3	3	3	3	3	2	2	2	2	3	2	3	3	3	3	2
CO3	3	3	3	3	3	2	3	2	2	3	3	3	3	3	3	3
CO4	3	3	2	3	2	2	3	2	3	3	2	3	3	3	2	2
CO5	3	3	3	3	3	2	3	2	3	3	3	3	3	3	3	3

"3" – Strong; "2" – Moderate; "1"- Low; "-" No Correlation

Detailed Syllabus:

Unit No.	Topics	No. of Lectures	CO No.
I	**Introduction to Bioinformatics:** Definition and History of Bioinformatics, Internet and Bioinformatics, Introduction to Data Mining, Applications of Data Mining to Bioinformatics, **Biological Database:** Protein and nucleic acid databases. Structural data bases. Collecting and storing the sequence and Applications of Bioinformatics.	12	1
II	**Sequence analysis:** Sequence alignment, pair wise alignment techniques, multiple sequence analysis, multiple sequence alignment; Flexible sequence similarity searching with the FAST3 program package, the use of CLUSTAL W and CLUSTAL X for the multiple sequence alignment. Tools used for sequence analysis.	12	2
III	**Protein informatics:** Introduction; Force field methods; Energy, buried and exposed residues, side chains and neighbours; Fixed regions, hydrogen bonds, mapping properties onto surfaces; Fitting monomers, R & S fit of conformers, assigning secondary structures; Sequence alignment-methods, evaluation, scoring; Protein completion, backbone construction and side chain addition; Small peptide methodology, software accessibility, building peptides; Protein displays; Substructure manipulations, annealing. **Protein structure prediction:** Protein folding and model generation; Secondary structure prediction, analyzing secondary structures; Protein loop searching, loop generating methods, loop analysis; Homology modeling, concepts of homology modeling, potential applications, description, methodology, homologous sequence identification; Align structures, align model sequence; Construction of variable and conserved regions, threading techniques, Topology fingerprint approach for prediction, evaluation of alternate models; Structure prediction on a mystery sequence, structure aided sequence techniques of structure prediction, structural profiles, alignment algorithms, mutation tables, prediction, validation, sequence based methods of structure prediction, prediction using inverse folding, fold prediction; Significance analysis, scoring techniques, sequence- sequence scoring. **Docking:** Docking problems, methods for protein- ligand docking, validation studies and applications; Screening small molecule databases, docking of combinatorial libraries, input data, analyzing docking results.	12	3
IV	**Diversity of Genomes:** Prokaryotic and Eukaryotic Gene Families. Genome Analysis: Introduction, Gene prediction methods, Gene mapping and applications- Genetic and Physical Mapping, Integrated map, Sequence assembly and gene expression. **Completed Genomes:** Bacterium, Nematode, Plant and Human **Evolution of Genomes:** Lateral or Horizontal Transfer among Genomes,	12	4

	Transcriptome and Proteome-General Account **Phylogenetic analysis:** Evolutionary Change in Nucleotide Sequences, Rates and Patterns of Nucleotide Substitution, Models for Nucleotide Substitution, Construction of Phylogenetic Tree, Genome Annotation technique.		
V	**Target searching and Drug Designing:** Target and lead, timeline for drug development, target discovery, target modulators, In-silico gene expression, microarray, and lead discovery, libraries of ligands, active site analysis, and prediction of drug quality.	12	5

Books Recommended:

1. David W. Mount, Bioinformatics Sequence and Genome Analysis, CBS Publishers and Distributors
2. S. C. Rastogiet. al. Bioinformatics- Concepts Skill and Applications, CBS Publishers and Distributors
3. T. E. Creighton, Protein Structure and Molecular Properties, W. H.Freeman and Company
4. Andreas D. Baxevanis, B. F. Francis Ouellette, Bioinformatics; A Practical Guide to the Analysis of Genes and Proteins, John Wiley & Sons, Inc.
5. Arthur M. Lesk, Introduction to Bioinformatics, Oxford University Press.
6. Shui Qing Ye. Bioinformatics: A Practical Approach, Chapman & Hall/CRC.
7. David Posada, Bioinformatics for DNA Sequence Analysis, Humana press.
8. Lesk, A.M. Introduction to Bioinformatics. Oxford University Press.
9. Letovsky, S.I. Bioinformatics. Kluwer Academic Publishers.
10. Baldi, P. and Brunak, S. Bioinformatics. The MIT Press.

