EAST POINT COLLEGE OF PHARMACY
East Point Campus, Jnana Prabha, Virgo Nagar Post,
Bengaluru – 560049, Karnataka

QUESTION BANK

M Pharmacy

PHARMACOLOGY

Semester-II

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Advanced Pharmacology-II

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LONG ESSAYS 7.5 MARKS

1. Outline the significance of Insulin in Type -1 Diabetes Mellitus and discuss the mechanism of action of Insulin
2. What are Beta lactam antibiotics and classify Cephalosporin. Discuss the Cellular mechanism and clinical uses of Cephalosporins
3. Classify Anticancer agents , Discuss the mechanism of action , adverse effects , contraindications and clinical uses of Antimetabolites
4. Classify purgatives and outline its Therapeutic uses . Discuss the Pharmacology of stimulated and Osmotic Purgatives
5. Define Chrono pharmacology . Discuss the application of Chronotherapy with suitable examples
6. Define and classify Asthma. Discuss the Pharmacology of Asthma
7. Explain the mechanism Chemotherapeutic agents that influences Protein synthesis with suitable examples
8. Discuss the cellular and Biochemical mediators associated with inflammation
9. Classify Antivirals, describe the pharmacology of any 2 antiviral drugs
10. Write the mechanism of action and pharmacology of Oral Hypoglycaemic agents
11. Describe any two drugs used in the treatment of Helminthiasis
12. Discuss the Cellular and biochemical mediators of Inflammation
13. Describe the pharmacology of any two drugs used in the treatment of Diarrhoea.
14. What is Chronopharmacology? Discuss the principles and concepts of Chronopharmacology
15. Discuss the recent advances in the treatment of Parkinson’s disease
16. Describe any two drugs used in the treatment of Tuberculosis
17. Explain any two drugs used in the Peptic Ulcer
18. Discuss the role of Antioxidants in Oxidative stress
19. Explain the mechanisms of Antimicrobial
20. Give the Pathophysiology and Pharmacotherapy of Myasthenia Gravis

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Pharmacological and Toxicological Screening Methods-II

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LONG ESSAY 7.5 MARKS

1. Explain the significance of the OECD's Mutual Acceptance of Data (MAD) system in the context of toxicity studies.
2. Discuss the role of the OECD Guidelines in regulatory decision-making for human health and environmental safety.
3. Explain the ICH guideline M3 (R2) on nonclinical safety studies for the conduct of human clinical trials and marketing authorization for pharmaceuticals.
4. Describe the purpose and requirements of the ICH S7A guideline on the safety pharmacology studies for pharmaceuticals.
5. What are the key differences between the EPA guidelines and those of other regulatory bodies such as OECD and ICH?
6. Discuss the requirements for conducting acute, subchronic, and chronic toxicity studies under EPA guidelines.
7. What are the fundamental principles of the OECD GLP, and why are they important for conducting non-clinical laboratory studies?
8. Describe the procedures for dose selection and administration in acute oral toxicity testing.Explain the significance of the LD50 value in acute oral toxicity studies.
9. How do sub-acute oral toxicity studies contribute to the identification of target organ toxicity?
10. Describe the procedures for conducting acute dermal toxicity studies according to OECD TG 402.
11. Discuss the importance of proper dosing and application techniques in sub-acute dermal toxicity studies.
12. Describe the endpoints and measurements that are critical in chronic dermal toxicity studies.
13. What are the criteria for classifying substances based on their dermal irritation potential?
14. Discuss the role of Good Laboratory Practice (GLP) in ensuring the reliability of test item characterization data.

15. Describe the typical study design, including animal selection, dosing regimen, and duration, for male reproductive toxicity studies.
16. Discuss the significance of evaluating implantation sites, early embryonic development, and pre-implantation loss in Segment I studies.
17. Explain the importance of evaluating maternal health, gestation, parturition, and lactation in Segment III studies.
18. Describe the typical study design, including species selection, dosing regimen, and duration, for teratogenicity studies.
19. Explain the limitations of the Ames test and how they are addressed in a comprehensive genotoxicity testing strategy.
20. Discuss the significance of evaluating both cytokinesis-blocked and non-blocked cells in the micronucleus test.
21. Explain how the in vivo micronucleus test provides additional information on genotoxicity compared to in vitro assays.
22. Explain the role of the chromosomal aberration test in a comprehensive genotoxicity assessment strategy.
23. Describe the typical study design for in vivo carcinogenicity studies, including species selection, dosing regimen, and duration. How are the occurrence and types of tumors evaluated and reported in in vivo carcinogenicity studies?
24. Describe the regulatory framework governing IND submissions in major regions such as the FDA in the United States and the EMA in Europe.
25. How does the IND application process facilitate the safety and efficacy evaluation of new drug candidates
26. Discuss the strategic importance of IND-enabling studies in the overall drug development timeline.
27. Discuss how safety pharmacology studies contribute to the identification and mitigation of potential adverse effects of new drugs.
28. Describe the methodologies used to evaluate cardiovascular function in safety pharmacology studies.
29. Discuss the importance of assessing potential effects on motor activity, behavior, and seizure potential.

