INSTITUTE OF CHEMICAL TECHNOLOGY

MASTER OF TECHNOLOGY
IN
PHARMACEUTICAL BIOTECHNOLOGY

REVISED SYLLABUS
2020-2021

M Tech. Pharmaceutical Biotechnology Syllabus 2020

Semester- I

No.	Contents	Course Code	Subjects	Hours/Week (L+T)	Marks	Credits
1.	Core I	PBT2201	Fundamentals of Pharmaceutical Biotechnology	**(2+1)**	**50**	**3**
2.	Core II	PBT 2202	Analytical and Biophysical techniques	**(2+1)**	**50**	**3**
3.	Core III	PBT 2203	Plant and Animal cell technology	**(2+1)**	**50**	**3**
4.	Core IV	PBT 2204	Bridging course in A: Biotechnology B:Biochemical engineering	**(2+1)**	**50**	**3**
5.	Elective I			**(2+1)**	**50**	**3**
6.	Seminar and Critical Review	PBT 2214	Project – I (Seminar and Critical Review)	**6**	**50**	**3**
7	Practical	PHP 2201	Laboratory I- Instrumental Methods of Analysis	**6**	**50**	**3**
8	Research I	PBT 2215	Research I	**12**	**100**	**6**
TOTAL				**39**	**450**	**27**

Semester- II

No.	Contents	Course Code	Subjects	Hours/Week (L+T)	Marks	Credits
1.	Core V	PHT 2101	Research Methodology	**(2+1)**	**50**	**3**
2.	Core VI	PBT 2205	Immunotechnology	**(2+1)**	**50**	**3**
3.	Core VII	PBT 2206	Formulation of Biologicals	**(2+1)**	**50**	**3**
4.	Core VIII	PBT 2207	Enzyme technology	**(2+1)**	**50**	**3**
5.	Elective II			**(2+1)**	**50**	**3**
6.	Practical	PHP 2202	Laboratory II- Microbiology, Molecular biology and Immunology	**6**	**50**	**3**
7.	Research II	PBT 2216	Research II	**18**	**150**	**9**
TOTAL				**39**	**450**	**27**

Semester- III

No.	Course	Hours/Week	Marks	Credits
PBT 2219	**Research III**	**40**	**450**	**30**
TOTAL		**40**	**450**	**30**

Compulsory In-Plant Training for 12 weeks
(Treated as Audit Course - Certificate from Industry to be provided)

Semester- IV

No.	Course	Hours/Week	Marks	Credits
PBT 2220	Research, Thesis and Open defense	**40**	**450**	**30**
TOTAL		**40**	**450**	**30**

Syllabus for Semester I

PBT2201 Fundamentals of Pharmaceutical Biotechnology

Sr. No.	Topic	H (L + T)
1	Biotechnology in the Pharmaceutical Industry (Pre-biotechnology products, impact of biotechnology, post-biotechnology products: biologics and biopharmaceuticals)	3 + 1
2	Cells and cellular processes: Universal features of cells; cell chemistry and biosynthesis: chemical organization of cells; internal organization of the cell - cell membranes; Cell cycle and its regulation; cell division: mitosis, meiosis and cytokinesis; cell differentiation: stem cells, their differentiation into different cell types and organization into specialized tissues; Cell-ECM and cell-cell interactions; cell receptors and trans-membrane signaling; cell motility and migration; cell death: different modes of cell death and their regulation	2 + 1 2 + 1
3	Genetic manipulation methods: Genetic manipulation in bacterial, plant and animal cells: Natural recombination in bacterial cells, Principles of Recombinant DNA Technology; Vectors and types, expression systems, molecular biology methods to study recombinant biomolecules, Plant Transformation methods: Agrobacterium mediated transformation; Hairy root culture; Plant products of industrial importance, Production of secondary metabolites; Accessing germline of animals; transfection methods of animal cells, Non-transgenic Methods of Animal Manipulation	3 + 1 2 + 1 1 + 1
4	Basic principles of biochemical engineering: Isolation, screening and maintenance of industrially important microbes; strain improvement for increased yield and other desirable characteristics.	4 + 2
5	Fermentation technology and bioreactors: Batch and continuous fermenters; modifying batch and continuous reactors: chemostat with recycle, multistage chemostat systems, fed-batch operations; conventional fermentation v/s biotransformations; large scale animal and plant cell cultivation; upstream processing: media formulation and optimization; sterilization; aeration, agitation and heat transfer in bioprocess; scale up and scale down; measurement and control of bioprocess parameters.	4 + 2 4 + 2
6	Enzyme fermentation using immobilized enzymes: Different techniques of immobilization of enzymes and whole cells; Advantages and disadvantages of immobilization, Application and future of immobilized enzyme technology.	3 + 1
7	Application of fermentation technology in producing compounds of pharmaceutical interests: Therapeutic proteins, Vitamins, Amino acids, Monoclonal Antibodies	3 + 1
	Total	**31 + 14= 45**

Course objectives

The objectives of this course are to sensitize the students to the fact that as we go down the scale of magnitude from cells to organelles to molecules, the understanding of various biological processes becomes deeper and inclusive and to educate students about the fundamental concepts of bioprocess technology and its related applications

Course outcomes

Students should be able to:

1. Know the significance and application of biotechnology in healthcare sector
2. Appreciate relevance of microorganisms from industrial context
3. Explain and apply design and operations of various fermenters; the fundamental principles for basic methods in production technique for bio-based products
4. Explain and apply of important microbial/enzymatic industrial processes