Semester-II

Program	Subject	Year	Semester
M. Pharm.	**Pharmaceutical Biotechnology**	I	II
Course Code	Course Title		Course Type
MPB 204T	BIOLOGICAL EVALUATION OF DRUG THERAPY		Core
Credit	Hours Per Week (L-T-P)		
	L	T	P
4	4	–	--

Maximum Marks	CIA	ESE
100	25	75

Learning Objective (LO):

To understand the concepts of biological standardization, the role of transgenic and knockout animals in research, and the development of biological medicines for various diseases. They will also gain knowledge in the biological evaluation of drugs, both in vitro and in vivo. This will enable students to evaluate the safety and efficacy of pharmaceutical products.

Course Outcomes (CO):

CO No.	Expected Course Outcomes At the end of the course, the students will be able to :	CL
1	Understand the principles of biological standardization, bioassay techniques, and toxicity studies for pharmaceutical products.	Ap
2	Describe the methods of pyrogen testing, microbiological assay, and biological evaluation using in vivo and in vitro models.	Ap
3	Identify biologic medicines developed for different diseases and understand their categories and therapeutic relevance.	U
4	Explain regulatory considerations and processes for approval of drugs, biologics, and medical devices at the global level.	An
5	Understand bioavailability, bioequivalence studies, and pharmacokinetics in the context of biopharmaceutical product development.	U

CL: Cognitive Levels (**R**-Remember; **U**-Understanding; **Ap**-Apply; **An**-Analyze; **E**-Evaluate; **C**-Create).

CO-PO/PSO Mapping for the course:

PO / CO	POs											PSO				
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	3	3	2	3	2	2	3	2	2	2	2	3	2	2	2	2
CO2	3	3	2	3	2	3	2	1	2	2	2	3	3	2	2	2
CO3	3	2	3	2	3	1	2	2	2	2	2	3	3	3	2	2
CO4	3	3	3	2	3	2	3	3	2	3	3	3	3	3	3	3
CO5	3	3	3	3	3	2	3	2	2	3	3	3	3	3	3	3

"3" – Strong; "2" – Moderate; "1"- Low; "-" No Correlation

Detailed Syllabus:

Unit No.	Topics	No. of Lectures	CO No.
I	**Biological Standardization:** General principles, Scope and limitation of bio-assay, bioassay of some official drugs. **Preclinical drug evaluation:** Preclinical drug evaluation of its biological activity, potency and toxicity-Toxicity test in animals including acute, sub-acute and chronic toxicity, ED50 and LD50 determination, special toxicity test like teratogenecity and mutagenecity. **Guidelines for toxicity studies:** Various guidelines for toxicity studies. Animal experiments assessing safety of packaging materials.	12	1
II	**Pyrogens:** Pyrogens: Sources, Chemistry and properties of bacterial pyrogens and endotoxins, Official pyrogen tests. **Microbiological assay:** Assay of antibiotics and vitamins. **Biological evaluation of drugs:** Screening and evaluation (including principles of screening, development of models for diseases: In vivo models / In vitro models / cell line study).	12	2
III	**Biologic Medicines in Development for various diseases -** **By Therapeutic Category** • Genetic Disorders • Eye related Disorders • Digestive Disorders • Diabetes/Related Conditions • Cardiovascular Disease • Cancer/Related Conditions • Blood Disorders • Autoimmune Disorders • Infectious Diseases • Neurologic Disorders • Skin Diseases • Organ Transplantation **Biologic Medicines in Development for various diseases – by Product Category** • Antisense • Vaccines • Recombinant Hormones/Proteins • Monoclonal Antibodies (mAb) • Interferons • Growth Factors • Gene Therapy • RNA Interference	12	3

