M. Sc. Pharmaceutical Biotechnology

School of Life Sciences & Biotechnology,
C.S.J.M. University, Kanpur

Course Highlights:

The program Masters in Pharmaceutical Biotechnology at the Chhatrapati Shahuji Mahahraj University, Kanpur is being started from academic session 2022-23 to contribute to the fascinating and emerging role in drug discovery process and development of biologicals. This program is focused to imparting quality education and providing an excellent environment for training in the field of exploration of biotechnological aspects of the field of pharmacy and pharmaceutical industry. The program deals with an in depth study of the role and development of biotechnology based pharmaceuticals, hybridomas, pharmacogenomics, fermentation technology, biotech based drug discovery process and pharmaceutical biotechnology products as proteins, antibodies, r-DNA products etc. that find applications in Industrial areas.

In view of the Growing avenues in Pharma and Biotech based companies, in areas related to proteomics, microbiology, RDT & fermentation technology, this course will provide highly skilled manpower for production of different biotech and RDT based therapeutics, diagnostics and vaccines.

A student with Masters in Pharmaceutical Biotechnology can take up jobs in diverse fields such as Research and Development, biopharmaceuticals production with avenues in biotechnological companies like Biocon, Wockhardt, Lupin, Serum Institute, Panacea biotech, etc, Quality Control and Assurance of Biopharmaceuticals, Academics and Entrepreneurship.

Eligibility of course: Admission to M.Sc. Pharmaceutical Biotechnology program shall be open to a person who holds a B.Sc. with biology with at least 40% marks in aggregate or equivalent CGPA. (relaxation of 5% for SC/ST/Differently abled students).

Course Duration: 2 Years

13/05/2022

PROGRAM OUTCOMES (PO's)

[PO.1] Critical Thinking: Take informed actions after identifying the assumptions that frame our thinking and actions, checking out the degree to which these assumptions are accurate and valid, and looking at our ideas and decisions (intellectual, organizational and personal) from different perspectives.

[PO.2] Effective Communication: Speak, read, write and listen clearly in person and through electronic media in English and in one Indian language, and make meaning of the world by connecting people, ideas, books, media and technology.

[PO.3] Social Interaction: Elicit views of others, mediate disagreements and help reach conclusions in group settings.

[PO.4] Effective Citizenship: Demonstrate empathetic social concern and equity centred national development, and the ability to act with an informed awareness of issues and participate in civic life through volunteering.

[PO.5] Ethics: Recognize different value systems including your own, understand the moral dimensions of your decisions, and accept responsibility for them.

[PO 6] Research related skills: Will develop ability to identify problems, give justifications for solutions by lab investigations & critical analysis by using appropriate research related biological skills.

[PO.7] Environment and Sustainability: Understand the issues of environmental contexts and sustainable development.

[PO.8] Self-directed and Life-long Learning: Acquire the ability to engage in independent and life-long learning in the broadest context socio-technological changes.

PROGRAM SPECIFIC OUTCOMES (PSO's)

[PSO.1] To understand fundamental principles of molecular and cellular biology, biochemistry, bioinformatics, the 'omics technologies including proteomics, transcriptomic, metabolomics and bioprocessing.

[PSO.2] Detail understanding of theoretical and practical knowledge of all core and allied aspects of pharmaceutical sciences.

[PSO.3] Empower the students to acquire technological knowhow by connecting disciplinary and interdisciplinary aspects of pharmaceutical biotechnology.

[PSO.4] Recognize the importance of Bioethics, IPR, entrepreneurship, using statistical tools, Communication and management skills, written and oral reports, scientific publications so as to usher next generation of Indian biotechnologists.

Evaluation Scheme

Chhatrapati Shahuji Mahahraj University, Kanpur

Department of Life Science & Biotechnology

M. Sc. Pharmaceutical Biotechnology Semester – I

Choice Based Credit System (CBCS)

Course Code	Course Title	Type of Paper	Periods/ Week			Evaluation Scheme				Maximum Marks	Credits	Total Credit
			L	T	P	CT	TA	Total	ESE			
MPB-101	Fundamentals of Pharmaceutical Biotechnology	Core	2	0	0	15	10	25	75	100	3:1:0	4
MPB-102	Cell Biology	Core	2	0	0	15	10	25	75	100	3:1:0	4
MPB-103	Microbiology	Core	3	1	0	15	10	25	75	100	3:1:0	4
MPB-104	Biochemistry	Core	3	1	0	15	10	25	75	100	3:1:0	4
MPB-105	Microbiology & Biochemistry Lab	Practical	0	0	8	15	10	25	75	100	0:0:4	4
MPB-106	Project Work *1,2	Practical exposure								-	-	-
	Total									500		20

NOTE: In first year, student shall opt one minor elective paper from any other faculty of minimum 4 credits.

Chhatrapati Shahuji Mahahraj University, Kanpur

Department of Life Science & Biotechnology

M. Sc. Pharmaceutical Biotechnology Semester – II

Choice Based Credit System (CBCS)

Course Code	Course Title	Type of Paper	Periods			Evaluation Scheme				Maximum Marks	Credits	Total Credit
			L	T	P	CT	TA	Total	ESE			
MPB-201	Recombinant DNA Technology	Core	3	1	0	15	10	25	75	100	3:1:0	4
MPB-202	Immunology & Immunotechnology	Core	3	1	0	15	10	25	75	100	3:1:0	4
MPB-203	Molecular Biology	Core	3	1	0	15	10	25	75	100	3:1:0	4
MPB-204	Drug Discovery & Development	Elective	3	1	0	15	10	25	75	100	3:1:0	4
MPB-205	Toxicology											
MPB-206	RDT and Immunology Lab	Practical	0	0	8	15	10	25	75	100	0:0:8	4
MPB-207	Project Work*1,2	Practical exposure								100	0:0:8	8
MPB-208	Educational/ Industrial tour*3									Satisfactory / Unsatisfactory		
	Total									600		28

*** Note:**

1. Short term internship/ summer internship/industrial training mandatory for students in Ist yr.

2. Presentation and approval of synopsis for in-house research project in 2nd yr to be completed by end of 2nd semester

3. The students of M.Sc. Pharmaceutical Biotechnology have to undergo an educational/ industrial tour in microbiology/biotechnology/pharma based industry/ Research Institution for practical awareness at the end of second semester.

Chhatrapati Shahuji Mahahraj University, Kanpur

Department of Life Science & Biotechnology

M. Sc. Pharmaceutical Biotechnology Semester – III

Choice Based Credit System (CBCS)

Course Code	Course Title	Type of Paper	Periods/ Week			Evaluation Scheme				Subject Total	Credit Hours	Total credits
			L	T	P	CT	TA	Total	ESE			
MPB-301*	Bioanalytical & Separation Techniques	Elective	3	1	0	15	10	25	75	100	3:1:0	4
MPB-302*	Novel Drug Delivery Technology	Elective	3	1	0	15	10	25	75			
MPB-303*	Nanomedicine & Biomaterial technology	Elective	3	1	0	15	10	25	75	100	3:1:0	4
MPB-304	Biostatistics & Bioinformatics	Core	3	1	0	15	10	25	75	100	3:1:0	4
MPB-305	Entrepreneurship, IPR, Biosafety & Bioethics	Core	2	0	0	15	10	25	75	100	3:1:0	4
MPB-306	Bioanalytical, Pharmaceutics and Bioinformatics Lab	Practical	0	0	8	15	10	25	75	100	0:0:8	4
MPB307	Project Work*2	Practical exposure								-	-	-
	Total					90	60	150	450	500		20

** Any two of three electives to be chosen*

Chhatrapati Shahuji Mahahraj University, Kanpur

Department of Life Science & Biotechnology

M. Sc. Pharmaceutical Biotechnology Semester – IV

Choice Based Credit System (CBCS)

Course Code	Course Title	Type of Paper	Periods/ week			Evaluation scheme				Subject Total	Credit	Total Credits
			L	T	P	CT	TA	Total	ESE			
MPB-401	Biopharmaceutics & Pharmaco-kinetics	Core	3	1	0	15	10	25	75	100	4:1:0	5
MPB-402*	Analysis, Diagnostics & cell based screening	Elective	3	1	0	15	10	25	75	100	4:1:0	5
MPB-403*	Protein Engineering	Elective	3	1	0	15	10	25	75	100	4:1:0	5
MPB-404*	Omics technologies	Elective	3	1	0	15	10	25	75	100	4:1:0	5
MPB-405*	Biochemical Engineering	Elective	3	1	0	15	10	25	75	100	4:1:0	5
MBM 3005M*	Molecular Medicine	Elective	3	1	0	15	10	25	75	100	4:1:0	5
MPB-406	Project Work		-							100	8	8
	Total									500		28

** Any three electives to be chosen*

Evaluation scheme for the Project Work:

	Course Code	Dissertation	Presentation	Viva/Discussion	Total
Project Work	MPB- 406	30	30	40	100

Credit Précis

S.No.	Semester	Total Marks	Total Credit
1	I	500	20
2	II	600	28
3	III	500	20
4	IV	500	28
Grand Total	-	**2100**	**96**

NOTE: In first year, student shall opt *one minor elective paper from any other faculty* of min. 4 credits, thereby amounting to a total of 100 credits.

MPB101 Fundamentals of Pharmaceutical Biotechnology

Course Objectives:
This course imparts a basic and fundamental understanding of pharmaceutical biotechnology.