PBT2202 Analytical and biophysical techniques

Sr. No.	Topic	H (L + T)
1	Spectroscopic and Advanced spectroscopic techniques: Beer-Lambert's Law, Ultraviolet and Visible light Spectroscopy, Infrared and Raman Spectroscopy, Nuclear Magnetic Resonance (NMR) Spectroscopy, Spectro fluorimetry, Circular Dichroism (CD) Spectroscopy, Atomic Spectroscopy.	4 + 1
2	Mass spectroscopic techniques: Principle, Components of Mass spectrometer, Ionization techniques, Electrospray and ion spray techniques; Analysers- Magnetic, Electric, Quadrupole mass filter (Q); Detectors- Faraday Cup, Array detectors	4 + 1
3	Radio-isotopic techniques: Detection and measurement of radioactivity; Advantages and Restrictions of Radiotracer experiments; Applications in aspects of metabolomic investigations	4 + 1
4	Electrophoretic techniques and Molecular Methods: Agarose and Polyacrylamide gels; SDS PAGE, Native Gels, Isoelectric Focussing gels; Two Dimensional PAGE (2D PAGE), Cellulose Acetate Electrophoresis and Continuous Flow Electrophoresis; Pulsed field gel Electrophoresis (PFGE) and Electrophoresis of RNA; Capillary Electrophoresis (CE), Blotting techniques, PCR and related techniques	4 + 1
5	Genomic and Post-Genomic Analytical Biotechnology: Gene purification and sequencing, Protein sequencing and purification, Sequencing and amplification techniques, applications of genomics and proteomics, techniques in use for gene and protein analysis, e.g. crystallography, magnetic resonance	4 + 1
6	Immunological Methods: Antibody production and labeling, Immunochemical techniques for in situ analyses (ICC and IHC), Immunochemical techniques for measurement (ELISA, etc), Immunochemical techniques for separation (Immunoprecipitation, etc)	4 + 1

7	Introduction to Bioinformatics: organization of biological data, databases (raw and processed), quering in databases, primer designing, gene finding, motif finding, sequence alignment, protein sequence analysis	4 + 1
8	**In-silico analysis:** High through put screening; High through put pharmacokinetic analysis; Use of reference drugs and interpretation of results.	4 + 1
9	Confocal microscopy, Electron microscopy, flow cytometry	4 + 1
	Total	**36 + 9= 45**

Course Objectives

The objectives of this course are to introduce basic analytical and biophysical techniques and explain their principle and methodology and to understand their applications in academic research and industries.

Course outcomes

At the completion of this course, students should be able to:

1. Understand the principles and basic theory behind several analytical and biophysical techniques
2. Apply these techniques successfully in practical situations

PBT2203 Plant and Animal cell culture

Sr. No.	Topic	H (L + T)
1	Animal cell culture: Animal Cell Culture: Historical Background, Importance of and progress in Animal Cell Culture, Technology, Biology of Animal Cell; Cellular Interactions, Importance of Serum and Serum Free Media, Culturing and Sub-Culturing of	3 + 1
2	Animal Cells, InVitro Transformation of Animal Cells, Cell Differentiation & Cell Movement, Cloning of Animal Cells, Cell Line Preservation, Cell Line Characterization	3 + 1
3	Chromosome Spreading and Karyotype Analysis, Mycoplasma: Detection and Control, Monoclonal Antibody Production, Insect Cell Culture: An Overview; Mechanisms of drug resistance and cell death	3 + 1
4	Plant cell culture: History and evolution, Basics of aseptic culture, In vitro propagation, use of plant growth regulators in tissue culture, plant regeneration, organogenesis, somatic embryogenesis, protoplast isolation and culture, somaclonal variation,	3 + 1
5	In vitro mutagenesis, in vitro selection, secondary metabolite production and cell transformation techniques (including protoplast fusion, direct DNA uptake and plant/ bacterial co-cultivation), use of in vitro techniques for crop improvement.	3 + 1
6	Secondary metabolite production: Isolation, characterization and production of secondary metabolites from different plant cell types	3 + 1

7 8	Omics: Proteomics, Genomics and Metabolomics: Introduction to the definitions of various 'omics', introduction to the general field of genomics and proteomics, Introduction to some methods used in analyzing gene expression at the mRNA and protein level, basic principles of DNA/Protein microarrays and their applications.	3 + 1 3 + 1
9 10 11	Physical aspects of the genome. Construction and study of various types of genome maps and large-scale sequencing. The human genome project and the plant genome program. Structural genomics and gene discovery, isolation, localization and characterization. Developing diagnostic tests for plant, animal and human diseases. Identification of biomarkers. Finding genetic markers for plant breeding purposes. Environmental impacts on gene expression. Protein complex 'structures and amino acids. Protein shapes as affecting its function. Amino acid sequencing. Cellular proteome changes in response to environmental and neighboring cells conditions. Cataloguing the proteins produced by different cells. Discovering the function of a protein. Determining three-dimensional structure of proteins. Protein crystallography	3 + 1 2 + 1 3 + 1
12	Integrons and transposons	1 + 1
	Total	**33 + 12 = 45**

Course Objectives

The objectives of this course is to educate students about the fundamental concepts of animal and plant cell system, bioprocess technology using eukaryotic system and their related applications, thus preparing them to meet the challenges of the new and emerging areas of biotechnology industry.