IV	**Regulatory aspects :** Drugs, biologics and medical devices An introduction to the regulations and documents necessary for approval of a medical product. **Regulatory consideration:** Regulatory consideration for pre-clinical testing and clinical testing of drugs, biologics and medical devices. New Drug Applications for Global Pharmaceutical Product Approvals	12	4
V	**Bioavailability:** Objectives and consideration in bio-availability studies of Biopharmaceuticals, Concept of equivalents, Measurements of bio-availability. Determination of the rate of absorption, Bioequivalence and its importance, Regulatory aspects of bio-availability and bioequivalence studies for conventional dosage forms and controlled drug delivery systems of Biopharmaceuticals. **Pharmacokinetics:** Pharmacokinetics:- Basic consideration, Pharmacokinetic models, Application of Pharmacokinetics in new drug development of Biopharmaceuticals and designing of dosage forms and Novel drug delivery systems of Biopharmaceuticals.	12	5

Books Recommended:

1. Perkins F.T., Hennessen W. Standardization and Control of Biologicals Produced by Recombinant DNA Technology, International Association of Biological Standardization
2. J.H. Burn., Biological Standardization, Oxford University Press
3. Drug Discovery and Evaluation in Pharmacology assay: Vogel
4. Chow, Shein, Ching, Design and analysis of animal studies in pharmaceutical development,
5. Nodine and Siegler, Animal and Clinical pharmacologic Techniques in Drug Evaluation.
6. Screening methods in pharmacology (vol I & II), R.A. Turner.

Semester-II

Program	Subject	Year	Semester
M. Pharm.	**Pharmaceutical Biotechnology**	I	II
Course Code	Course Title		Course Type
MPB 205P	PHARMACEUTICAL BIOTECHNOLOGY PRACTICAL - II		Core
Credit	Hours Per Week (L-T-P)		
	L	T	P
06	-	--	20

Maximum Marks	CIA	ESE
150	50	100

Learning Objective (LO):

- To acquire hands-on experience in protein identification, characterization, and biochemistry, along with skills in recombinant DNA technology, gene expression, and protein formulations.
- Student will learn advanced techniques such as PCR, RT-PCR, sequence analysis, gene transformation, and various molecular biology methods for studying protein-DNA interactions and gene expression.

Course Outcomes (CO):

CO No.	Expected Course Outcomes At the end of the course, the students will be able to :	CL
1	Develop proficiency in protein identification, characterization, and biochemistry, along with a strong understanding of recombinant DNA technology, gene transformation, and protein expression systems.	Ap
2	Skilled up with hands-on experience with PCR, RT-PCR, and gene amplification methods, including primer design, Southern hybridization, and Western blotting for gene and protein analysis.	Ap
3	How to utilize bioinformatics tools for database searching, sequence analysis, and protein structure prediction, as well as understand gene annotation methods and phylogenetic analysis for evolutionary studies.	U
4	Get expertise in studying protein-DNA binding interactions and apply these skills to molecular research, enabling the identification and analysis of functional relationships between proteins and DNA.	An
5	Conduct DNA isolation, quantification, and purity assessment, preparing them for PCR applications and other downstream molecular biology techniques.	U

CL: Cognitive Levels (**R**-Remember; **U**-Understanding; **Ap**-Apply; **An**-Analyze; **E**-Evaluate; **C**-Create).

CO-PO/PSO Mapping for the course:

PO / CO	POs											PSO				
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	3	2	3	2	2	2	2	1	2	2	1	3	2	2	2	1
CO2	3	3	3	3	3	2	2	2	2	3	2	3	3	3	3	2
CO3	3	3	3	3	3	2	3	2	2	3	3	3	3	3	3	3
CO4	3	3	2	3	2	2	3	2	3	3	2	3	3	3	2	2
CO5	3	3	3	3	3	2	3	2	3	3	3	3	3	3	3	3

"3" – Strong; "2" – Moderate; "1"- Low; "-" No Correlation

Detailed Syllabus:

LIST OF PRACTICALS
1. Protein identification 2. Protein characterization 3. Protein biochemistry 4. Recombinant DNA Technology 5. Protein expression 6. Protein formulations 7. Database searching 8. Sequence analysis methods 9. Protein structure prediction 10. Gene annotation methods 11. Phylogenetic analysis 12. Protein, DNA binding studies 13. Preparation of DNA for PCR applications - Isolation, Purity and Quantification 14. Introduction to PCR – working of PCR, Programming. 15. Introduction to RT-PCR – working, programming. 16. Primer design using softwares. 17. Gene DNA amplification by random / specific primers. 18. Southern Hybridization 19. Western Blotting 20. Gene transformation

