M.Pharm Syllabus

Semester 02

Pharmaceutical Biotechnology

Subjects

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MPB201T - Proteins and Protein Formulation

Theory

Unit 1

- Protein engineering Concepts for protein engineering. Isolation and purification of proteins, Stability and activity based approaches of protein engineering, Chemical and Physical Considerations in Protein and Peptide Stability, Different methods for protein engineering, gene shuffling, and direct evolution.

Unit 2

- Peptidomimetics Introduction, classification; Conformationally restricted peptides, design, pseudopeptides, peptidomimetics and transition state analogs; Biologically active template; Amino acid replacements;
- Peptidomimetics and rational drug design; CADD techniques in peptidomimetics; Development of non peptide peptidomimetics.

Unit 3

- 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 4

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

Unit 5

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

MPB202T - Immunotechnology

Theory

Unit 1

- Fundamental aspects of immunology Introduction, cells and organs of the immune system, cellular basis of Immune response, primary and secondary lymphoid organs, antigen antibody and their structure.
- Types of immune responses, anatomy of immune response.
- Overview of innate and adaptive Immunity.
- Humoral Immunity B - Lymphocytes and their activation. Structure and function of immunoglobulins, idiotypes and anti idiotypic antibodies.
- Cell mediated Immunity Thymus derived lymphocytes (T cells) - their ontogeny and types, MHC complex, antigen presenting cells (APC), mechanisms of T cell activation, macrophages, dendritic cells, langerhans cells, mechanism of phagocytosis

Unit 2

- Immune Regulation and Tolerance Complement activation and types and their biological functions, cytokines and their role in immune response.
- Hypersensitivity Hypersensitivity Types I-IV, Hypersensitivity reactions and treatment Autoimmune diseases

Unit 3

- Vaccine technology Vaccine and their types, conventional vaccines, novel methods for vaccine production, antiidiotype vaccine, DNA vaccine, genetically engineered vaccine, iscoms, synthetic peptides, and immunodiagnostics.
- Stem cell technology Stem cell technology and applications to immunology

Unit 4

- Hybridoma Technology Hybridoma techniques - fusion methods for myeloma cells and B-Lymphocytes, selection and screening techniques. Production and purification of monoclonal antibodies and their applications in Pharmaceutical industry.

Unit 5

- Immunological Disorder Autoimmune disorders and types, pathogenic mechanisms, treatment, experimental models of auto immune diseases, primary and secondary immunodeficiency disorders.
- Immunodiagnosis Antigen antibody interaction - Precipitation reaction, Agglutination reactions, Principles and applications of ELISA, Radio Immuno Assay, Western blot analysis, immune-electrophoresis, immuno fluorescence, chemiluminescence assay, complement fixation reaction.

MPB203T - Bioinformatics and Computer Technology

Theory

Unit 1

- Introduction to Bioinformatics Definition and History of Bioinformatics, Internet and Bioinformatics, Introduction to Data Mining, Applications of Data Mining to Bioinformatics, Biological Database Protein and nucleic acid databases. Structural data bases.
- Collecting and storing the sequence and Applications of Bioinformatics.

Unit 2

- Sequence analysis Sequence alignment, pair wise alignment techniques, multiple sequence analysis, multiple sequence alignment; Flexible sequence similarity searching with the FAST3 program package, the use of CLUSTAL W and CLUSTAL X for the multiple sequence alignment. Tools used for sequence analysis.

Unit 3

- Protein informatics Introduction; Force field methods; Energy, buried and exposed residues, side chains and neighbours; Fixed regions, hydrogen bonds, mapping properties onto surfaces; Fitting monomers, R & S fit of conformers, assigning secondary structures; Sequence alignment-methods, evaluation, scoring; Protein completion, backbone construction and side chain addition; Small peptide methodology, software accessibility, building peptides; Protein displays; Substructure manipulations, annealing.
- Protein structure prediction Protein folding and model generation; Secondary structure prediction, analyzing secondary structures; Protein loop searching, loop generating methods, loop analysis; Homology modeling, concepts of homology modeling, potential applications, description, methodology, homologous sequence identification;
- Align structures, align model sequence; Construction of variable and conserved regions, threading techniques, Topology fingerprint approach for prediction, evaluation of alternate models;
- Structure prediction on a mystery sequence, structure aided sequence techniques of structure prediction, structural profiles, alignment algorithms, mutation tables, prediction, validation, sequence based methods of structure prediction, prediction using inverse folding, fold prediction; Significance analysis, scoring techniques, sequence-sequence scoring.
- Docking Docking problems, methods for protein-ligand docking, validation studies and applications; Screening small molecule databases, docking of combinatorial libraries, input data, analyzing docking results.