Course Objectives: Upon completion of the course, student shall be able to

1. Understand the importance of immobilized enzymes in Pharmaceutical industries.
2. Understand genetic engineering applications in relation to production of pharmaceuticals.
3. Understand importance and medical applications of monoclonal antibodies
4. Learn about the production of bio-therapeutics and immunotherapy
5. Appreciate the use of microorganisms in fermentation technology

SYLLABUS:

Unit I: Introduction to Pharmaceutical Biotechnology

Brief introduction to Biotechnology with reference to Pharmaceutical Sciences, Enzyme immobilization and applications, Biosensors in Pharmaceutical Industries, Concepts of Protein Engineering, Microbes for Enzyme production- Amylase, Penicillinase

Unit II: Genetic engineering and application in medicine

Identification and Cloning of Antigens with Vaccine Potential - DNA/Oligonucleotide Hybridization, Hybrid Selection and Cell-free Translation, Expression cloning and Genomic Sequencing, Analysis of Vaccine Antigens - B-cell Epitopes and T-cell Epitopes, Protein or Cytokines - recombinant antibodies, Interferon, Vaccines - hepatitis-B, Generation of Subunit Vaccines etc., Hormones - Growth hormones, Insulin, Interleukin.

Unit III: Immunity

Innate Immunity and Adaptive Immunity - Humoral immunity, Cellular immunity, Structure of Immunoglobulins, Structure and Function of MHC, Hypersensitivity reactions, Immune stimulation and Immune suppressions.

Unit IV: Production of Bio-therapeutics and Evaluation Assays:

General method of the preparation of bacterial vaccines, toxoids, viral vaccine, antitoxins, serum-immune blood derivatives and other products relative to immunity, Storage conditions and stability of official vaccines, Hybridoma technology- Production, Purification and Applications, Blood products and Plasma substitutes, Immunoblotting techniques- ELISA, Western blotting, Neutralization Assays.

Unit V: Microbial Bioprocess and large scale production of Biopharmaceuticals

Microbial genetics including transformation, transduction, conjugation, plasmids and transposons, Fermentation methods and general requirements, study of media, equipments,

sterilization methods, aeration process, stirring, Introduction to Microbial biotransformation and applications, Large scale production fermenter design and its various controls, Study of the production of - penicillins, Griseofulvin etc.

Recommended Books:

1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of Recombinant DNA: ASM Press Washington D.C.
2. RA Goldshy et. al.,: Kuby Immunology.
3. J.W. Goding: Monoclonal Antibodies.
4. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal Society of Chemistry.
5. Zaborsky: Immobilized Enzymes, CRC Press, Degraland, Ohio.
6. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.
7. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi

MPB102 Cell Biology

Course Objectives:
This course imparts in depth knowledge of cell structure, functions and cellular processes including the signaling pathways involved in growth and development. Also the course connects the cellular functioning with the application of technology and molecular genetics, enabling the students to explore and identify novel research leads for the greatest benefit of mankind.

Course Outcomes (CO): Upon completion of the subject student shall be able to-

1. Students will understand the structure and function of basic components (membranes & organelles) of prokaryotic & eukaryotic cells, and transport of molecules and ions across cells.
2. Students will understand cellular components underlying cell division and cell cycle.
3. Students will learn about cell communication and signaling through distinct signaling pathways that will help them to discover novel therapeutic targets/agents.
4. Students will understand pathways and mechanisms of intracellular protein targeting.
5. They will be able to understand the procedure of RDT based technologies cell culture and their various applications for humankind.

SYLLABUS:

UNIT I: Ultrastructure and Organization of eukaryotic cell: Structural organization of Cytoskeleton (Microtubules, Microfilaments, actins etc.); Structure and functions of cell membrane, Transport across cell membrane: Diffusion, Facilitated diffusion, Active transport.

UNIT II: Cell division and cell cycle: Mitosis and Meiosis; Cell cycle: Check points, role of cyclin and cyclin dependent kinases in its regulation, Programmed cell death, aging and senescence.

UNIT III: Cell communication and signaling: Cell - cell and cell – extracellular matrix interactions: Plasmodesmata, Gap junction, Tight junction, Adherens, Cohesin, Elastin, Collagen, Fibronectins, Laminins, Integrins; Basics of signal transduction: Role of calcium, cAMP, G-protein, inositol phosphates, phospholipases and protein kinases in signal transduction.

UNIT IV: Protein traffic in cells: Protein sorting and signal sequences; protein translocation in ER and vesicular transport to Golgi, lysosomes and plasma membrane; protein import into nuclei, mitochondria, chloroplasts and peroxisomes.

UNIT V: Applied Cell Biology: Basic techniques in mammalian cell culture; Cell culture media; Serum free media; maintenance of the culture and cell lines; Cloning in mammalian cells; transgenics, viral vectors, Stem cell and their applications, gene knockout technology.

References

Bruce Alberts, Alexander Johnson, Julian Lewis, Martin Raff, Dennis Bray, Karen Hopkin, Keith Roberts, Peter Walter "Essential Cell Biology"
Baltimore "Molecular Cell Biology"
Bruce Alberts, Alexander Johnson, Julian Lewis, Martin Raff, Keith Roberts, Peter Walter "Molecular Biology of the Cell"
Lodish H, Baltimore D, Berk A, Zipursky SL, Matsudaira P, Darnell J. (1995) Molecular cell biology.
Cooper ""Molecular Cell Biology"
Karp & Karp "Molecular Cell Biology"

MPB103 Microbiology

Course Objectives: The objectives of this course are to introduce the students to the field of microbiology with emphasis on microbial growth, reproduction, microbial diversity, morphology and nutrition; basic techniques implied in microbiology including concept of aseptic work, isolation, identification, and cultivation of microbes from different habitats/sources especially for the production of alcohol antibiotics, vaccines, vitamins, enzymes etc.

Course Outcome: Upon completion of the course student shall be able to

1. Understand how to identify and classify various microorganisms.
2. Understand methods for isolation, study, cultivation and preservation of various microorganisms
3. Learn about various microbes and understand the importance and implementation of sterilization in pharmaceutical processing and industry
4. Learn mode of action, resistance, standardization of antibiotics and about prebiotics and probiotics.
5. Learn about preservation of Pharmaceutical products.

SYLLABUS:

Unit I Microbial classification & identification: Introduction to Prokaryotes and Eukaryotes Microbial taxonomy, recent criteria used in microbial taxonomy including numerical taxonomy and methods based on genetic relatedness, rRNA based phylogenetic relationship. Identification of bacteria by staining (simple, Gram's & Acid fast staining) and biochemical tests (IMViC).

Unit II Study and cultivation of bacteria: Study of different types of (phase contrast and electron) microscopy, Study of ultra-structure and morphological classification of bacteria, nutritional requirements, culture media and growth, isolation and preservation methods for pure cultures, cultivation of anaerobes, quantitative measurement of bacterial growth (total & viable count). Biofilms, Quorum sensing.

Unit III Study of fungi, viruses and sterilization: Study of morphology, classification, reproduction/replication of Fungi (yeast) and Viruses (TMV, Retroviruses- HIV, Influenza virus). Classification and mode of action of disinfectants Factors influencing disinfection, antiseptics and their evaluation. Sterilization. Evaluation of efficiency of sterilization methods. Equipments employed in large scale sterilization. Sterility indicators Sterility testing of products (solids, liquids, ophthalmic and other sterile products) according to IP, BP and USP. Designing of aseptic area, laminar flow equipments; study of different sources of contamination in an aseptic area and methods of prevention, clean area classification. Principles and methods of different microbiological assay.

Unit IV Antibiotics: classification, mode of action and antibiotic resistance, Methods for standardization of antibiotics, vitamins and aminoacids. New antibiotic assessment. Prebiotics and probiotics.

Unit V Spoilage & Preservation: Types of spoilage, factors affecting the microbial spoilage of pharmaceutical products, sources and types of microbial contaminants, assessment of microbial contamination and spoilage. Preservation of pharmaceutical products using antimicrobial agents, evaluation of microbial stability of formulations.

Reference Books:

Madigan MT, Martinko JM, Parker J. (1997) Biology of Microorganisms, Prentice Hall International Inc.
Pelczar Jr. MJ, Chan ECS, Krieg NR (1993). Microbiology – Mc Graw Hill. Inc, New York.
Stanier RY, Ingraham JL, Wheelis ML, Painter PR (1992). General Microbiology, Mac Millan Education Ltd. London.
Tauro T, Kapoor KKT, Yadav S. (1997) An Introduction to Microbiology, Haryana Agricultural University, Hissar, Prentice Hall of India Pvt. Ltd., Delhi.
Crueger and A Crueger; (English Ed.; TDW Brock); Biotechnology: A textbook of Industrial Microbiology; Sinaeur Associates; 1990.
G Reed; Prescott and Dunn's; Industrial Microbiology; 4th Ed.; CBS Publishers; 1987.

MPB104 Biochemistry

Course Objectives:

The course aims to provide students with an understanding of biomolecules, the basic building blocks of living organisms, their structural underpinnings, unique properties, biological roles, and functions and metabolic pathways. Emphasis is on the association between structure and function of various biomolecules at a chemical level with a biological perspective.

Course Outcomes (CO): Upon completion of the subject student shall be able to understand

1. Significance of physiological buffer, bioenergetics & mitochondrial respiratory chain reactions
2. To study the structure and metabolic pathways of carbohydrates and their regulation.
3. To study the structure, metabolic pathways and regulation of amino acids and proteins.
4. To understand purine and pyrimidine nucleotide structure, metabolism & regulation.
5. Structure, biosynthesis and degradation of triglycerides, fatty acids and phospholipids.

SYLLABUS:

UNIT I: Structure and properties of water. Buffers-Acid Base in biological system. Henderson-Hasselbach equation. Biological importance of Buffers. Bioenergetics-Laws of thermodynamics, standard free energy, enthalpy, and entropy. Exergonic and endergonic reactions. Role of high energy compounds. Electron transport chain (ETC)-Components and reactions. Oxidative phosphorylation, P/O ratio. Inhibitors of ETC and uncouplers of oxidative phosphorylation.