Semester-II

Program	Subject	Year	Semester
M. Pharm.	**Pharmaceutical Biotechnology**	1	II

Course Code	Course Title	Course Type
--	Seminar /Assignment	Core

Credit	Hours Per Week (L-T-P)		
	L	T	P
4	–	–	--

Maximum Marks	CIA	ESE
100	--	100

Learning Objective (LO):

The subject is designed to create an environment where teachers provide the students a critical eye and openness to fortify the presentation and academic writing skills of students in the field of Pharmaceutics and industrial pharmacy.

Course Outcomes (CO):

CO No.	Expected Course Outcomes At the end of the course, the students will be able to :	CL
1	Develop skills to gather, organize, deliver information, and defend a given topic in Pharmaceutics and industrial pharmacy.	Ap
2	Learn to organize complex concepts using audio-visual aids.	Ap
3	Acquire communication and presentation skills.	U
4	Effectively respond to questions raised by peers and stand scientific scrutiny.	An
5	Develop a write-up on the subject of seminar presentation and cultivate continuous learning.	U

CL: Cognitive Levels (**R**-Remember; **U**-Understanding; **Ap**-Apply; **An**-Analyze; **E**-Evaluate; **C**-Create).

CO-PO/PSO Mapping for the course:

PO CO	POs											PSO				
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	3	3	2	2	2	2	3	3	2	2	2	3	2	2	2	2
CO2	3	3	3	2	2	2	2	3	2	2	2	2	2	2	2	2
CO3	3	3	3	3	2	2	2	3	3	3	3	3	2	2	2	2
CO4	3	3	3	3	2	3	3	3	3	3	3	3	3	2	2	2
CO5	3	3	3	2	3	3	2	2	2	2	3	3	3	3	3	2

"3" – Strong; "2" – Moderate; "1"- Low; "-" No Correlation

Semester-III

Program	Subject	Year	Semester
M. Pharm.	**Pharmaceutical Biotechnology**	2	III
Course Code	Course Title		Course Type
MRM 301T	**Research Methodology and Biostatistics**		Core
Credit	Hours Per Week (L-T-P)		
	L	T	P
4	4	–	--

Maximum Marks	CIA	ESE
100	25	75

Learning Objective (LO):

- Understand the fundamentals of research methodology including study designs, bias elimination, controls, and randomization techniques.
- Apply biostatistical methods for analyzing data, interpreting statistical tests, and understanding the role of sample size in research.
- Comprehend the ethical principles and dilemmas in medical research, including patient autonomy, informed consent, confidentiality, and conflicts of interest.
- Learn the CPCSEA guidelines for proper laboratory animal care and management in compliance with ethical and regulatory standards.
- Recognize the significance of the Declaration of Helsinki in framing ethical standards for medical research involving human subjects.

Course Outcomes (CO):

CO No.	Expected Course Outcomes At the end of the course, the students will be able to :	CL
1	Explain general research methodology, including study designs, bias elimination, controls, randomization, and blinding techniques.	Ap
2	Apply biostatistical concepts including sample size determination, parametric and non-parametric tests, and interpretation of results.	Ap
3	Discuss medical ethics principles, including autonomy, beneficence, informed consent, confidentiality, and ethical dilemmas.	U
4	Understand and implement CPCSEA guidelines for ethical treatment and management of laboratory animals in research facilities.	An
5	Describe the history, principles, and applications of the Declaration of Helsinki for ethical medical research.	U

CL: Cognitive Levels (**R**-Remember; **U**-Understanding; **Ap**-Apply; **An**-Analyze; **E**-Evaluate; **C**-Create).