Unit 4

- Diversity of Genomes
- Prokaryotic and Eukaryotic Gene Families. Genome Analysis: Introduction, Gene prediction methods, Gene mapping and applications-Genetic and Physical Mapping, Integrated map, Sequence assembly and gene expression.
- Completed Genomes Bacterium, Nematode, Plant and Human Evolution of Genomes Lateral or Horizontal Transfer among Genomes, Transcriptome and Proteome-General Account Phylogenetic

analysis Evolutionary Change in Nucleotide Sequences, Rates and Patterns of Nucleotide Substitution, Models for Nucleotide Substitution, Construction of Phylogenetic Tree, Genome Annotation technique.

Unit 5

- Target searching and Drug Designing Target and lead, timeline for drug development, target discovery, target modulators, In-silico gene expression, microarray, and lead discovery, libraries of ligands, active site analysis, and prediction of drug quality.

MPB204T - Biological Evaluation of Drug Therapy

Theory

Unit 1

- Biological Standardization General principles, Scope and limitation of bio-assay, bioassay of some official drugs.
- Preclinical drug evaluation Preclinical drug evaluation of its biological activity, potency and toxicity-Toxicity test in animals including acute, sub-acute and chronic toxicity, ED50 and LD50 determination, special toxicity test like teratogenecity and mutagenecity.
- Guidelines for toxicity studies Various guidelines for toxicity studies. Animal experiments assessing safety of packaging materials.

Unit 2

- Pyrogens Pyrogens: Sources, Chemistry and properties of bacterial pyrogens and endotoxins, Official pyrogen tests.
- Microbiological assay Assay of antibiotics and vitamins.
- Biological evaluation of drugs Screening and evaluation (including principles of screening, development of models for diseases: In vivo models / In vitro models / cell line study).

Unit 3

- Biologic Medicines in Development for various diseases - By Therapeutic Category
- Genetic Disorders
- Eye related Disorders
- Digestive Disorders
- Diabetes/Related Conditions
- Cardiovascular Disease
- Cancer/Related Conditions
- Blood Disorders
- Autoimmune Disorders
- Infectious Diseases
- Neurologic Disorders
- Skin Diseases
- Organe Transplantation Biologic Medicines in Development for various diseases - by Product Category
- Antisense
- Vaccines
- Recombinant Hormones/Proteins
- Monoclonal Antibodies (mAb)

- Interferons
- Growth Factors
- Gene Therapy
- RNA Interference

Unit 4

- Regulatory aspects : drugs, biologics and medical devices An introduction to the regulations and documents necessary for approval of a medical product.
- Regulatory consideration Regulatory consideration for pre-clinical testing and clinical testing of drugs, biologics and medical devices.
- New Drug Applications for Global Pharmaceutical Product Approvals

Unit 5

- Bioavailability Objectives and consideration in bio-availability studies of Biopharmaceuticals, Concept of equivalents, Measurements of bio-availability.
- Determination of the rate of absorption, Bioequivalence and its importance, Regulatory aspects of bio-availability and bioequivalence studies for conventional dosage forms and controlled drug delivery systems of Biopharmaceuticals.
- Pharmacokinetics Pharmacokinetics:- Basic consideration, Pharmacokinetic models, Application of Pharmacokinetics in new drug development of Biopharmaceuticals and designing of dosage forms and Novel drug delivery systems of Biopharmaceuticals.

MPB205P - Pharmaceutical Biotechnology II

Practical

- Protein identification
- Protein characterization
- Protein biochemistry
- Recombinant DNA Technology
- Protein expression
- Protein formulations
- Database searching
- Sequence analysis methods
- Protein structure prediction
- Gene annotation methods
- Phylogenetic analysis
- Protein, DNA binding studies
- Preparation of DNA for PCR applications - Isolation, Purity and Quantification
- Introduction to PCR - working of PCR, Programming.
- Introduction to RT-PCR - working, programming.
- Primer design using softwares.
- Gene DNA amplification by random / specific primers.
- Southern Hybridization
- Western Blotting
- Gene transformation

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