UNIT II: Carbohydrates: Classification, structure, properties and biological functions of homo polysaccharides and heteropolysaccharides. Structure and biological importance of glycosaminoglycans and proteoglycans. Carbohydrate metabolism-Glycolysis, Citric acid cycle, Glycogenesis, Glycogenolysis, Gluconeogenesis and their regulatory mechanisms.

Unit III: Amino acids and Protein: Structure, Classification and properties of amino acids. Fibrous and Globular proteins and their functions. Structure of proteins and peptide bond. Ramachandran plot. Levels of organization of proteins. Metabolism of amino acids-glucogenic and ketogenic amino acids. Transamination, deamination and decarboxylation reactions. Urea cycle and its regulation.

UNIT IV: Nucleic acids: Structure of purine and pyrimidine bases. Nucleosides and Nucleotides. Structure of DNA. Physical properties - Buoyant density, viscosity, hypochromicity, denaturation and renaturation. Cot curve and C-value paradox. Purine metabolism-Biosynthesis (de novo and salvage pathway) & degradation of purine nucleotides. Pyrimidine metabolism-Biosynthesis and catabolism.

UNIT V: Lipids: Structure, classification, properties and biological functions of fatty acids. Role of lipoproteins in biological system. Biosynthesis of phospholipids, glycolipids, Steroids-types structure and functions. Triglycerides-Biosynthesis, degradation and functions. B-oxidation of fatty acids.

References:

1. Textbook of Biochemistry by D. Voet and J. G. Voet, 3rd Edition (2004), Publisher: J. Wiley & Sons.
2. Harper's Illustrated Biochemistry 28th edition (2009), Publisher: McGraw-Hill Companies.
3. Biochemistry by L. Stryer, 4thEdition (2014), Publisher: W H Freeman & Co, New York.
4. Lehninger Principles of Biochemistry by David L. Nelson and Michael M. Cox., 5th Edition (2012) Publisher: Freeman/Worth, New Delhi.
5. Biochemistry by U. Satyanarayana and U. Chakrapani, 4th edition (2013), Publisher: A division of Reed Elsevier India Pvt. Ltd., India.

MPB105 Microbiology & Biochemistry Lab

Course Objectives:
This course has been designed to provide the students a practical hand on various biochemical assays that are being used on regular basis in the biochemistry labs i.e. tests for carbohydrates, proteins, amino acids, cholesterol, DNA and RNA. In addition, student will also perform microbiology experiments i.e. detection of gram positive and negative bacteria, preparation on culture media sterilization and growth pattern in bacteria etc.

Course Outcome (CO): Upon completion of the subject student shall be able to

1. Know the principles and instruments used in microbiology and various techniques.
2. Learn and use pure culture techniques and enumerate microbes from soil samples
3. Know how to perform Gram staining, spore staining for bacteria, and fungal staining followed by microscopic examination and biochemical identification of bacteria
4. Know how to determine bacterial motility and isolate Rhizobium from nodules
5. Perform biochemical estimations of macromolecules in a given sample

LIST OF EXPERIMENTS:

1. Handling of microscopes, Calibration and measurement of microscopic objects
2. Pure culture techniques: serial dilution, pour plate, spread plate, streak plate methods.
3. Culture and microscopic examination of bacteria by staining methods - Gram's, capsule and spore staining.
4. Culture and microscopic examination of fungi by Lacto-phenol cotton blue staining.
5. Measurement of bacterial growth/growth curve.
6. Determination of MIC values (tube dilution and spot plate method)
7. Screening for antibiotic producing microbes
8. Microbiological examination of milk and milk products
9. Microbiological quality testing of milk (MBRT test)
10. Microbial examination of industrial waste water/sewage.Estimation of carbohydrates
11. Estimation of protein
12. Estimation of DNA
13. Estimation of RNA
14. Estimation of chlorophyll

Reference Books:

Cappuccino, JC & Sherman, N (1992). *Microbiology: A laboratory manual,* Addison Wesley Pub. Co
Benson HJ (1994). Microbiological Applications, WmC Brown Publishers, Oxford.
Collins C.H, Lyne P.M, (1985). Microbiological methods. Butterworths, London.
Rhodes P.M, Stanbury P.F. Applied Microbial Physiology - A practical approach. IRL Press, Oxford University Press, Oxford.
Wilson K, Walker J. (1995) Practical Biochemistry Principles and Techniques, Cambridge University Press
K.R. Aneja
Bergey's Manual of Determinative Bacteriology

MPB201 Recombinant DNA Technology

Course Objectives: The objectives of this course are to develop the understanding of Genetic Manipulations and introduce the concepts of different Enzymes, concept of Transformation, Gene Cloning and its expression, transgenic plants, animal, GMOs.

Course Outcome (CO): Upon completion of the subject student shall be able to

1. Learn about different enzymes used in genetic engineering for DNA manipulations
2. Have knowledge of different plasmid vectors and their characteristics
3. Have knowledge of different cloning vectors and their characteristics
4. Have knowledge of Transformation methods and their use in Genetic Engineering. Determine the selection parameters of r-DNA, creation of different gene libraries.
5. Sequencing techniques, mutagenesis, gene silencing, DNA amplification, DNA Sequencing

SYLLABUS:

UNIT I Enzymes in RDT: Restriction endonucleases: Class I, II & III restriction enzymes, Nomenclature, Isoschizomers, Heterohypekomers, Unit of restriction enzymes, Restriction digestion: partial and complete, Star activity; Homopolymer tailing, Synthetic Linkers, Adaptors; Roles of DNA ligase, T4 DNA polymerase, Alkaline phosphatase, Reverse transcriptase in cloning.

UNIT II Plasmids: Plasmid size range, Plasmid classification on basis of phenotypic traits: Cryptic, Fertility, Resistance, Bacteriocinogenic, Degradative, Virulence; Conjugative / non conjugative plasmids; Relaxed and stringent control of copy number; Plasmid incompatibility; Plasmid host range, Mobilizable plasmids and Triparental mating; Plasmid as cloning vector (recombinant plasmids): Properties of ideal plasmid cloning vectors, Plasmid vectors for *E. coli* and *Agrobacterium*; Transcriptional and translational fusion vectors; Selectable markers; Reporter genes.

UNIT III Cloning vectors: Phage lambda vector, *In vitro* packaging, Insertional and replacement vectors; Cosmid vectors; M13 phage; Phagemids; Yeast as cloning vector: Basic principles of development of yeast vectors; Artificial chromosomes: YACs, BACs and PACs.

UNIT IV Basic Techniques - I: Gene bank / Genomic library and cDNA library construction; Overview of techniques for recombinant selection and screening: Functional and nutritional complementation, Colony/ plaque hybridization, Plus-Minus screening, Immunological screening, HART, HAT.

UNIT V Basic Techniques - II: Rapid DNA sequencing techniques: Sanger method, Maxam and Gilbert procedure, automated DNA sequencing, pyrosequencing; Genomics: High throughput Sequencing: Microarray; Types, Principle & applications of PCR, Applications of PCR in gene cloning, TA cloning, pathogen diagnostics, environmental monitoring; Site directed mutagenesis; Overview of methods for DNA introduction in living cells, *Agrobacterium* mediated transformation, microprojectile bombardment, electroporation, microinjection; Antisense RNA technology; RNA interference.

References

Freifelder, DM "Molecular Biology".
Brown, TA "Genomes".
Rastogi &Pathak Genetic Engineering
Brown, T.A. "Gene cloning: An introduction"
Old & Primrose "Principles of Gene Manipulation"
Primrose, SB "Molecular Biotechnology"

MPB202 Immunology & Immunotechnology

Course Objectives:
The objective of the course is to apprise the students about components associated with immune system and molecular mechanism of their working. The course also deals with implications of deregulation of basic regulatory networks that lead to immune system related disorders. The students will be able to describe the roles of the immune system in both maintaining health and contributing to disease.

Course Outcomes (CO):
1. The student will learn the fundamental principles of immune response including molecular, biochemical and cellular basis of immune homeostasis
2. The course will aid in understanding various aspects of immunological response and how its triggered and regulated.
3. The student will understand the rationale behind various assays used in immunodiagnosis of diseases and will be able to transfer knowledge of immunology in clinical scenario.
4. The course will aid in understanding the principles of Graft rejection, Auto immunity and Antibody based therapy.
5. The student will develop the capacity for problem-solving about immune responsiveness, knowledge of the pathogenesis of diseases and designing of immunology-based interventions for effective treatment.

SYLLABUS:

UNIT I Fundamentals of Immunology: Fundamentals of Immunology: Cells and organs of immunity: Memory, specificity, diversity, self vs. non-self discrimination, Structure of primary and secondary lymphoid organs, Cell mediated vs. humoral immunity, T and B-lymphocytes; Nature of antigen and antibody: Antigen vs. Immunogen, Structure of antibody: constant and variable regions, Fab and Fc; isotype, allotype and idiotype; Abzymes.

UNIT II Antigen-antibody interactions: Antigen-antibody interactions and its measurement: Direct binding assays, Agglutination and precipitation, radioimmunoassay and ELISA, fluorescence analysis, Hybridoma technology, applications of monoclonal antibodies in biomedical research, clinical diagnosis and treatment

UNIT III Generation of diversity in the immune response: Generation of diversity in the immune response: Clonal selection theory-concept ofantigen specific receptors, genes encoding antigen specific receptors on T and B- lymphocytes, genetic rearrangement, class switch, Comparison of receptors and Band T lymphocytes.

UNIT IV Differentiation of B and T lymphocyte: Differentiation of B and T lymphocyte. Activation of T cells and B cells by antigen: Antigen processing, Antigen presentation to T cells, Products and factors released by T cell activation-interleukins, interferons, B cell activating factors, T cell and B cell interactions leading to antibody synthesis. Central role of major histocompatibility complex (MHC), genes and products in immune response: T cell recognition of antigen and MHC products, Structure of MHC gene complex and its products polymorphism of MHC gene products, Associated MHC functions- allograft, graft vs. host and mixed leucocyte responses.