Course outcomes

Student should be able to explain and use plant and animal based cell cultures system for producing compounds of therapeutic interests

PBT2204 Bridging course in A. Biotechnology and B. Biochemical Engineering

Sr. No.	Topic	H (L + T)
1 2 3	Fundamentals of Microbiology: Microbes – types, size shape and arrangement of bacterial cells, Nutritional requirements – Common ingredients, culture media and types of media, Sterilization – Importance and various methods of sterilization, Cultivation and Preservation of microorganisms – Isolation, pure culture, study of cultural characteristics and methods of preservation, Measurement of microbial growth – Total count and viable count methods,	2 + 1 2 + 1 2 + 1

4	Preparation of microbes for microscopic observation – Compound microscope, stains used, simple staining, differential staining and special staining techniques.	2 + 1
5	Pathways and pathogenicity: Biochemical pathways: Energy transduction in microbial systems, phosphoketolase, Entner doudoroff and glyoxylate pathways; Anaerobic respiration;	2 + 1
6	Microbial pathogenicity; Recycling of energy sources: Bioassays; Recycling of carbon, nitrogen and sulphur;	2 + 1
7	Role of microbes in agriculture, public health, medicine and industry.	2 + 1
8	Microbial metabolites:Industrially important microbial metabolites: Process technology for the production of primary metabolites eg citric acid, lactic acid, amino acids, polysaccharides, nucleosides and bioplastics; Production of secondary metabolites-penicillin, cephalosporins, streptomycin, vitamins etc.	2 + 1
9	Bioprocesses and byproducts: Industrially important bioprocesses:	2 + 1
10	Applications of enzymes in pharmaceutical industry, therapeutics and clinical analysis, use of enzymes for the production of different types of drugs and drugs intermediates, future directions	2 + 1
11	Fundamentals of Chemical Engineering (15 lectures): Transport phenomenon, Heat transfer, Mass transfer,	4 + 2
12	Process and equipment design for various operations in processing of pharmaceutical biotechnology based products and discussions on scale-up of operations;	4 + 2
13	Prediction of freezing, heating and drying times	2 + 1
	Total	**30 + 15 = 45**

Course objectives

The objectives of this course are to acquaint the students with general microbiological principles and practices prevalent in industries and to make them aware of the common processes in chemical engineering

Course outcomes

Students should be able to:

1. Identify and isolate industrially important microbes;
2. Explain various biological processes which regulate the growth of microbes;
3. Explicate and use microbes for producing different metabolites produced
4. Explain and apply basic chemical engineering processes for producing biotechnological compounds

PHP 2201 Laboratory I -Instrumental methods of analysis

Sr. No.	Topic	H (L + T)
1	Preparation of buffer systems	1 + 1
2	UV/Visible Spectroscopy i. Calibration of UV spectrophotometer	4 + 2

	ii. Study effect of solvent on wavelength maxima of drugs. iii. Find Beer's law limit of drugs in a suitable solvent. iv. Standard calibration curve by UV spectroscopy at a) λ max b) λ max + 10 nm c) λ max – 10 nm v. Determination of pKa by U.V. spectroscopy. vi. Multicomponent analysis by UV-Spectrophotometry vii. Absorbance corrected for interference method viii. Simultaneous equation method ix. Absorbance ratio method x. Area under curve method xi. First derivative spectrophotometric method	
3	Analysis of drugs from formulations focusing on separation of drug from the formulation excipients	4 + 1
4	IR Spectroscopy i. Calibration of IR spectrophotometer ii. Sample preparation for I.R. spectroscopy (solid/liquids) and interpretation of IR bands for important functional groups.	4 + 1
5	DSC analysis of drugs in crystalline and amorphous forms.	3 + 1
6	Chromatography: i. HPLC calibration of HPLC column and determination of response factor by HPLC ii. GC Instrumental handling and few analyses of the API intermediates iii. TLC mobile phase selection of a various combination of compounds and reaction monitoring. iv. Preparative TLC analysis. v. pH stability evaluation of a drug by TLC. vi. Separation of components by column chromatography.	4 + 1
7	Structural Interpretation by Spectroscopy: i. Basic interpretations of simple Mass spectra and NMR for determination of mass of small molecules and fragmentation patterns ii. Structural elucidation workshop: Interpretation of 1H NMR, 13C NMR, IR and Mass spectrometry of simple compounds (maximum 12 carbon atoms).	3 + 1 3 + 1
8	Techniques of estimation of proteins and carbohydrates	4 + 1
9	Biophysical methods (Circular dichroism spectroscopy, fluorescence spectroscopy)	4 + 1
	Total	**34 + 11= 45**

Course objectives

The objectives of this laboratory course are to prepare the students in all the biophysical and analytical techniques required in research or industry

Course Outcomes

At the end of the course, students should be able to perform the basic biochemical, biophysical and analytical techniques for analyzing/characterizing/assessing compounds of pharmaceutical interests

Syllabus for Semester II

PHT 2101 Research methodology

Sr. No.		H (L + T)
1	Research Meaning of Research, Purpose of Research, Types of Research (Educational, Clinical, Experimental, Historical, Descriptive, Basic applied and Patent Oriented Research) – Objective of research, choosing a mentor, lab and research question	4 + 1
2	Literature survey – Use of Library, Books, & Journals- Medline- Internet, getting patents and reprints of articles as sources for literature survey.	4 + 1
3	Selecting a problem and preparing research proposal for different types of research mentioned above. Processes of communication and scientific communication	4 + 1
4	Methods and tools used in Research • Qualitative studies, Quantitative Studies • Simple data organization, Descriptive data analysis • Limitations and sources of Error • Inquiries in form of Questionnaire, Opinionnaire or by interview Statistical analysis of data including variance, standard deviation, students 't' test and annova, correlation data and its interpretation, computer data analysis	4 + 1
5	Documentation • "How" of Documentation • Techniques of Documentation • Importance of Documentation, Uses of computer packages in Documentation	4 + 1
6	The Research Report / Paper writing / thesis writing • Different parts of the Research paper • Title – Title of project with author's name • Abstract – Statement of the problem Background list in brief and purpose and scope • Key-words- • Methodology-Subject, Apparatus / Instrumentation, (if necessary) and procedure • Results – tables, Graphs, Figures, and statistical presentation • Discussion – Support or non- support of hypothesis – practical & theoretical implications, conclusions • Acknowledgements • References • Errata • Importance of spell check for Entire project • Use of footnote	4 + 1
7	Presentation (Specially for oral) • Importance, types, different skills	4 + 1