CO-PO/PSO Mapping for the course:

PO / CO	POs											PSO				
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	4	4	3	3	2	1	3	1	1	2	1	2	2	2	1	2
CO2	4	4	4	5	2	1	4	1	1	2	1	3	4	2	1	3
CO3	3	4	4	2	4	3	3	2	4	3	3	2	2	3	1	2
CO4	3	3	3	2	2	2	2	2	4	2	1	4	2	3	5	3
CO5	3	3	3	2	2	2	3	2	5	2	2	3	3	3	2	3

"3" – Strong; "2" – Moderate; "1"- Low; "-" No Correlation

Detailed Syllabus:

Unit No.	Topics	No. of Lectures	CO No.
I	**General Research Methodology:** Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.	4	1
II	**Biostatistics:** Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests(students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.	4	2
III	**Medical Research:** History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.	4	3
IV	**CPCSEA guidelines for laboratory animal facility:** Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.	4	4
V	**Declaration of Helsinki:** History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.	4	5

Books Recommended:

1. Research Methodology: Methods and Techniques by C.R. Kothari
2. Biostatistics: A Foundation for Analysis in the Health Sciences by Wayne W. Daniel and Chad L. Cross
3. Statistical Methods for Practice and Research by Ajai S. Gaur and Sanjaya S. Gaur
4. Principles of Biomedical Ethics by Tom L. Beauchamp and James F. Childress
5. Medical Ethics: Accounts of Ground-Breaking Cases by Gregory Pence
6. Ethics and the Practice of Psychology by Gerald P. Koocher and Patricia Keith-Spiegel
7. Guide for the Care and Use of Laboratory Animals by Institute for Laboratory Animal Research (ILAR)
8. CPCSEA Guidelines on Laboratory Animal Facilities and Ethics
9. Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects

Semester-III

Program	Subject	Year	Semester
M. Pharm.	**Pharmaceutical Biotechnology**	2	III
Course Code	Course Title		Course Type
	JOURNAL CLUB		Core
Credit	Hours Per Week (L-T-P)		
	L	T	P
1	1	–	--

Maximum Marks	CIA	ESE
75	25	-

Learning Objective (LO):

The subject is designed to create an environment where students present a published research paper, and critically analyse it, that would enhance the communication, presentation and analytical skills of the students. This subject is designed to understand the advanced knowledge for research methodology, ethics in research, medical research, design, conduct and interpretation of results. This subject deals with principles of statistics and their applications in biostatistics involving parametric tests, non-parametric tests, correlation, regression, probability theory and statistical hypotheses.

Course Outcomes (CO):

CO No.	Expected Course Outcomes At the end of the course, the students will be able to :	CL
1	Organize and present complex research concepts effectively using audio-visual aids.	Ap
2	Develop strong communication and presentation skills in the context of scientific research.	Ap
3	Critically analyze published research papers and respond effectively to scientific queries and scrutiny	U
4	Understand and apply principles of research methodology, ethics, and biostatistics in research analysis.	An
5	Foster continuous self-learning and knowledge upgradation in advanced research techniques.	U

CL: Cognitive Levels (**R**-Remember; **U**-Understanding; **Ap**-Apply; **An**-Analyze; **E**-Evaluate; **C**-Create).

CO-PO/PSO Mapping for the course:

PO / CO	POs											PSO				
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	3	3	2	2	2	2	3	3	2	2	2	3	2	2	2	2
CO2	3	3	3	2	2	2	2	3	2	2	2	3	2	2	2	2
CO3	3	3	3	3	2	3	3	3	3	3	3	3	3	2	2	2
CO4	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
CO5	3	3	3	2	3	3	2	2	2	2	3	3	3	3	3	2

"3" – Strong; "2" – Moderate; "1"- Low; "-" No Correlation

Semester-III

Program	Subject	Year	Semester
M. Pharm.	**Pharmaceutical Biotechnology**	2	III
Course Code	Course Title		Course Type
	DISCUSSION / PRESENTATION (PROPOSAL PRESENTATION)		Core
Credit	Hours Per Week (L-T-P)		
	L	T	P
2	2	–	--

Maximum Marks	CIA	ESE
50	50	--

Learning Objective (LO):

The subject is designed to create an environment where students present a published research paper, and critically analyse it, that would enhance the communication, presentation and analytical skills of the students. This subject is designed to understand the advanced knowledge for research methodology, ethics in research, medical research, design, conduct and interpretation of results. This subject deals with principles of statistics and their applications in biostatistics involving parametric tests, non-parametric tests, correlation, regression, probability theory and statistical hypotheses.