UNIT V Tolerance vs. activation of immune response: Tolerance vs. activation of immune response. Complement- components of classical and alternative pathways. Hypersensitivity: Types I, II, III and IV responses. Autoimmunity.

References

Coleman, R.M, "Fundamental Immunology"
Richard A. Goldsby Thomas J. Kindt Janis Kuby Barbara A. Osborne "Immunology".
Peter Parkham Peter Parham "The Immune System".
Abul K Abbas, Andrew H. Lichtman, Abdul K. Abbas, Jordan S. Pober "Cellular & Molecular Immunology"
Janeway Charles A., Travers Paul, Walport Mark, Shlomchik Mark, Immunobiology LehningerAL "Principles of Biochemistry".

MPB203 Molecular Biology

Course Objectives:
The objective of the course is learning and understanding the fundamentals of molecular biology like nucleic acid as genetic material, replication, gene organization and its regulation etc. The application of the course lays the foundation to understand the disease processes.

Course Outcomes (CO): After the successful course completion, learners will:

1. Learn about nucleic acid as genetic information carriers, Possible modes of replication, and roles of helicase, primase, gyrase, topoisomerase, DNA Polymerase, DNA ligase, and Regulation of replication.
2. Understand the detailed mechanism and regulation of Eukaryotic DNA replication
3. Learn about mechanism and regulation of transcription in prokaryotes along with Reverse transcription.
4. Learn about the classes of DNA sequences, Genome-wide and Tandem repeats, Retroelements, Transposable elements, Centromeres, Telomeres, Satellite DNA, Minisatellites, Microsatellites; Applications of satellite DNA and Split genes.
5. Develop understanding of the movable genes, transposons and mechanism of transposition

SYLLABUS:

UNIT I Nucleic acid as genetic information carriers
Details of Griffith experiment, Avery, McLeod and McCarty experiment, Hershey and Chase experiment; Possible modes of replication: Details of Meselson and Stahl experiment; Prokaryotic DNA replication: Initiation, elongation and termination; Origin of replication; Roles, properties and mechanism of action of DnaA, Helicase, HD protein, Primase, DNA gyrase, Topoisomerase, DNA Polymerase, DNA ligase, Leading and lagging strands; Okazaki fragments; RNA primers; Regulation of replication; Fidelity of replication; □ or Rolling circle replication in ϕX174.

UNIT II Eukaryotic DNA replication
Initiation, elongation and termination; Multiple initiation sites; Autonomously replicating sequence; Significance of Origin recognition complex, Minichromosome maintenance proteins, DNA dependent DNA polymerases, Nucleases, DNA ligase and Telomeres in eukaryotic nuclear DNA replication; Regulation of eukaryotic DNA replication.

UNIT III Transcription in prokaryotes
Outline of the process - Initiation, elongation and termination; Prokaryotic promoter; DNA dependent RNA polymerase (RNA polymerase): Physical properties, X-Ray crystallographic structure, Subunits; Recognition of promoter; Binding and initiation sites; Melting of DNA; Direction of chain growth; Abortive initiations; Promoter clearance; Rho dependent and Rho independent termination of transcription; Sigma cycle; RNA - dependent DNA polymerase and Reverse transcription.

UNIT IV Classes of DNA sequences
Unique DNA sequences, Repetitive DNA sequences; Zero time binding DNA; Reasons for generation of reiterative DNA sequences; Highly repetitive and Moderately repetitive DNA sequences; Direct and Inverted repeats; Genome - wide and Tandem repeats; Overview of repetitive DNA sequences: Pseudogenes, LINEs, SINEs, Retroelements, Transposable elements, rRNA, tRNA and Histone genes, Centromeres, Telomeres, Satellite DNA, Minisatellites, Microsatellites; Applications of satellite DNA. Methods of distinguishing or separating double stranded and single stranded DNA; C-value and C-value paradox; Split genes: Exons and Introns

UNIT V Movable genes

Transposons: Simple and Composite transposons, Mechanism of transposition, Example of transposons: Ds/ Ac family of transposon, Ty of yeast, Copia, P and FB element of Drosophila, LINES and SINES.

References

Lewin "Genes"

- Freifelder, DM "Molecular Biology"
- Brown, TA "Genomes"
- Watson, JD "Molecular Biology of the cell"
- Twyman, R.M.Advanced Molecular Biology"
- Brown, TA"Gene cloning: An introduction"
- Old & Primrose "Principles of Gene Manipulation"
- Primrose, SB "Molecular Biotechnology"
- Jose B. Cibelli, Robert P. Lanza, Keith Campbell, Michasel D. West "Principles of Cloning"
- Voet & Voet "Biochemistry"
- Lubert Stryer "Biochemistry"

MPB204 Drug Discovery and Development

Course Objective: This course is designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

Course Outcomes: Upon completion of this course it is expected that students will understand:

1. Role of Computers in Pharmaceutical Research and Development
2. Optimization Techniques in Pharmaceutical Formulation
3. Computers in Clinical Development
4. Artificial Intelligence (AI) and Robotics
5. Computational Modeling of Drug Disposition

SYLLABUS:

Unit I: An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery. Target Discovery and validation-Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein micro arrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation.

Unit II Molecular docking: Rigid docking, flexible docking, manual docking; Docking based screening. Denovo drug design. Quantitative analysis of Structure Activity Relationship History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them.

Unit III a. Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fedvs. Fasted state, Invitro dissolution and in vitro-invivo correlation, Biowaiver considerations

b. Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.

c. Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems

Unit IV Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.

Unit V Computational Modeling Of Drug Disposition: Introduction, Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution, Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.

References:

1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.

2. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, Jelena Djuris, Woodhead Publishing

3. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.

MPB205 Toxicology

(From Pharmacy department)

Course Objective: The objective of this course is to impart a detailed understanding of the various aspects of studies carried out to study the toxicity of drugs.

Course Outcomes: Upon completion of this course it is expected that students will understand:

1. Regulations and ethical requirement for the usage in animal experimentation
2. Describe various newer screening methods involved in the drug discovery process
3. Correlate the preclinical data to human
4. Explain various types of toxicity
5. Importance of ethical and regulatory requirement for toxicity studies.

SYLLABUS:

Unit I Laboratory Animals and bioassay

Common laboratory 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. Bioassay-Principle, scope and limitations and methods.

Unit II Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive) Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y OECD principles of Good laboratory practice (GLP) History, concept and its importance in drug development.

Unit III Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. General principles of preclinical screening. CNS Pharmacology: behavioral and muscle co ordination, 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.

Unit IV Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines. Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies. Test item characterization- importance and methods in regulatory toxicology studies.

Unit V Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenecity studies(segment II). Genotoxicity studies (AmesTest, invitro and invivo Micronucleus and Chromosomal aberrations studies) Invivo carcinogenicity studies Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing.

References:

1. Biological standardization by J.H.Burn D.J. Finney and I.G. Goodwin
2. Screening methods in Pharmacology by Robert Turner.
3. Evaluation of drugs activities by Laurence and Bachrach
4. Methods in Pharmacology by Arnold Schwartz.
5. Fundamentals of experimental Pharmacology by M.N. Ghosh
6. Pharmacological experiment on intact preparations by Churchill Livingstone
7. Drug discovery and Evaluation by Vogel H.G.
8. Experimental Pharmacology by R.K. Goyal.
9. Preclinical evaluation of new drugs by S.K.Guta
10. Handbook of Experimental Pharmacology, SK. Kulkarni
11. Practical Pharmacology and Clinical Pharmacy, SK. Kulkarni,3rd Edition.
12. David R. Gross. Animal Models in Cardiovascular Research, 2nd Edition, Kluwer Academic Publishers, London, UK.
13. Screening Methods in Pharmacology, Robert A.Turner.
14. Rodents for Pharmacological Experiments, Dr. Tapan Kumar chatterjee.
15. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash
16.OECD test guidelines.
17. Principles of toxicology by Karen E. Stine, Thomas M. Brown.
18.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/guidance_compliance_regulatory_information/_guidances/_ucm073246.pdf)

MPB206 RDT & Immunology Lab

Course Objectives:
The lab is designed to train the students to use the immunology and molecular biology techniques for advanced genetic engineering practicals.

Course Outcomes (CO): Upon completion of the course, student shall be able to

1. Able to isolate and visualize plasmid DNA,
2. Prepare competent cells and carry out transformation and restriction digestion.
3. Capable of setting up PCR reactions, blotting (Southern and Northern) and separating proteins
4. by SDS-PAGE
5. Capable of identifying antigen & antibody interactions by double Immunodiffusion: Ouchterlony's Method, performing Immunoelectrophoresis and Enzyme Linked Immunosorbent Assay (ELISA) Learn how to design and scale up fermentation parameters.

LIST OF EXPERIMENTS:

1. Isolation of plasmid DNA from bacteria.
2. Size characterization of DNA by agarose gel electrophoresis.
3. Preparation of competent *E. coli* cells and transformation of plasmid DNA to the *E. coli* cells
4. Restriction digestion.
5. PCR amplification – demonstration.
6. Separation of proteins by SDS – PAGE and native gel.
7. To identify sensitivity of antigen & antibody by double Immunodiffusion: Ouchterlony's Method, Immunoelectrophoresis
8. Enzyme Linked Immunosorbent Assay (ELISA)
9. Immobilization (calcium alginate/ polyacrylamide/ glutaraldehyde) of whole cells and enzymes.
10. Organic acid/ alcohol/ enzyme production through fermentation, estimation of product, its separation and its purification
11. Design and scale-up of fermentation parameters

Reference Books

Ausubch FM, Brent R, Kingston, RE, Moore, D.D, Seidman J.G., Smith J.A and m Struhl K. (1994). Current Protocols in molecular biology

Brawshaw LJ. (1988). Laboratory Immunology, Sandders College Publishing.