	• Content of presentation, format of model, Introduction and ending • Posture, Genstures, Eye contact, facial expressions stage fright • Volume- pitch, speed, pauses & language • Visual aids and seating • Questionnaire	
8	Protection of patents and trademarks, Designs and copyrights • The patent system in India – Present status Intellectual property Rights (IPR), Future changes expected in Indian Patents • Advantages • The Science in Law, Turimetrics (Introduction) • What may be patented • Who may apply for patents • Preparation of patent proposal • Registration of patent in foreign countries and vice-versa	4 + 1
9	Sources for procurement of Research Grants	4 + 1
	Total	**36 + 9 = 45**

Course Objectives

The objective of this course is to develop a research orientation among students and to familiarize them with fundamentals of research methods. Further, the course will make the students aware of the basic concepts used in research, sampling techniques, design and analysis of research, presenting it through reports and oral presentations and strategies of protecting the intellectual property rights associated with research.

Course outcomes

Upon completing this course, each student will be able to:

1. Demonstrate knowledge of research processes (reading, evaluating, and developing)
2. Conduct literature reviews using print and online databases
3. Identify, explain, compare and prepare the key elements of a research proposal or report
4. Compare and contrast quantitative and qualitative research
5. Describe, compare, and contrast descriptive and inferential statistics
6. Present research projects
7. Explain the rationale for research ethics
8. Know about protecting the intellectual property generated from research

PBT 2205 Immunotechnology

Sr. No.	Topic	H (L + T)
1	Fundamental concepts and anatomy of the immune system: Components of innate and acquired immunity; Important organs and cells of immune responses, complement and inflammatory responses; pathogen recognition receptors (PRR) and pathogen associated molecular pattern (PAMP); innate immune response; mucosal immunity; antigens - immunogens, haptens; Major histocompatibility complex (MHC) genes, Role of MHC in infectious diseases and disease susceptibility, HLA typing.	4 + 1

2	Immune responses generated by B and T lymphocytes: Immunoglobulins-basic structure, classes & subclasses of immunoglobulins, antigenic determinants; multigene organization of immunoglobulin genes; B-cell receptor; Immunoglobulin superfamily; principles of cell signaling; basis of self & non-self discrimination; kinetics of immune response, memory; B cell maturation, activation and differentiation; generation of antibody diversity;	4 + 1
3	T-cell maturation, activation and differentiation and T-cell receptors; functional T Cell subsets; cell-mediated immune responses, ADCC; cytokines-properties, receptors and therapeutic uses; antigen processing and presentation- endogenous antigens, exogenous antigens, non-peptide bacterial antigens and super-antigens; cell-cell co-operation.	4 + 1
4	Antigen-antibody interactions: Precipitation, agglutination and complement mediated immune reactions; advanced immunological techniques - RIA, ELISA, Western blotting, ELISPOT assay, immunofluorescence, flow cytometry and immunoelectron microscopy; surface plasmon resonance, biosensor assays for assessing ligand–receptor interaction, CMI techniques- lymphoproliferation assay, mixed lymphocyte reaction, cell cytotoxicity assays, apoptosis, microarrays, transgenic mice, gene knock outs,	4 + 1
5	Hybridoma and monoclonal antibodies, Applications of monoclonal antibodies, design of chimeric and bi-specific antibodies, phage display	4 + 1
6	Vaccinology: Active and passive immunization; live, killed, attenuated, subunit vaccines; vaccine technology- role and properties of adjuvants, recombinant DNA and protein-based vaccines, reverse vaccinology; peptide vaccines, conjugate vaccines;	4 + 1
7	Antibody genes and antibody engineering- chimeric, hybrid monoclonal antibodies; catalytic antibodies and generation of immunoglobulin gene libraries, idiotypic vaccines and marker vaccines, viral-like particles (VLPs), dendritic cell-based vaccines, vaccine against cancer, T cell based vaccine, edible vaccine and therapeutic vaccine; Success stories in vaccinologye.g. Hepatitis, Polio, Small pox, DPT. Genetic vaccines	4 + 1
8	Immunology and diseases: Immunity to infection: bacteria, viral, fungal and parasitic infections (Tuberculosis, HIV/AIDS, Schistosomiasis, Kala Azar, Chickungunya, Dengue); hypersensitivity reactions– Type I-IV; autoimmunity;	4 + 1
9	Types of autoimmune diseases; mechanism and role of CD4+T cells; MHC and TCR in autoimmunity; transplantation –immunological basis of graft rejection; clinical transplantation and immunosuppressive therapy; tumor immunology – tumor antigens; immune response to tumors and tumor evasion of the immune system, cancer immunotherapy; immunodeficiency-primary immunodeficiencies, acquired or secondary immunodeficiencies, anaphylactic shock.	4 + 1
	Total	**36 + 9 = 45**

Course objectives

The objectives of this course are to learn about structural features of components of immune system as well as their function. Major emphasis will be to make the students aware about the immune mechanisms, to be able to predict nature of immune response that develops against bacterial, viral or parasitic infections and to be able to design experiments to prove the mechanisms and develop vaccines against the same.

