M.Pharm Syllabus

Semester 02

Pharmacology

Subjects

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MPL201T - Advanced Pharmacology II

Theory

Unit 1

- Endocrine Pharmacology Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids.
- Drugs affecting calcium regulation

Unit 2

- Chemotherapy Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as ß-lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs.

Unit 3

- Chemotherapy Drugs used in Protozoal Infections Drugs used in the treatment of Helminthiasis Chemotherapy of cancer Immunopharmacology Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD.
- Immunosuppressants and Immunostimulants

Unit 4

- GIT Pharmacology Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome.
- Chronopharmacology Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer

Unit 5

- Free radicals Pharmacology Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer.
- Protective activity of certain important antioxidant
- Recent Advances in Treatment: Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus

MPL202T - Pharmacological and Toxicological Screening Methods II

Theory

Unit 1

- 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 2

- 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 3

- Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenecity studies (segment II) Genotoxicity studies (Ames Test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies) In vivo carcinogenicity studies

Unit 4

- IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission.
- Safety pharmacology studies-origin, concepts and importance of safety pharmacology.
- Tier1-CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2-GI, renal and other studies

Unit 5

- Toxicokinetics-Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies.
- Alternative methods to animal toxicity testing.

MPL203T - Principles of Drug Discovery

Theory

Unit 1

- 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 microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation.

Unit 2

- Lead Identification-combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development for hit identification.
- Protein structure Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction

Unit 3

- Rational Drug Design Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design, Rational Drug Design Methods: Structure and Pharmacophore based approaches Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,

Unit 4

- Molecular docking: Rigid docking, flexible docking, manual docking; Docking based screening. De novo 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 5

- QSAR Statistical methods - regression analysis, partial least square analysis (PLS) and other multivariate statistical methods.
- 3D-QSAR approaches like COMFA and COMSIA Prodrug design-Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design

MPL204T - Clinical Research and Pharmacovigilance

Theory

Unit 1

- Regulatory Perspectives of Clinical Trials: Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant-Schedule Y, ICMR Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process

Unit 2

- Clinical Trials: Types and Design Experimental Study-RCT and Non RCT, Observation Study: Cohort, Case Control, Cross sectional Clinical Trial Study Team Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management

Unit 3

- Clinical Trial Documentation-Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring-Safety Monitoring in CT Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment.Predictability and preventability assessment, Management of adverse drug reactions; Terminologies of ADR.

Unit 4

- Basic aspects, terminologies and establishment of pharmacovigilance History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance

Unit 5

- Methods, ADR reporting and tools used in Pharmacovigilance International classification of diseases, International Non-proprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.

Unit 6

- Pharmacoepidemiology, pharmacoeconomics, safety pharmacology

MPL205P - Experimental Pharmacology II

Practical

- To record the DRC of agonist using suitable isolated tissues preparation.
- To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.
- To determine to the strength of unknown sample by matching bioassay by using suitable tissue preparation.
- To determine to the strength of unknown sample by interpolation bioassay by using suitable tissue preparation
- To determine to the strength of unknown sample by bracketing bioassay by using suitable tissue preparation
- To determine to the strength of unknown sample by multiple point bioassay by using suitable tissue preparation.
- Estimation of PA2 values of various antagonists using suitable isolated tissue preparations.
- To study the effects of various drugs on isolated heart preparations
- Recording of rat BP, heart rate and ECG.
- Recording of rat ECG
- Drug absorption studies by averted rat ileum preparation.
- Acute oral toxicity studies as per OECD guidelines.
- Acute dermal toxicity studies as per OECD guidelines.
- Repeated dose toxicity studies-Serum biochemical, haematological, urine analysis, functional observation tests and histological studies.
- Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
- Protocol design for clinical trial.
- Design of ADR monitoring protocol.
- In-silico docking studies.
- In-silico pharmacophore based screening.
- In-silico QSAR studies.
- ADR reporting

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