30. Explain the significance of assessing effects on renal blood flow, glomerular filtration rate, and electrolyte balance.
31. Describe the primary objectives and key endpoints of Tier 1 safety pharmacology studies for the cardiovascular, CNS, and respiratory systems, as well as the hERG assay.
32. Describe the typical study design for toxicokinetic evaluations, including species selection, dosing regimens, and sample collection.
33. What bioanalytical methods are commonly used to quantify test substances and their metabolites in biological samples?
34. Describe the mechanisms that lead to saturation of drug metabolism and transport processes.
35. How do toxicokinetic evaluations support dose selection, formulation development, and the design of clinical trials?
36. Discuss the ethical, scientific, and regulatory drivers for developing and implementing alternative methods.
37. Discuss the importance of toxicokinetic evaluation in preclinical studies. Include the key parameters assessed, the methods used, and how toxicokinetic data are integrated with toxicology findings.
38. Discuss the importance of toxicokinetic evaluation in preclinical studies. Include the key parameters assessed, the methods used, and how toxicokinetic data are integrated with toxicology findings.
39. Discuss the role of organizations such as OECD, ICCVAM, and ECVAM in the validation and acceptance of alternative methods.
40. Describe the various alternative methods to animal toxicity testing, including in vitro, in silico, and ex vivo methods. Discuss the challenges and benefits of these methods and their role in modern toxicology.

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Principles of Drug Discovery

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LONG ESSAYS 7.5 MARKS

1. Elaborate the DNA microarray technique in target identification process.
2. Explain the role of bioinformatics in target identification and validation process.
3. Elaborate on De novo drug design with example.
4. Write a short note on domains motifs and folds in protein structure.
5. What is virtual screening? Discuss about drug likeness screening.
6. Explain the structure based pharmacophore modeling for drug design.
7. Write a note on different types of molecular docking. Enlist the softwares used for molecular docking.
8. Enumerate the difference between SAR and QSAR. Add a note on Hansch Analysis.
9. Explain the various statistical methods used in QSAR.
10. How prodrug can be designed to improve patient acceptability , drug solubility and absorption?
11. Explain the role of proteomics in target identification and validation in drug discovery.
12. Explain the Fee Wilson methods with suitable example.
13. What are the application of NMR and X-Ray crystallography in protein structure prediction?
14. Discuss on fundamentals of QSAR in analysis of results.
15. Explain about the role of antisense technologies in target identification and validation.
16. Write a note on lead optimization and economics of drug discovery.
17. Explain the role of protein microarrays and antisense oligonucleotides.
18. How prodrug can be designed to improve solubility, absorption and distribution?
19. Discuss the role of rigid and flexible docking based drug design.
20. Discuss the role of transgenic animals and antisense technology in target identification.
21. Discuss various traditional drug design method and list out the rational drug design methods.
22. Discuss the role of DNA microarray in target identification.

23. Write a note on types and major steps in molecular docking. Give examples of softwares used for molecular docking.
24. Explain the structure based pharmacophore modeling for drug design.
25. What are the role of zinc finger proteins and antisense technologies in target identification and validation.
26. Explain the various levels of proteins. Write a note on role of QSAR in drug design.
27. Explain about Genomics in target idenfication and validation.
28. Discuss the threading and homology protein structure modelling methods.
29. Explain about the role of high throughput screening in rational drug design.
30. What are importance of proteomics in identification and validation of targets.
31. Explain about COMFA and COMSIA.
32. Explain about manual docking.
33. Explain the factors to be considered in prodrug design with example.
34. Explain various in silico techniques for drug likeliness prediction.
35. Discuss the physicochemical parameters used to quantify structure in QSAR.