Course outcomes

On completion of this course, students should be able to:

1. Evaluate the significance of immune system and immune responses to tackle various disease conditions
2. Apply their knowledge and design immunological experiments to demonstrate innate, humoral or cytotoxic T lymphocyte responses and predict the kind of immune responses in the setting of infections (viral or bacterial)
3. Apply knowledge to design vaccines against various diseases

PBT 2206 Formulation of biologicals

Sr. No.	Topic	H (L + T)
1	Basic characteristics of biologicals: Temperature and stress sensitive, sensitive to pressure and solvent, water activity and biological activity, storage stability, aggregation behavior, dormant forces causing aggregation of biologicals, degradation pattern, difference between degradation, aggregation and precipitation.	4 + 1
2	Specific requirements for stabilization of protein, carbohydrate, lipids and nucleic acids.	4 + 1
3	Excipients and additives: Role of excipients and additives on stabilizing biologicals; Pharmacopoeia approved excipients, additives and stabilizers, mechanism of action of additives, excipients and stabilizers;	4 + 1
4	Chemical modification to improve stability, pegylation and silyation	4 + 1
5	Formulation processing: Preparation and powder and liquid formulation; Methods of preparation; Use of crystallization, polymorphs for improving stability of biological;	4 + 1
6	Characteristics of liquid and powder formulation.	4 + 1
7	Particulate formulation for biologicals: Polymeric particle based formulation, liposomal formulation and solid lipid nanoparticle formulation.	4 + 1
8	Different nano carrier based formulation; Examples of nano formulation in industry.	4 + 1
9	Examples of biological formulation: Insulin formulation, formulation of monoclonal antibodies, vaccines, anticancer drugs and antibiotics.	4 + 1
	Total	**36 + 9 = 45**

Course Objectives

This course will give students a brief overview of formulation of biological compounds citing various examples and processes involved.

Course outcomes

On completion of this course, students should be able to understand the basis of formulation and development of biologicals and should also be able to formulate basic compounds.

PBT 2207 Enzyme technology

Sr. No.	Topic	H (L + T)
1	Enzymes and enzymology: Classification, mode of action, activation, specificity, Source of enzymes; production, isolation and purification of enzymes; Characterization in terms of pH, temperature, ionic strength, substrate and product tolerance, effects of metal ions etc.	4 + 1
2	Coenzymes and cofactors: Coenzymes, classification of vitamins, role and mechanism of action of some important coenzyme (NAD+/NADP+, FAD, lipoic acid, tetrahydrofolate, B12-coenzyme), role of cofactors with specific examples	4 + 1
3	Enzyme kinetics: Enzyme as biological catalysts; Enzyme action, active site, functional group, enzyme substrate complex, cofactors, Michaelis-Menten equation, Km and Vmax, enzyme inhibition; order of reaction, methods of plotting enzyme kinetics data; Enzyme turnover number.	4 + 1
4	Competitive, non-competitive, uncompetitive, irreversible; order of reaction, methods of plotting enzyme kinetics data; determination of Kcat, Km, Vmax, Ki, Half-life, activation and deactivation energy etc.	4 + 1
5	Cross-linked enzyme aggregates, Cross linked enzymes, enzyme crystals, their use and preparation. Solution of numerical problems;	4 + 1
6	Energy yielding and energy-requiring reactions; Calculation of equilibrium constants; Activation energy etc.; Multisubstrate enzymes and kinetics mechanisms; Enzyme induction, repression, covalent modification, Isoenzymes, allosteric effects.	4 + 1
7	Enzyme engineering: Random and rational approach of protein engineering;	4 + 1
8	Directed evolution and its application in the biocatalysis; various approaches of creating variant enzyme molecules; Future of Biocatalysis; Ideal biocatalyst.	4 + 1
9	Enzyme in organic solvents and ionic liquids: Various organic solvents and ionic liquids used in biocatalysis; Potential in organic solvents and ionic liquids; Applications of enzymes in analysis.	4 + 1
	Total	**36 + 9 = 45**

Course objectives

This course will describe various technologies used in enzyme engineering and purification. It will also give an overview of the technologies used in pharmaceutical industries.

Course outcomes

On completion of this course, students should be able to understand the basics of enzyme technologies used in pharmaceutical industry.

PHP 2202 Laboratory II: Microbiology, Molecular biology and Immunology

Sr. No.	Topic	H (L + T)
1	Basic techniques: Sterilization, disinfection and safety in microbiological laboratory, good Laboratory practices; Preparation of media for cultivation of bacteria, liquid and agar	3 + 1
2	Culture techniques:Spread plate method, Pour plate method, Streaking, Bacterial plate count method, Maintenance of stock cultures: slants, stabs	3 + 1
3	Bacterial growth curve	3 + 1
4	Agarose gel electrophoresis	3 + 1
5	Polymerase Chain Reaction	3 + 1
6	Blotting: Western blot for protein analysis	3 + 1
7	SDS-PAGE analysis	3 + 1
8	Basics of mammalian cell culture	3 + 1
9	Expression systems: Transfection	4 + 1
10	Introductory lab in immunology I: demonstration experiments in Complement fixation test, Ouchterlony double immunodiffusion, Coombs test (Direct and Indirect)	3 + 1
11	Introductory lab in immunology II: demonstration experiments in ELISA, Haemagglutination assay, Haemagglitination inhibition assay and Fluorescent antibody technique	3 + 1
	Total	**34 + 11= 45**

Course Objectives

The objective of this laboratory course is to provide the students practical skills on basic microbiological and molecular biology as well as cell culture techniques. Basic as well as advanced methods will be taught to detect different antigen and antibody interactions and how they can be used in respective research work.