Dharmalingam K. (1986). Experiments with M_{13}, Macmillan India Ltd. Chennai.

Gerhardt P, Murray RG, Wood WA & Kreig NR. (1994), Methods for general & molecular Bacteriology.

Gerhardt P, Murray RG, Wood WA and Kreig NR. (ed) (1994) Methods for General and Molecular Bacteriology – American Society for Microbiology, Washington D.C.

Hames BD & Rickwood D (1990) Gel Electrophoresis – a practical approach, Oxford Press, NY.

Harwod AJ. (1994). Protocols for Gene Analysis. Humana Press.

Lorian V. (1991) Antibiotics in Laboratory Medicine Williams & Wilkins.

Sambrook J and Russell DW (2001) Molecular cloning - A Laboratory manual (3rd edition Vols, 1,2,3). Cold Spring Harbor Laboratory). Cold Spring Harbor Laboratory Press, New York.

Westermeier R. (1993) - Electrophoresis in Practice – VCH – Federal Republic of Germany

Willett JE. (1991) Gas Chromatography John Wiley & Sons.

Wilson K and Walker. (1995) Practical Biochemistry Principles and Techniques, Cambridge Uni. Press.

MPB-207 Educational/Industrial Tour

The students of M.Sc. Pharmaceutical Biotechnology will undergo educational/Industrial tour in industry/research institution for practical awareness at the end of 2nd semester. The students have to submit the report of the visit based on which Satisfactory or Unsatisfactory non-creditable grades will be given to the students.

Course Objectives:
The main objective of this course is to provide the students an exposure to various research activities in the country and acquaint the student with state of the art technique/instruments used in various research institutions and industries of national repute. The student needs to submit a report after completion of the tour.

Course Outcomes

1. Develop understanding of state of the art techniques/instruments used in various reputed research institutions. and industries.
2. Take part in Group discussion and learn Team work.
3. Enhance communication and social skills by communication with peers.
4. Student shall be able to plan and improve the Technical Report writing skills
5. Have created Interest to pursue lifelong learning.

MPB301 BIOANALYTICAL & SEPARATION TECHNIQUES

(From Pharmacy Department)

Course Objective: the objective of this course is to impart practical knowledge for identification, characterization and quantification of drugs using suitable spectroscopic tools and chromatographic techniques.

Course Outcomes: Upon completion of this course it is expected that students will understand:

1. To understand the analytical tools for the identification, characterization and quantification of drugs
2. To select suitable analytical techniques for the qualitative and quantitative evaluation of drugs
3. To apply the theoretical knowledge of instruments for effective practical handling and use
4. To evaluate structure of organic compounds using suitable spectroscopic tools
5. To understand principles, instrumentation and application of various chromatographic techniques employed

SYLLABUS:

UNIT-I UV Visible spectroscopy

Electronic transitions, chromophores, auxochromes, spectral shifts, solvent effect on absorption spectra, Beer and Lambert's law, Derivation and deviations.

Instrumentation-Sources of radiation, wavelength selectors, sample cells, detectors-Photo tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode.

Applications- Spectrophotometric titrations, Single component and multi component analysis

IR spectroscopy

Introduction, fundamental modes of vibrations in poly atomic molecules, sample handling, factors affecting vibrations Instrumentation-Sources of radiation, wave length selectors, detectors-Golay cell, Bolometer, Thermocouple, Thermister, Pyroelectric detector and applications

UNIT-II Nuclear Magnetic Resonance spectroscopy

Principles of H-NMR and C-NMR, chemical shift, factors affecting chemical shift, coupling constant, Spin-spin coupling, relaxation, instrumentation and applications. **Mass Spectrometry**- Principles, Fragmentation, Ionization techniques –Electron impact, chemical ionization, MALDI, FAB, Analyzers-Time off light and Quadrupole, instrumentation, applications.

UNIT–III Introduction to chromatography

Thin layer chromatography- Introduction, Principle, Methodology, Rf values, advantages, disadvantages and applications. **Paper chromatography-**Introduction, methodology, development techniques, advantages, disadvantages and applications. **Electrophoresis–**Introduction, factors affecting electrophoretic mobility, Techniques of paper, gel, capillary electrophoresis, applications.

UNIT–IV

Gas chromatography - Introduction, theory, instrumentation, derivatization, Temperature programming, advantages, disadvantages and applications. **High performance liquid chromatography (HPLC)-** Introduction, theory, instrumentation, advantages and applications.

UNIT–V

Gel chromatography-Introduction, theory, instrumentation and applications **Affinity chromatography-**Introduction, theory, instrumentation and applications. **Radio immune assay :** Importance, various components, Principle, different

methods, Limitation and applications of Radio immunoassay.

Extraction techniques: General principle and procedure involved in the solid phase extraction and liquid-liquid extraction.

Text Book(s):

- Keith Wilson and John Walker Principles and Techniques of Biochemistry and Molecular Biology, Sixth Edition 2015
- Peter Atkins, Julio de Paula (2014) Atkins' Physical Chemistry, 10th Edition, Oxfod University Press, UK

Reference Books:

- Fifield F.W., 2016. Principles and Practice of Analytical Chemistry. Blackwell, Scientific Publishers.
- Marques MP, Batista de Carvalho LAE, Haris PI (2013) Spectroscopy of Biological Molecules Ed. IOS Press, Netherlands
- Avinash Upadhyay; Kakoli Upadhyay; Nirmalendu Nath 2015 Biophysical chemistry: (principles and techniques) Himalaya Pub. House Mumbai.
- Nag, A. 2016. Analytical Techniques In Agriculture Biotechnology And Environmental Engineering. Prentice Hall India, New Delhi.
- Philopose P.M. 2016. Analytical Biotechnology. Domihant Publishers & distributors, New Delhi.
- Lack, C. 2015. Ewing`s analytical instrumentation handbook. Marcel and Dekker Inc.
- Boyer, Rodney F. 2015 Biochemistry laboratory: modern theory and techniques. 2nd edition

MPB302 Novel Drug Delivery Technology

(From Pharmacy Department)

Course Objective: This course is designed to impart knowledge on novel strategies of drug delivery for drug targeting.

Course Outcomes: Upon completion of this course it is expected that students will understand:

1. To understand the concept, events and biological process involved in drug targeting
2. Apply latest drug delivery knowledge and think to develop new formulation based on the individual requirement.
3. To identify various targeting strategies including nanoparticles, liposomes, microspheres and their applications in disease management
4. Ability to communicate different types of Drug carrier used in the process of drug delivery which serves to improve the selectivity, effectiveness, and/or safety of drug administration.
5. Discuss the preparation and evaluation of polymeric nanoparticles and liposomes.

SYLLABUS:

Unit-I

Controlled drug delivery systems: Introduction, terminology/definitions and rationale, advantages, disadvantages, selection of drug candidates. Approaches to design controlled release formulations based on diffusion, dissolution and ion exchange principles. Physicochemical and biological properties of drugs relevant to controlled release formulations

Polymers: Introduction, classification, properties, advantages and application of polymers in formulation of controlled release drug delivery systems.

Unit-II

Microencapsulation: Definition, advantages and disadvantages, microspheres /microcapsules, microparticles, methods of micro encapsulation, applications

Mucosal Drug Delivery system: Introduction, Principles of bioadhesion /mucoadhesion, concepts, advantages and disadvantages, transmucosal permeability and formulation considerations of buccal delivery systems

Implantable Drug Delivery Systems: Introduction, advantages and disadvantages, concept of implants and osmotic pump

Unit-III

Transdermal Drug DeliverySystems: Introduction, Permeation through skin, factors Affecting permeation, permeation enhancers, basic components of TDDS, formulation approaches

Gastroretentive drug delivery systems: Introduction, advantages, disadvantages, approaches for GRDDS–Floating, high density systems, inflatable and gastroadhesive systems and their applications

Nasopulmonary drug delivery system: Introduction to Nasal and Pulmonary routes of drug delivery, Formulation of Inhalers (dry powder and metered dose), nasal sprays, nebulizers

Unit-IV

Targeted drug Delivery: Concepts and approaches advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications

Unit-V

Ocular Drug Delivery Systems: Introduction, intra ocular barriers and methods to overcome–Preliminary study, ocular formulations and ocuserts

Intrauterine Drug Delivery Systems: Introduction, advantages and disadvantages, development of intrauterine devices(IUDs) and applications

Recommended Books: (Latest Editions)

1. YW. Chien, Novel DrugDeliverySystems,2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.

2. Robinson, J.R., Lee V.H.L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.

3.Encyclopedia of Controlled Delivery. Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York. Chichester/ Weinheim

4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997(reprint in 2001).

5. S.P .Vyas and R.K. Khar, Controlled Drug Delivery -concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.

MPB303 Nanomedicine and Biomaterial Technology
(From Pharmacy Department)

Course Objective: This course is designed to provide students an in-depth knowledge on nanomedicine and biomaterials.

Course Outcomes: Upon completion of this course it is expected that students will understand:

1. Introduction and Basic Concepts on Polymers, Polymeric nanoparticles: the future of nanomedicine
2. Design concepts of nanomedicines, Characterization, challenges& Nanotoxicology
3. Understand the Morphogenesis & cell sources for biomaterials
4. Understand ECM Analogues, biomaterials, and Scaffolds, Biomimetics, fabrication technology
5. Use of In vitro tissue models for drug testing; engineered tissues

SYLLABUS:

Unit 1: Nanomaterials – Types and their applications in nanomedicine: Self-assembly as in proteins, lipids and nucleic acids; Polymeric nanoparticles; Inorganic nanoparticles- quantum dots, silica based nanostructures; metallic nanoparticles like silver and gold; nanotubes, nanowires and nanofibers; Physical, chemical and Biological means of synthesis; Biomimetic approaches of production: ferritins, silica in diatoms, FeNPs in magnetosomes; Merits and demerits of bio-based approaches; Strategies for chemical and biological functionalization; Applications in tissue engineering, and regenerative medicine.