Course Outcomes (CO):

CO No.	Expected Course Outcomes At the end of the course, the students will be able to :	CL
1	Understand the significance of clear vision and well-defined objectives in pharmaceutical research	Ap
2	Identify and analyze the key components of vision and objectives statements in research proposals.	Ap
3	Develop a comprehensive and coherent vision and objectives statement for pharmaceutical research projects.	U
4	Enhance scientific communication and presentation skills through proposal and final presentations.	An
5	Critically evaluate peer presentations and provide constructive feedback to improve research quality.	U

CL: Cognitive Levels (**R**-Remember; **U**-Understanding; **Ap**-Apply; **An**-Analyze; **E**-Evaluate; **C**-Create).

CO-PO/PSO Mapping for the course:

PO / CO	POs											PSO				
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	3	2	2	2	1	2	1	1	1	1	1	3	2	1	2	2
CO2	3	3	2	2	1	2	2	2	1	1	1	3	2	1	2	2
CO3	3	3	3	3	2	3	2	2	2	2	2	3	3	2	3	3
CO4	3	3	3	2	2	2	2	3	2	2	2	3	2	2	2	2
CO5	3	3	3	3	2	3	3	3	3	2	2	3	3	3	3	3

"3" – Strong; "2" – Moderate; "1"- Low; "-" No Correlation

Semester-III

Program	Subject	Year	Semester
M. Pharm.	**Pharmaceutical Biotechnology**	2	III
Course Code	Course Title		Course Type
	RESEARCH WORK		Core
Credit	Hours Per Week (L-T-P)		
	L	T	P
14	--	–	28

Maximum Marks	CIA	ESE
350	--	350

Course Outcomes (CO):

CO No.	Expected Course Outcomes At the end of the course, the students will be able to :	CL
1	Design, conduct, and analyze original pharmaceutical research to contribute to the advancement of knowledge in pharmacy	Ap
2	Apply theoretical and practical knowledge to solve real-world pharmaceutical problems, develop research hypotheses, and critically evaluate scientific literature	Ap
3	Develop research skills including study design, data collection, analysis, interpretation, and prepare scientific manuscripts and presentations	U
4	Demonstrate expertise in a specific pharmacy area and innovate new methodologies or technologies to improve pharmaceutical practice and patient care.	An
5	Effectively communicate and present research findings through scientific writing, posters, and oral presentations to prepare for research and academic careers.	U

CL: Cognitive Levels (**R**-Remember; **U**-Understanding; **Ap**-Apply; **An**-Analyze; **E**-Evaluate; **C**-Create).

CO-PO/PSO Mapping for the course:

PO / CO	POs											PSO				
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	3	3	3	3	2	3	2	2	2	2	2	3	3	2	3	3
CO2	3	3	3	2	2	3	2	2	2	2	2	3	3	2	3	2
CO3	3	3	3	3	3	3	3	2	2	2	2	3	3	3	3	3
CO4	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
CO5	3	3	3	3	3	3	2	3	3	3	3	3	3	3	3	3

"3" – Strong; "2" – Moderate; "1"- Low; "-" No Correlation

Semester- IV

Program	Subject	Year	Semester
M. Pharm.	**Pharmaceutical Biotechnology**	2	III
Course Code	Course Title		Course Type
	DISCUSSION / PRESENTATION (PROPOSAL PRESENTATION)		Core
Credit	Hours Per Week (L-T-P)		
	L	T	P
2	2	--	--

Maximum Marks	CIA	ESE
75	75	--

Learning Objective (LO):

The subject is designed to create an environment where students present a published research paper, and critically analyse it, that would enhance the communication, presentation and analytical skills of the students. This subject is designed to understand the advanced knowledge for research methodology, ethics in research, medical research, design, conduct and interpretation of results. This subject deals with principles of statistics and their applications in biostatistics involving parametric tests, non-parametric tests, correlation, regression, probability theory and statistical hypotheses.