Course outcomes

On completion of this laboratory course, students should be able to:

1. Isolate, characterize and identify common bacterial organisms
2. Perform antimicrobial sensitivity test
3. Preserve bacterial cultures.
4. Acquire basic molecular biology techniques and principles for DNA isolation and characterization, protein identification
5. Apply their knowledge and design immunological experiments for antigen-antibody detection

Elective subjects

PBT 2221 Applied statistics (biostatistics)

Sr. No.	Topic	H (L + T)
1	Introduction to biostatistics: Application of Statistics, bioinformatics and experimental design to biotech processes: Sampling procedures, populations; types of data, data organization and presentation	4 + 1
2	Introduction to probability: Probability: Basic concepts; Common probability distributions and probability distributions related to normal distribution	4 + 1
3	Sampling: Simple random and other sampling procedures; Distribution of sample mean and proportion.	4 + 1
4	Parameter estimation and parametric hypothesis testing: Estimation and Hypothesis testing: Point and interval estimation; Concepts of hypothesis testing and types of errors; Student-t and Chi square tests;	4 + 1
5	Sample size and power; Experimental design and analysis of variance: Completely randomized, randomized blocks; Latin square and factorial designs; Post- hoc procedures	4 + 1
6	Nonparametric hypothesis testing: Non-parametric tests: Sign; Mann-Whitney U; Wilcoxon matched pair; Kruskal Wallis and Friedman two way ANOVA tests; Spearman rank correlation;	4 + 1
7	Statistical techniques in pharmaceutics: Experimental design in clinical trials; Parallel and crossover designs; Statistical test for bioequivalence; Dose response studies; Statistical quality control.	4 + 1
8	Regression: Correlation and regression: Graphical presentation of two continuous variables; Pearson's product moment correlation coefficient; its statistical significance; Multiple and partial correlations; Linear regression; Regression line; Coefficient of determination; Interval estimation and hypothesis testing for population slope; Introduction to multiple linear regression models; Probit and logit transformations.	4 + 1
9	Concepts and use of software. RSM and ANN techniques for optimization of fermentative processes	4 + 1
	Total	**36 + 9 = 45**

Course objectives

The objective of this course is to give conceptual exposure of statistics, error analysis, hypothesis testing, and design of experiments.

Course outcomes

Students should be able to:

1. Gain broad understanding in mathematics and statistics;
2. Recognize the importance and value of mathematical and statistical thinking, training, and approach to problem solving, on a diverse variety of disciplines.

PBT 2222 Product development in biopharmaceuticals

Sr. No.	Topic	H (L + T)
1	Pharmaceutical Product development: Product life cycle management, Pharmaceutical product design and development, ICH perspectives, Strategies in product development,	5 + 1
2	Design of Experiments, Preformulation studies, Formulation development and scale-up, Process validation and post approval changes	5 + 1
3	Unit operations for pharmaceutical development: Equipment design and operation, mixing, milling, drying, filtration etc.	5 + 1
4	Facility design: Personnel & Material flows considered, Floors, walls, and ceilings, Temperature and humidity controls, Air control, HEPA, Schedule M, layout setup, factory site, factory buildings, operation areas, facilities, GMP in solid dosage forms, liquids, parenterals.	5 + 1
5	Scale-up considerations: Large scale manufacturing of monophasic and biphasic liquids, semisolids and solids	5 + 1
6	Quality control, quality assurance and quality-by-design (regulatory requirements): Generic Drug Product development, Hatch-Waxman Act	4 + 1
7	Regulatory requirements for product approvals: Clinical research process, IND, NDA, ANDA, SUPAC, Post marketing surveillance.	4 + 1
8	FDA Approval Process: Data procession for Global submission, Common Technical Document, (CTD)/ electronic Common Technical Document (eCTD) Format, and CMC Regulatory Compliance, FDA Medical Device Regulation.	4 + 1
	Total	**37 + 8 = 45**

Course objectives

This course is designed to impart fundamental knowledge on pharmaceutical product development and translation from laboratory to market

Course outcomes

At the end of the course students will be able to:

1. Know the process of pilot plant and scale up of pharmaceutical dosage forms
2. Understand the process of technology transfer from lab scale to commercial batch
3. Know different Laws and Acts that regulate pharmaceutical industry
4. Understand the approval process and regulatory requirements for drug products