Unit 2: Characterization, challenges & Nanotoxicology*:* Optical techniques like UV-Vis and fluorescence spectroscopy; FTIR spectroscopy; electron microscopy (TEM and SEM); Atomic Force Microscopy, dynamic light scattering, zeta potential measurement, XRD (with emphasis on how these techniques aid in characterizing nanoparticles).; SPR and SERS based imaging. Routes of exposure; Fate of nanoparticles- short and long term; Cellular interaction; environmental safety; Risk assessment and regulatory mechanisms.

Unit 3: Morphogenesis & cell sources for biomaterials: Morphogenesis and organ development in human; repair and regeneration; cell sources; stem cells and its types; Differentiation, differentiation and trans-differentiation; Intercellular communication- gap junctional and microvescular; Cell aggregation; adhesion dependence; Role of ECM in term of decellularized allo-/xeno-genic tissues in tissue engineering

Unit 4: ECM Analogues, biomaterials, and Scaffolds: Definition, ideal properties and types; biomimetics; Properties like -- mechanical property, wetability, biodegradability and surface

property; Types of polymeric nano-materials (natural and synthetic), ceramic composites and metallic. Definition, 3-dimentionality; porosity and pore-size; fabrication technology: conventional (such as electrospinning, phase separation, freeze drying, solution casting) and solid free form technology (such as stereolithography, 3D printing)

Unit 5: Bioactive molecules, and engineering of specific tissues: Types, growth factors, peptides, genes; *In vitro* tissue models for drug testing; regenerative templates; engineered tissues like musculoskeletal, nerve and cardiac; TE advances and current trends. TE Products: Regulatory guidelines, clinical trials and commercialization

Text Book(s):

1. Nanobiotechnology I: Concepts, applications and perspectives, eds. CM Niemeyer, CA Mirkin, Wiley-VCH Verlag GmbH & Co., KgaA, Weiheim (2015)
2. Nanobiotechnology II: More concepts, applications and perspectives, eds. CA Mirkin,CM Niemeyer Wiley-VCH Verlag GmbH & Co., KgaA, Weiheim (2015)
3. Palsson, Bhatia (2016) Tissue Engineering, Pearson Education India.
4. Robert P Lanza, Robert Langer, Vacanti JP (2013) Principle of Tissue Engineering, 4 thEdition, Academic Press

Reference Books:

5. Bionanotechnology: Lessons from Nature, David S. Goodsell, John Wiley & Sons - Science, ISBN: 978047146958 (2015)
6. Nanocarriers for Drug Delivery: Nanoscience and Nanotechnology in Drug Delivery, Mohapatra SS, Ranjan S, Dasgupta N, Mishra RK, Thomas S, Elsevier
7. Ravi Birla, (2014) Introduction to Tissue Engineering: Applications and Challenges, WileyIEEE Press.
8. Robert A. Brown, (2012) Extreme Tissue Engineering: Concepts and Strategies for tissue fabrication, Wiley Blackwell

MPB304 Bioinformatics and Biostatistics

Course Objectives:
The objective of this course is to understand the basics of the computer bioinformatics and statistical analysis.

Course Outcome (CO): Upon completion of the course, student shall be able to

1. Understand the Basics of computers.
2. Understand the biological data formats
3. Understand the mechanisms of sequence analysis.
4. Understand the biostatistics
5. Understand the correlation analysis

SYLLABUS:

UNIT I Basics of computers – block diagram of computer, input and output devices, storage devices, operating systems – DOS, Windows, Linux. Basics of networking and their types, topologies, INTERNET: TCP/IP, World Wide Web, e-mail etc.

UNIT II Biological data file formats: *.FASTA, *.PIR, *.GDE, *.PDB, Alignment files (*.ALN) etc. Search engines: ENTREZ, DBGET, SRS etc. Primary nucleotide sequence atabases: Genbank, EMBL, DDBJ; Primary Protein sequence databases: SwissProt, Protein information resources, TR-EMBL. Etc. Secondary databases: PROSITE, PRINTS, BLOCKS, PFAM.; Microbiology DATABASES: ICTV, AnimalVirusInformation System (AVIS).

UNIT III Sequence analysis –Pair wise Sequence Alignment: Needleman wunsch, Smith Watermann algorithms, Sequence similarity search programs – BLAST and FASTA. Substitution matrices: PAM, BLOSSUM. Multiple sequence alignments: Center Star method, Clustal, PRAS. **Phylogenetic analysis**: Character based (Parsimony) and distance based methods (UPGMA, neighbor joining), Protein structure prediction: Homology modeling, Primer Designing, Multi dimensional protein identification technology – identification using database.

UNIT IV Biostatistics: Measures of central tendency – mean (arithmetic, harmonic & geometric) median and mode; Measures of dispersion- range, quartile deviation, mean deviation and standard deviation. Coefficient of variation.

UNIT V: Correlation analysis: positive and negative correlation, Karl Pearson's coefficient of correlation, Spearman's rank correlation. Regression analysis: regression line Y on X and X on Y, angle between two regression lines. Test of significance: null and alternative hypothesis, level of significance, Z-test, Student't'-test, Chi-square test for goodness of fit and independence of attributes.

Reference Books

1. Developing Bioinformatics Computer Skills: Cynthia Gibas & Per Jambeck – 2001 –Shroff
2. Bioinformatics Basics: Applications in Biological Science and Medicine – 2002 - HH Rashidi & LK Buehler, CRC Press, London
3. Bioinformatics: Sequence, structure and databanks – 2000 - Des Higgins & Willie Taylor – Bioinformatics: A practical guide to the analysis of genes and proteins – 2001 - AD Baxevanis & BFF Ouellette – Wiley Interscience – New York
4. Biostatistics (1996) Arora PN & Malhon PK – Imalaya Publishing House, Mumbai.
5. Primer of Biostatistics – Stanton A & Clantz – The McGraw Hill Inc., New York.

MPB305 Entrepreneurship, IPR, Biosafety and Bioethics

Course Objectives:
This course is designed to impart knowledge and skills necessary to train the students to be onpar with the routine of Industrial activities in drug regulatory affairs. This course is designed to impart knowledge and skills necessary to train the students on entrepreneurship management.

Course Outcome: On completion of this course it is expected that students will be able to

1. Assist in Regulatory Audit process.
2. Understand the Regulatory requirements for contract research organization
3. Understand the Role of enterprise in national and global economy
4. Understand the dynamics of motivation and concepts of entrepreneurship
5. Understand the demands and challenges of Growth Strategies and Networking

SYLLABUS:

UNIT 1 Introduction to Indian Patent Law. World Trade Organization and its related intellectual property provisions. Intellectual/Industrial property and its legal protection in research, design and development. Patenting in Biotechnology, economic, ethical and depository considerations. Patent costs and values; and the post-grant processes for enforcing, Safeguarding IPR.

UNIT 2 Entrepreneurship: Selection of a product, line, design and development processes, economics on material and energy requirement, stock the product and release the same for making etc.The basic regulations of excise: Demand for a given product, feasibility of its production under given constraints of raw material, energy input, financial situations export potential etc.

UNIT 3 Bioethics – Necessity of Bioethics, different paradigms of Bioethics – National & International. Ethical issues against the molecular technologies.

UNIT 4 Biosafety– Introduction to biosafety and health hazards concerning biotechnology. Introduction to the concept of containment level and Good Laboratory Practices (GLP) and Good Manufacturing Practices (GMP). Safety guidelines of rDNA research; containment facilities and its disposal; Laboratory, industrial and environmental applications.

Suggested Readings

1. Hirsch RD & Peters MP, "Entrepreneurship," Tata McGraw Hill Publishers, New Delhi,2002.

2. Holt DH, "Entrepreneurship – New Venture Creation," Prentice Hall of India, 1999.

MPB306 Bioanalytical, Pharmaceutics and Bioinformatics Lab

Course Objectives: The objective of this course is to develop the understanding and basic knowledge of formulation development, bimolecular testing and bioinformatics.

The students will be able to summarize and present the existing data related to a specific topic in the form of a report. Every student will present a seminar on a topic related to theoretical or experimental, advanced topic.

Course Outcomes: Upon completion of the course, student shall be able to

1. Design transdermal batches and microspheres and calculate pharmacokinetic parameters from given data
2. separate amino acids and sugars by TLC and paper chromatography
3. Analyze HPLC and IR spectra data
4. Understanding basics of computers – basic commands – file creation, copying, moving & deleting in DOS & Windows. Internet - Using browsers – search engines and understanding use of various biological databases-GENBANK, EMBL, Swissprot – Protein Data Bank
5. Performing different types of sequence analysis queries in BLAST and FASTA. (Homology search), Multiple sequence alignments (Clustal) and Phylogenetic Analysis. (Phylip or Clustal) and Gene Prediction.

LIST OF EXPERIMENTS

1. To design and evaluation of transdermal patches containing diclofenac sodium
2. To calculate various pharmacokinetic parameters from the given blood data of IV infusion (one compartment model)
3. Formulation and evaluation of gelatin/albumin microspheres
4. Separation of amino acids by paper chromatography/ thin layer chromatography
5. Demonstration experiment on HPLC
6. Analysis and interpretation of active pharmaceutical ingredient by IR spectroscopy
7. Basics of computers – basic commands – file creation, copying, moving & deleting in DOS & Windows. Internet - Using browsers – search engines.
8. Using biological databases – GENBANK, EMBL, Swissprot – Protein Data Bank.
9. Different sequence analysis queries in BLAST and FASTA. (Homology search)
10. Multiple sequence alignments (Clustal) and Phylogenetic Analysis. (Phylip or Clustal)
11. Gene Prediction.