Course Outcomes (CO):

CO No.	Expected Course Outcomes At the end of the course, the students will be able to :	CL
1	Understand the significance of clear vision and well-defined objectives in pharmaceutical research	Ap
2	Identify and analyze the key components of vision and objectives statements in research proposals.	Ap
3	Develop a comprehensive and coherent vision and objectives statement for pharmaceutical research projects.	U
4	Enhance scientific communication and presentation skills through proposal and final presentations.	An
5	Critically evaluate peer presentations and provide constructive feedback to improve research quality.	U

CL: Cognitive Levels (**R**-Remember; **U**-Understanding; **Ap**-Apply; **An**-Analyze; **E**-Evaluate; **C**-Create).

CO-PO/PSO Mapping for the course:

PO / CO	POs											PSO				
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	3	2	2	2	1	2	1	1	1	1	1	3	2	1	2	2
CO2	3	3	2	2	1	2	2	2	1	1	1	3	2	1	2	2
CO3	3	3	3	3	2	3	2	2	2	2	2	3	3	2	3	3
CO4	3	3	3	2	2	2	2	3	2	2	2	3	2	2	2	2
CO5	3	3	3	3	2	3	3	3	3	2	2	3	3	3	3	3

"3" – Strong; "2" – Moderate; "1"- Low; "-" No Correlation

Semester-IV

Program	Subject	Year	Semester
M. Pharm.	**Pharmaceutical Biotechnology**	2	III
Course Code	Course Title		Course Type
	RESEARCH WORK		Core
Credit	Hours Per Week (L-T-P)		
	L	T	P
31	--	–	16

Maximum Marks	CIA	ESE
400	--	400

Course Outcomes (CO):

CO No.	Expected Course Outcomes At the end of the course, the students will be able to :	CL
1	Design, conduct, and analyze original pharmaceutical research to contribute to the advancement of knowledge in pharmacy	Ap
2	Apply theoretical and practical knowledge to solve real-world pharmaceutical problems, develop research hypotheses, and critically evaluate scientific literature	Ap
3	Develop research skills including study design, data collection, analysis, interpretation, and prepare scientific manuscripts and presentations	U
4	Demonstrate expertise in a specific pharmacy area and innovate new methodologies or technologies to improve pharmaceutical practice and patient care.	An
5	Effectively communicate and present research findings through scientific writing, posters, and oral presentations to prepare for research and academic careers.	U

CL: Cognitive Levels (**R**-Remember; **U**-Understanding; **Ap**-Apply; **An**-Analyze; **E**-Evaluate; **C**-Create).

CO-PO/PSO Mapping for the course:

PO / CO	POs											PSO				
	1	2	3	4	5	6	7	8	9	10	11	1	2	3	4	5
CO1	3	3	3	3	2	3	2	2	2	2	2	3	3	2	3	3
CO2	3	3	3	2	2	3	2	2	2	2	2	3	3	2	3	2
CO3	3	3	3	3	3	3	3	2	2	2	2	3	3	3	3	3
CO4	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
CO5	3	3	3	3	3	3	2	3	3	3	3	3	3	3	3	3

"3" – Strong; "2" – Moderate; "1"- Low; "-" No Correlation

Semester wise credits distribution

Semester	Credit Points
I	26
II	26
III	21
IV	20
Co-curricular Activities (Attending Conference, Scientific Presentations andOther Scholarly Activities)	Minimum=02 Maximum=07*
Total Credit Points	Minimum=95 Maximum=100*

*Credit Points for Co-curricular Activities

Guidelines for Awarding Credit Points for Co-curricular Activities

Name of the Activity	Maximum Credit Points Eligible / Activity
Participation in National Level Seminar/Conference/Workshop/Symposium/ Training Programs (related to the specialization of the student)	01
Participation in international Level Seminar/ Conference/Workshop/Symposium/ Training Programs (related to the specialization of the student)	02
Academic Award/Research Award from State Level/National Agencies	01
Academic Award/Research Award from International Agencies	02
Research / Review Publication in National Journals (Indexed in Scopus / Web of Science)	01
Research / Review Publication in International Journals (Indexed in Scopus / Web of Science)	02

Note: International Conference: Held Outside India
International Journal: The Editorial Board Outside India

*The credit points assigned for extracurricular and or co-curricular activities shallbe given by the Principals of the colleges and the same shall be submitted to the University. The criteria to acquire this credit point shall be defined by the colleges from time to time.