PBT 2223 Biopharmaceutical Research and Development

Sr. No.	Topic	H (L + T)
1	Target identification and molecular modelling: Identification of target or drug leads associated with a particular disease by a number of different techniques including combinations of molecular modeling, combinatorial libraries and high-throughput screening (HTS); Conceptualizing the automation of the HTS process and the importance of bioinformatics and data processing in identification of lead compounds	4 + 1
2	Rational drug design, based on understanding the three-dimensional structures and physicochemical properties of drugs and receptors; Modeling drug/receptor interactions with the emphasis on molecular mechanisms, molecular dynamics simulations and homology modelling; Conformational sampling, macromolecular folding, structural bioinformatics, receptor-based and ligand-based design and docking methods, in silico screening of libraries, semi-empirical and ab-initio methods, QSAR methods, molecular diversity, design of combinatorial libraries of drug-like molecules, macromolecular and chemical databases.	4 + 1
3	Lead optimization: Identification of relevant groups on a molecule that interact with a receptor and are responsible for the biological activity; Understanding structure activity relationship; Structure modification to increase potency and therapeutic index	4 + 1
4	Concept of quantitative drug design using Quantitative structure–activity relationship models (QSAR models) based on the fact that the biological properties of a compound are a function of its physicochemical parameters such as solubility, lipophilicity, electronic effects, ionization, stereochemistry, etc. Bioanalytical assay development in support of in vitro and in vivo studies (LC/MS/MS, GC/MS and ELISA).	4 + 1
5	Preclinical development: Principles of drug absorption, drug metabolism and distribution - intestinal absorption, metabolic stability, drug-drug interactions, plasma protein binding assays, metabolite profile studies, Principles of toxicology, Experimental design for preclinical and clinical PK/PD/TK studies, Selection of animal model; Regulatory guidelines for preclinical PK/PD/TK studies	4 + 1
6	Scope of GLP, SOP for conduct of clinical & non clinical testing, control on animal house, report preparation and documentation, integration of non-clinical and preclinical data to aid design of clinical studies.	4 + 1
7	Drug manufacturing; Requirements of GMP implementation, Documentation of GMP practices, CoA, Regulatory certification of GMP, Quality control and Quality assurance, concept and philosophy of TQM, ICH and ISO 9000; ICH guidelines for Manufacturing, Understanding Impurity Qualification Data, Stability Studies.	4 + 1
8	Clinical trial design: Objectives of Phase I, II, III and IV clinical studies, Clinical study design, enrollment, sites and documentation, Clinical	4 + 1

	safety studies: Adverse events and adverse drug reactions, Clinical PK, pharmacology, drug-drug interaction studies, Statistical analysis and documentation.	
9	Fundamentals of regulatory affairs and bioethics: Global Regulatory Affairs and different steps involved, Regulatory Objectives, Regulatory Agencies; FDA guidelines on IND and NDA submissions, Studies required for IND and NDA submissions for oncology, HIV, cardiovascular indications, On-label vs. off-label drug use GCP and Requirements of GCP Compliance, Ethical issues and Compliance of current ethical guidelines, Ethical Committees and their set up, Animal Ethical issues and compliance.	4 + 1
	Total	**36 + 9 = 45**

Course objectives

This course will give a broad overview of research and developments carried out in pharmaceutical industrial setup.

Course outcomes

On completion of this course, students should be able to understand basics of R&D in pharmaceutical industry and should be able to apply knowledge gained.

PHT 2106 Models for Drug Delivery Systems Evaluation

Sr. No.	Topic	H (L + T)
1	Pharmacodynamic models for evaluation of DDS containing drugs of various categories eg. Cardiovascular agents; Antidiabetic; Antiinflammatory; Antiepileptic; Anticancer; Hepatoprotectives; Analgesics; Antistress; Antiasthmatic and Antitussives etc.	5 + 1
2	In vitro cell culture techniques for evaluation of drug permeation from DDS including isolation maintenance of cell lines, culturing monolayers, evaluation of drug transport.	5 + 1
3	In vitro/ ex vivo models for evaluation of Drug absorption	5 + 1
4	In vitro cytotoxicity evaluation using cell cultures and techniques such as MTT assay, Dye uptake etc.	5 + 1
5	Toxicity testing: In-vitro: In -vitro toxicity testing and its application to safety evaluation, General perspectives, in vitro toxicity trends and issue, Ocular and cutaneous irritation, Validation of In vitro toxicity tests.	4 + 1
6	Acute, sub-acute and chronic toxicity testing – Biochemical basis of toxicity, Design of toxicological studies, Quality assurance in toxicology studies	4 + 1
7	Toxicity by routes – Parental, oral, percutaneous and inhalation, Target organ toxicity exemplified by hepatotoxicity and cutaneous (dermal) toxicity.	4 + 1
8	Regulatory status- Ethical, moral and professional issues.	5 + 1
	Total	**37 + 8 = 45**

Course objectives

Objective of the course is to make the students aware of various cellular, tissue-based and animal models that may be used for testing the efficacy and toxicity of pharmaceutical molecules and delivery systems.

Course outcomes

On completion of this course, students should be able to:

1. Design an animal model to evaluate a particular pharmaceutical molecules and delivery systems.
2. Understand cell lines and use cell culture techniques.
3. Carry out various cell assays/ tissue-based assays to evaluate a drug for its activity.
4. Design a toxicological study in cells and animals

List of other potential elective subjects and syllabi

PBT 2224 Advanced Biochemistry

Sr. No.	Topic	H (L + T)
1	Proteins: Structures – primary, secondary, tertiary, motifs, structural and functional domains, protein families and macromolecular assemblies.	5 + 1
2	Mechanisms for regulating protein function: Protein-protein interactions, interaction with ligands, Ca¬+2 and GTP as modulators, cyclic phosphorylation and dephosphorylation, proteolytic cleavage.	5 + 1
3	Purification and characterization of proteins: Electrophoresis, ultracentrifugation and liquid chromatography, use of biological assays, use of radioisotopes and MS, X-ray crystallography, NMR and Homology modeling, amino acid analysis, cleavage of peptides, protein sequencing.	6 + 1
4	Protein biosynthesis: Translation machinery in prokaryotic and eukaryotic systems, comparison of similarities and differences.	5 + 1
5	DNA and nucleic acids: DNA, RNA structure, nomenclature, double helix, conformations, higher order packing and architecture of DNA, transcription and replication of DNA – mechanisms in prokaryotic and eukaryotic systems, DNA repair mechanisms.	6 + 1
6	Carbohydrates: Mono, di and polysaccharides and their nomenclature, stereochemistry, linkages, conjugates of carbohydrates with other molecules - glycoproteins, glycolipids, proteoglycans, lipopolysaccharides and their biological roles.	6 + 1
7	Lipids: Classification, nomenclature, stereochemistry, storage lipids, membrane lipids, lipids as second messengers and cofactors, biological role of lipids	5 + 1
	Total	**38 + 7 = 45**