Reference Books

Gerhardt P. Murray RG, Wood WA, and Kreig NR (ed.) (1994) Methods for General and Molecular Bacteriology - American Society for Microbiology, Washington D.C.

Patrick R. Murray. (editor chief) (1999) Manual of clinical microbiology, 7th edition, ASM Press, Washington D.C.

Prakash M., Arora, C.K. (1998) Pathological techniques - Anmol Publications Pvt. Ltd. N.D.

Sambrook J, Fritsch EF, Maniatis T. (1989). Molecular coloning. Cold Spring Harbor Laboratory Press.

Sambrook J and Russell DW(2001) Molecular cloning - A laboratory manual (3rd edition, Vol 1,2,3), Cold Spring Laboratory Press, New York.

Ausubel FM (1994) Current protocols in molecular biology, Vol. 1 & 2. John Wicey & Sons Inc.

Laboratory manual for Pharmaceutical Technology and Biopharmaceutics Experiments, Bijaya Ghosh, Rajeshri Dhurke, CBS Publishers,
Experimental Biopharmaceutics and Pharmacokinetics, Prof. Dr. A. V. Yadav, Mr. V. B. Yadav, Mr. A. S. Shete, Nirali Publication

MPB401 Biopharmaceutics and Pharamcokinetics

(From Pharmacy Department)

Objectives: This subject is designed to impart knowledge and skills of Biopharmaceutics and pharmacokinetics and their applications in pharmaceutical development, design of dose and dosage regimen and in solving the problems arised therein.

Course Outcomes: Upon completion of the course student shall be able to:

1. Understand the basic concepts in biopharmaceutics and pharmacokinetics and their significance.
2. Use of plasma drug concentration-time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.
3. To understand the concepts of bioavailability and bioequivalence of drug products and their significance.
4. Understand various pharmacokinetic parameters, their significance & applications.
5. To understand the role of compartment models in elucidating the time course of plasma concentration of drug molecules in the body.

SYLLABUS:

UNIT-I Introduction Biopharmaceutics to Absorption; Mechanisms of drug absorption through GIT, factors influencing drug absorption though GIT, absorption of drug from Non per oral extra-vascular routes, Distribution Tissue permeability of drugs, binding of drugs, apparent, volume of drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs

UNIT-II Elimination: Drug metabolism and basic understanding metabolic pathways renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Nonrenal routes of drug excretion of drugs.

Bioavailability and Bioequivalence: Definition and Objectives of bioavailability, absolute and relative bioavailability, measurement of bioavailability, *in-vitro* drug dissolution models, *in-vitro-in-vivo* correlations, bioequivalence studies, methods to enhance the dissolution rates and bioavailability of poorly soluble drugs.

UNIT-III Pharmacokinetics: Definition and introduction to Pharmacokinetics, Compartment models, Non compartment models, physiological models, One compartment open model.

(a). Intravenous Injection(Bolus)

(b). Intravenous infusion and

(c) Extra-vascular administrations. Pharmacokinetics parameters-KE,t1/2,Vd,AUC,Ka, Clt and CLR -definitions methods of eliminations, understanding of their significance and Application.

UNIT-IV Multi compartment models: Two compartment open model. IV bolus Kinetics of multiple dosing, steady state drug levels, calculation of loading and Maintenance doses and their significance in clinical settings.

UNIT-V Nonlinear Pharmacokinetics: a. Introduction, b. Factors causing Non-linearity.
c. Michaelis-menton method of estimating parameters, Explanation with example of drugs.

Recommended Books:

1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.
2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
3. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4th edition,Prentice-Hall Inernational edition.USA
4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal,Vallabh Prakashan Pitampura, Delhi
5. Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc.
6. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
7. Biopharmaceutics; By Swarbrick
8. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
9. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company,Pennsylvania 1989.
10. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.
11. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvnia

PB402 Analysis, Diagnostics and Cell Based Screening

Course Objective: This course is designed to impart knowledge and skills necessary for the analysis, diagnostics and cell based screening of biologicals or biopharmaceutical products.

Course Outcomes: Upon completion of this course it is expected that students will understand:

1. Estimation of proteins and impurities in Pharmaceutical Research and Development
2. Methods and applications of DNA based diagnostics
3. High throughput screening
4. Cell viability and screening assays
5. Use of Yeast two hybrid system and GPCRs as targets for identification of drug molecules

SYLLABUS:

UNIT I

Total protein assay: Quantitative amino acids analysis, Bradford assay, Folin-Lowry protein assay, BCA assay, UV spectrophotometry, *etc.*

Purity: Protein impurities, contaminants, electrophoretic analysis, HPLC based analysis, DNA content analysis, Immunological assays for impurities, combined Immunological and electrophoretic methods, host-cell impurities, etc. ICH guidelines.

UNIT II

Principles, methods and applications of DNA-based diagnostics: DNA probe based diagnostics, sample preparation, hybridization, separation, detection, PCR-RFLP in paternity and forensic cases SNP detection MALDI and DHPLC.

Diagnostics: Cancer diagnostics, 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, Lateral flow assay.

UNIT I II

High-throughput screening: Requirements and parameters, Advantages and disadvantages of biochemical and cellular assays; miniaturization and automation, library based screening.

UNIT I V

Potency assays: In-vitro biochemical methods MTYT assay, assay for cell viability, cytotoxicity, necrosis, and apoptosis, cell line derived assays, whole animal assays, etc.

Cell-based screening assays: 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. Advantages over in vitro assays. Growth of

viruses in cell culture propagation and enumeration. In-vitro screening techniques- cytotoxicity, anti-tumor, anti-viral assays

UNIT V

Yeast two-hybrid system: Different Y2H systems, their advantages and disadvantages, examples.

GPCRs as targets: Identification of drug molecules; Important parameters: intracellular calcium, cAMP, β-arrestin, receptor internalization, reporter gene assays; orphan GPCRs; desensitization and internalization.

Reference Books:

1. J. Kubey, Immunology – an Introduction.
2. The immunoassay Handbook by David Wild

High Throughput Screening: The Discovery of Bioactive Substances by John Devlin

3. Practical Biochemistry: Principles and Techniques, by K. Wilson and J. Walker
4. R. Ian Freshney, Culture of animal cells – A manual of Basic techniques, 6th edition, Wileys publication house.
5. Principles of Biochemistry by Lehinger.
6. Biochemistry by L. Stryer Atul Prakashan.

MPB403 Protein Engineering

Course Objective: This course is designed to impart knowledge and skills necessary for the engineering of proteins.

Course Outcomes: Upon completion of this course it is expected that students will understand:

1. Basic concepts of protein engineering
2. Concept of peptidomimetics and rational drug design
3. Methods for protein identification and characterization
4. Strategies used for protein and DNA formulation
5. Methods for protein sequencing

SYLLABUS:

Unit I: **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. Various methods of purification of proteins, Peptides in drug development, Protein identification and characterization, Protein based formulations, Sequencing of proteins. Different methods for protein engineering, gene shuffling, and direct evolution, Site directed mutagenesis, Enzyme active site modification, Fusion protein or chimeric protein, Protein cyclisation, Split proteins, Chemical modification, Disulphides modification, Bioinformatics, Computer modelling, etc. Engineered protein as drugs or tool for therapy, Peptides in drug development.

Unit II: Peptidomimetics

Introduction and classification of peptidomimetics. 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.

Unit 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.

Unit IV: DNA and Protein formulation

Different strategies used in the formulation of DNA and proteins. Analytical and biophysical parameters of proteins and DNA in pre-formulation, Liposomes, PEGylation etc. Biological Activity, Biophysical Characterization Techniques, Forced degradation studies of protein.

Unit V: Methods of protein sequencing

Various methods of protein sequencing, characterization, Edman degradation, Tryptic and/or Chymotryptic Peptide Mapping.

Recommended Books:

1. H. Lodhishet. Al. Molecular Cell Biology, W. H. Freeman and Company
2. Protein Purification – Hand Book, Amersham pharmacia biotech
3. Engelbert Buxbaum, 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.

PB404 Omics Technologies

Course Objectives:
The course has been designed to make students aware of Genome sequencing, genome databases, Genome analysis, Proteomics and Metabolomics.

Course Outcome: On completion of this course it is expected that students will be able to

1. Get knowledge of genome sequencing and sequencing technology.
2. Gain knowledge about major genome databases and genome analysis.
3. Learn about basic proteomics technology.
4. Learn about the basics of technologies used in metabolomics.
5. Have knowledge of applications of genomics and proteomics in various fields of life.

SYLLABUS:

Unit-I Genome sequencing: Sanger sequencing, Pyrosequencing, Illumina/Solexa, SOLiD System. Pros and cons of sequencing Maxam-Gilbert sequencing, Whole shotgun genome sequencing.

Unit-II Structural & Functional Genomics: Classical ways of genome analysis, large fragment genomic libraries; Physical mapping of genomes; sequence assembly and annotation; Comparative genomics Functional genomics: DNA chips and their use in transcriptome analysis; Mutants and RNAi in functional genomics.

Unit-III Proteomics: Introduction to basic proteomics technology; Bioinformatics in proteomics; Proteome analysis. Proteomics classification. Yeast-two-hybrid system, cDNA microarrays 1D-SDS-PAGE, 2D-SDS PAGE. Detection and quantitation of proteins in gels. Pros and cons of various staining methods, Basics of mass spectrometry. MALDI TOFF and ESI, and their application in proteomics, Tandem MS/MS spectrometry, Peptide sequencing by tandem mass spectrometry, Affinity purification of protein TAP tag.

Unit-IV Metabolomics: Technologies in metabolomics, Role of Spectroscopy, Electrophoretic and Chromatographic techniques in metabolic profiling Nutrigenomics.