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Clinical Research and Pharmacovigilance

LONG ESSAY 7.5 MARKS

1. Discuss the Origin and Principles of the International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines.
2. Explain the Role and Responsibilities of the Ethical Committee: Institutional Review Board (IRB) and Ethical Guidelines for Biomedical Research and Human Participants according to Schedule Y and ICMR.
3. Describe the Structure and Content of an Informed Consent Process and the Ethical Principles Governing It.
4. Discuss the Different Types and Designs of Clinical Trials, with a Focus on Randomized Controlled Trials (RCTs) and Non-Randomized Controlled Trials (Non-RCTs).
5. Compare and Contrast Cohort, Case-Control, and Cross-Sectional Studies in the Context of Observational Clinical Trials.
6. Discuss the Role and Responsibilities of the Principal Investigator (PI) in a Clinical Trial.
7. Describe the Role and Responsibilities of the Study Coordinator in Clinical Trials.
8. Explain the Role and Responsibilities of the Sponsor in Clinical Trials.
9. Describe the Role and Responsibilities of Contract Research Organizations (CROs) in the Management of Clinical Trials.
10. Discuss the Management and Coordination of Clinical Trial Personnel to Ensure the Success of a Clinical Trial.
11. Discuss the Guidelines for the Preparation of Clinical Trial Documents and the Importance of Each Document in the Conduct of a Clinical Trial.
12. Explain the Steps Involved in the Preparation of a Clinical Trial Protocol and Its Critical Elements.
13. Describe the Role and Preparation of the Investigator Brochure in Clinical Trials.
14. Describe the Design and Importance of Case Report Forms (CRFs) in Clinical Trials.
15. Discuss the Preparation and Role of the Clinical Study Report (CSR) in Clinical Trials.
16. Explain the Types, Detection, and Reporting Methods of Adverse Drug Reactions (ADRs) in Clinical Trials.

17. Discuss the History and Progress of Pharmacovigilance and its Significance in Ensuring Medication Safety.
18. Explain the Pharmacovigilance Systems in India and Internationally, Including the WHO International Drug Monitoring Programme.
19. Define Key WHO and Regulatory Terminologies Related to Adverse Drug Reactions (ADRs) and Evaluate Methods for Medication Safety.
20. Discuss the Establishment of Pharmacovigilance Centres in Hospitals and Industry, and the Role of National Programmes Related to Pharmacovigilance.
21. Explain the Roles and Responsibilities of Key Stakeholders in Pharmacovigilance.
22. Discuss the Methods and Tools Used for Adverse Drug Reaction (ADR) Reporting in Pharmacovigilance, Including the International Classification of Diseases (ICD) and International Non-Proprietary Names (INNs) for Drugs.
23. Explain the Differences Between Passive and Active Surveillance Methods in Pharmacovigilance, and Their Roles in Ensuring Medication Safety.
24. the Role of Comparative Observational Studies and Targeted Clinical Investigations in Pharmacovigilance.
25. Discuss the Importance of Vaccine Safety Surveillance and the Methods Used for Monitoring Vaccine Safety.
26. Evaluate the Use of Pharmacovigilance Tools Such as Argus, Aris G, and VigiFlow, and Discuss the Statistical Methods for Evaluating Medication Safety Data.
27. Discuss the Role of Pharmacoepidemiology in Public Health and Its Methodologies for Studying Drug Use and Effects in Populations.
28. Evaluate the Importance of Pharmacoeconomics in Healthcare Decision-Making and Discuss the Key Methods Used in Pharmacoeconomic Evaluations.
29. Discuss the Principles and Applications of Safety Pharmacology in Drug Development and Regulatory Assessment.
30. Explain the Role of Pharmacoepidemiology and Pharmacoeconomics in Enhancing Drug Safety and Public Health Outcomes.

Vision and Mission of the Institution

Vision

The East Point College of Pharmacy aspires to be a globally acclaimed institution, **recognized** for **excellence in** pharmaceutical education, research and nurturing students for **holistic development.**

Mission

M1 Create pharmacy graduates through **quality education**

M2 Promote innovation, **creativity**, and excellence **in teaching**, learning, and **research**

M3 **Inspire** integrity, teamwork, critical thinking**, personal** development, and ethics in **students** and lay **the** foundation for lifelong learning

M4 **Serve** the **healthcare, technological, scientific**, and **economic** needs of then **society**.