PBT 2225 Advanced Bioinformatics

Sr. No.	Topic	H (L + T)
1	Motif and cis-Regulatory Module (CRM) Modeling: learning motif models, learning models of cis-regulatory modules, Gibbs sampling, Dirichlet priors, parameter tying, heuristic search, HMM structure search, sequence entropy and mutual information, duration modeling, semi-Markov models	5 + 1
2	Gene Finding: the gene finding task, maximal dependence decomposition, interpolated Markov models, back-off models, pairwise HMMs, Genscan, Twinscan, SLAM	5 + 1
3	RNA-Seq: RNA-Seq technology, transcript quantification with RNA-Seq	4 + 1
4	RNA Analysis: predicting RNA secondary structure, Nussinov/energy-minimization algorithms, stochastic context free grammars, Inside/Inside-Outside/CYK algorithms, searching sequences for a given RNA secondary structure, RSEARCH, RNA gene recognition via comparative sequence analysis, microRNA gene/target prediction	5 + 1
5	Large-Scale and Whole-Genome Sequence Alignment: large-scale alignment, whole-genome alignment, parametric alignment, suffix trees, locality sensitive hashing, k-mer tries, sparse dynamic programming, longest increasing subsequence problem, Markov random fields, MUMmer, LAGAN/MLAGAN, Mauve, Mercator	5 + 1
6	Biological network inference and evolution: Network inference, models of biological network evolution, network alignment	5 + 1
7	Genotype Analysis: haplotype inference, genome-wide association studies (GWAS), quantitative trait loci (QTL) mapping	4 + 1
8	Protein Structure Prediction: secondary structure prediction, threading, branch and bound search, ROSETTA	4 + 1
	Total	**37 + 8 = 45**

PBT 2226 Process Biotechnology

Sr. No.	Topic	H (L + T)
1	Selection of separation process. Chemical, physical and biochemical aspects of isolation and purification of biomolecules. Product release from a cell	3 + 1 3 3
2	Concentration and separation methods: membrane, ion-exchange, precipitation and extraction. Chromatographic methods of purification	5 + 1 3
3	Chemistry of adsorption, Adsorbents, Equilibria, Yield and purity, Batch adsorption, Kinetic analysis,	4 3 + 1 3 + 1

	Discrete stage analysis, Adsorption in fixed beds	3 + 1
4	Design and scale-up of adsorption and chromatography equipment	3 + 1
5	Design of downstream processing equipment. Downstream process economics	4 + 1
	Total	**38 + 7 = 45**

PBT 2227 Tissue Engineering and Biopolymers

Sr. No.	Topic	H (L + T)
1	Principles of materials science and cell biology underlying the design of medical implants, artificial organs, and matrices for tissue engineering	5 + 1
2	Methods for biomaterials surface characterization and analysis of protein adsorption on biomaterials	5 + 1
3	Molecular and cellular interactions with biomaterials are analyzed in terms of unit cell processes, such as matrix synthesis, degradation, and contraction Mechanisms underlying wound healing and tissue remodeling following implantation in various organs	6 + 1
4	Tissue and organ regeneration	5 + 1
5	Design of implants and prostheses based on control of biomaterials-tissue interactions	6 + 1
6	Comparative analysis of intact, biodegradable, and bioreplaceable implants by reference to case studies	6 + 1
7	Criteria for restoration of physiological function for tissues and organs	5 + 1
	Total	**38 + 7 = 45**

PBT 2228 Environmental Biotechnology

Sr. No.	Topic	H (L + T)
1	Environmental impact and control; Biosafety	3 + 1 3
2	Biological treatment: stabilization pond, aerated lagoon, Activated sludge process, trickling filter anaerobic treatment	5 + 1
3	Biodegradation of xenobiotic organic chemicals; Biological Detoxification of Hazardous chemicals	5 + 1
4	Environmental Policy & Legislation; Sampling of air and water pollutants; Monitoring techniques and methodology, pH, Dissolved Oxygen (DO); Chemical oxygen demand (COD); Biological Oxygen Demand (BOD); Speculation of metals, monitoring & analysis of CO, NO2, CO2, SO2; Pesticide residue; Phenols and petrochemicals	3 + 1 3 + 1 3 3

5	Environmental pollution control- Bioremediation, Bioaugmentation and Biostimulation; Biofilms in treatment of waste water; Biofilm development and biofilm Kinetics; Aerobic Biofilms; Bioreactors for waste water treatments	4 + 1 3 + 1 3
	Total	**38 + 7 = 45**

PHT 2107 Targeted Drug Delivery

Sr. No.	Topic	H (L + T)
1	Introduction: concept, basis, need, physicochemical and physiological basis, RES	6 + 2
2	Receptor mediated drug targeting	6 + 2
3	Colon targeting approaches	6 + 2
4	Targeting to brain	6 + 1
5	Targeting in cancer and infectious diseases	6 + 1
6	Ligands for targeted drug delivery: monoclonal antibodies	6 + 1
	Total	**36 + 9 = 45**

PHT 2105 Drug delivery Systems II