Unit-V Applications: Genomics & proteomics applications in agriculture, human health & industry.

Recommended Books: (Latest Editions)

1. O'Reilly, "Developing Bioinformatics Computer Skills".
2. Griffiths JF, "An Introduction to Genetic Analysis".
3. Hunter L, "Artificial Intelligence & Molecular Biology".
4. Gene Cloning and DNA Analysis: An Introduction, 6th Edition by T. A. Brown
5. Genomics & Proteomics: Functional and Computational Aspects by Suhai & Sándors,
6. Genomics and Proteomics: Principles, Technologies, & Applications by Devarajan Thangadurai and Jeyabalan Sangeetha
7. Genomics, Proteomics and Bioinformatics by Ira Milosevic and Nuno Raimundo
8. The Handbook of Metabolomics by Fan, Teresa Whei-Mei, Andrew N, Higashi, Richard
9. The Handbook of Metabonomics and Metabolomics by John C. Lindon, Jeremy K. Nicholson and Elaine Holmes

MPB405 Biochemical Engineering

Course Objectives:

The objective of the course is to enable students to design and optimize media for production of various bioproducts, study its kinetic behavior, perform material and energy balances for any biochemical process decide upon control strategies for process control.

Course Outcome: On completion of this course it is expected that students will be able to

1. Get knowledge of basics of thermodynamics of a biochemical reaction.
2. Gain knowledge about use of microbes appropriately for fermentation process.
3. Learn about designing bioreactor and scale up.
4. Learn about the basics of heat and mass transfer.
5. Have knowledge about downstream processing and commercial biopharmaceuticals.

SYLLABUS:

Unit 1: Thermodynamics and Biochemical Reaction*:* Thermodynamics: Laws; Internal Energy; Heat Transfer: Specific heat and latent heat of fusion / vaporization; pressure-volume relation; macrostates microstates; quasistatic and reversible process; PV diagrams and expansion. Biochemical Reaction: Reaction thermodynamics; Reaction yield, rate and kinetics calculation; Zero-order kinetics; First-order kinetics; Michaelis Menten kinetics; Determining enzyme kinetic constants.

Unit 2: Microbial Technology*:* Sterilization of air and medium: Different methods of sterilization; Kinetics of sterilization; batch and continuous sterilization; advantages and disadvantages thereof; Calculation of del factor and solving of numerical. Upstream process: Introduction to microbial growth, media formulation; sterilization, inoculum preparation. Microbial Growth Kinetics. Fermentation: Fermentation process design, operation and characteristics of fermentation processes; batch, fed-batch and continuous culture systems, instrumentation and bioprocess control.

Unit 3: Understanding Bioreactors for developing biopharmaceutics*: Bioreactor Design*: Bioreactor configurations; Stirred tank; Airlift reactor; Packed bed; Monitoring and control of bioreactors; Ideal reactor operation; Batch operation of a mixed reactor; Fed-batch and Continuous operation of a mixed reactor; Chemostat cascade; Continuous operation of a plug flow reactor; Detailed studies on the batch, continuous and fed-batch bioreactors. *Agitation*: Need, effect and types of agitation in fermentation; impeller design and relationship with fluid characteristics; flow behaviour etc. ***Aeration*:** Need and effect of aeration in fermentation; different types of aeration methods; aeration in high density fermentation; aeration in qualescence and non-qualescence medium; flow behaviour etc. ***Scale-up*:** Principles and criteria; Different methods and analysis; Instrumentation and control of bioprocesses**.**

Unit 4: Heat and Mass Transfer*:* *Heat Transfer*: Mechanisms; heat transfer between fluids, heat transfer coefficients Calculation; Heat transfer equipment; Steady state conduction; LMTD calculation; Relationship between heat transfers; Cell concentration and stirring conditions. Heat transfer and momentum transfer; Importance of dimensionless number in designing bioreactors, heat exchangers etc. *Mass Transfer*: Mass and energy balance in microbial processes; Resistance

in fermentation medium by oxygen; Role of Dissolved oxygen concentration in mass transfer; Determination of mass transfer co-efficient (KLa), Factors affecting KLa and relationship. Types of dimensionless analysis in mass transfer.

Unit 5: Downstream Processing & Industrial Examples of Biopharmaceutics: Downstream process: Introduction to downstream process operations in biopharmaceutical manufacturing. Biotechnology in pharmaceutical industry: Major areas as antibiotics, vaccines, diagnostics, antibodies, biopharmaceuticals (insulin, interferon, GSF, CSF and therapeutic proteins etc.); commercial aspects, priorities for future biotechnological research. Industrial enzymes in drug development: Penicillin amidase, lipase, oxidoreductase, nitrilase, protease etc.; use of all these enzymes for enantioselective synthesis of pharmaceutically important drugs/drug intermediates, future directions.

Text Book(s):

1. Michael L. Shuler, FikretKargi, Matthew DeLisa (2017). Bioprocess Engineering, 3rd Edition, Prentice Hall International Series.
2. Pauline M Doran (2013) Bioprocess Engineering Principles. 2nd Edition. Academic Press.
3. Treybal RE (2012) Mass Transfer Operations, 3rd Edition, McGraw-Hill

Reference Books:

1. Peter Stanbury, Principles of Fermentation technology 2015, third edition, Butterworth-Heinemann
2. Shigeo Katoh and Fumitake Yoshida, Biochemical Engineering (2010), A Textbook for
3. Engineers, Chemists and Biologists, WILEY-VCH Verlag GmbH & Co. KGaA, Weinheim
4. Warren McCabe, Julian Smith, Peter Harriott (2005) Unit Operations of Chemical Engineering, McGraw Hill Chemical Engineering Series 7th Edition.
5. Alan S. Foust, Leonard A. Wenzel, Curtis W. Clump, Louis Maus, L. Bryce Andersen (2008) Principles Of Unit Operations, 2Nd Ed, John Wiley & Sons
6. Theodore L Bergman, Adrienne S Lavine, Frank P Incropera, David P DeWitt (2011) Fundamentals of Heat and Mass Transfer, 7th Edition, Willey.

MBM 3005 Molecular Medicine

Course Objectives:
The objective of the course is to enable students to understand the molecular basis of diseases and use of molecules as diagnostics or therapeutics.

Course Outcome: On completion of this course it is expected that students will be able to

1. Get knowledge of the molecular basis of diseases.
2. Gain knowledge about use of molecular diagnostic techniques.
3. Learn about signal transduction and its role in human diseases.
4. Learn about various modern and traditional therapeutic strategies.
5. Have knowledge about molecular mechanism and challenges of various diseases.

SYLLABUS:

Unit – I Molecular basis of diseases-Human genetics relevant to diseases, DNA polymorphism, Single (Cystic fibrosis, Huntington's diseases, Familial hypercholesterolemia, Dunchenne muscular dystrophy, red-green colour blindness, Tay-Sachs's diseases, Pearsons' syndrome & Xeroderma pigmentosum) and polygenic diseases (Asthma and Diabetes Mellitus), Omics, Genetic and physical mapping of human genome and identification of genes in diseases.

Unit – II Molecular Diagnostic Technologies: PCR-Based Methods, DNA finger printing, Next generation sequencing techniques, Microarray Approaches to Gene Expression Analysis-CGH, Prenatal and postnatal genetic tests-Fluorescence In situ hybridization.

Unit – III Signal transduction and its role in human diseases, Cellular & tissue microenvironment in diseases, Defects in G protein-coupled signal transduction in human disease, NF-kB, TGFβ, Wnt-β, MAPK & The serine–threonine kinase Akt signaling pathways in human diseases, JAK-STAT signaling in asthma. Inhibiting signaling pathways through rational drug design.

Unit – IV Therapeutic Strategies: Mechanism of action and clinical application of Antisense Oligonucleotides, Ribozymes and medical applications, RNA interference: Mechanism, delivery and preclinical applications, MicroRNAs and disease-Aptamers-Gene therapy: types, methods of gene transfer, Applications -AYUSH, Plants and microbes as sources of natural metabolites, Establishing bioactive potential & screening of natural compounds against different targets, Healing herbs in Traditional medicinal system (*Butea monosperma, Curcuma longa* & *Yukyung Karne*).

Unit – V Molecular Mechanism and Challenges: Breast cancer & its subtypes, HER2 targeted therapy- HIV; diagnostics, strategies for treatment and vaccines- Heart failure and cardiac repair-Human African trypanosomiasis of the CNS- Dengue, Influenza Virus-Human embryonic stem cells for regenerative medicine. Antimicrobial resistance (*S. aureus*)- Multidrug resistance issues

References:

1. Jens Kurreck & Cy A. Stein, Molecular Medicine an Introduction, 2016, Wiley-VCH Verlag GmbH & Co. KGaA, Germany.
2. Andrew R.Marks & Ushma S Neill, Text book of Molecular Medicine2010, Jones & Bartlett Publishers, New Delhi.
3. Elles, R., Mountfield, R. (2011). Molecular Diagnosis of Genetic Diseases. Springer Publication.

MPB106/MPB207/MPB307/MPB406 Project Work

Course Objectives:

The main objective of this course is to develop independence in experimental design and interpretation and to develop research skills. To promote education and research in biotechnology and provide academic and professional excellence for immediate productivity in industrial, governmental, or clinical settings for an ultimate benefit of society and environment.

Course Outcomes (CO)

1. Perform literature review, identify state of the art in that field.
2. To be able define the problem and develop synopsis of a defined research problem.
3. Establish a methodology using advanced tools / techniques for solving the problem including project management and finances.
4. To prepare the research report and its oral demonstrations.
5. Have gained practical experience in project management in pharma or biotechnological industry, be able to use various techniques in contemporary research for project, perform numerical analysis and interpret the results.

18/05/2022