EAST POINT COLLEGE OF PHARMACY
East Point Campus, Jnana Prabha, Virgo Nagar Post,
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QUESTION BANK

Pharm D

5th Year

EAST POINT COLLEGE OF PHARMACY
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Clinical Research

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UNIT-I: Drug Development Process

1. INTRODUCTION

SHORT ESSAYS 05 MARKS

1. With schematic representation, discuss integrated drugdevelopment process.

1.1 PHARMACOLOGICAL APPROACH

SHORT ANSWERS 02 MARKS

1. Define therapeutic index
2. Short note on Helsinki declaration
3. What is LD50? And ED50
4. What is Human Equivalent Dose (HED)? How to convert animaldose to HED?
5. Define Proof of Concept
6. Define maximum tolerated dose

SHORT ESSAYS 05 MARKS

1. Explain the different pharmacological action studies in thedrug development process
2. explain pre-clinical trials
3. write a note ADME profiling
4. Write a note on lead selection and optimization drug development process

1.2 TOXICOLOGICAL APPROACH

SHORT ANSWERS 02 MARKS

1. Importance of chronic toxicity
2. Mutagenecity and carcinogenicity
3. Sub acute toxicity

SHORT ESSAYS 05 MARKS

1. Explain the toxicological approach to drug development process

1.3 IND APPLICATION

LONG ANSWERS 10 MARKS

1. Discuss in detail IND application

SHORT ESSAYS 05 MARKS

1. What is IND? Enlist the different criteria for IND application.

1.4 DRUG CHARACTERIZATION

SHORT ESSAYS 05 MARKS

1. Discuss various drug characterization techniques in drug development process.

1.5 DOSAGE FORM

SHORT ESSAYS 05 MARKS

1. Explain the importance of dosage form design in pre-clinical and clinical stages.

SHORT ANSWERS 02 MARKS

1. Biopharmaceutical classification of drugs
2. Name the critical pharmacokinetic parameter in drug development.
3. Drug bioavailability
4. Fixed dose combinations.

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UNIT-II: CLINICAL DEVELOPMENT OF DRUG

2.1 INTRODUCTION TO CLINICAL TRIALS

LONG ANSWERS 10 MARKS

1. Requirements to conduct trials as per Schedule Y.

SHORT ESSAYS 05 MARKS

1. Explain inclusion and exclusion criteria in selection of clinical trial subjects
2. Explain the role of BPOs in conducting clinical research in India

SHORT ANSWERS 02 MARKS

1. What is clinical trail
2. define single blind method
3. define double blind method
4. name different types of clinical trials
5. investigation product/drug
6. What is Belmont report?
7. Nuremberg trials
8. What is 'The Orange Book'
9. Note on Non-inferiority clinical study
10. Define bias
11. Regulations for orphan drugs
12. Regulations for Counterfeit drugs
13. drug labeling requirement in clinical studies
14. What is scurvy trail?

2.2 VARIOUS PHASES OF CLINICAL TRIALS

LONG ANSWERS 10 MARKS

Discuss in detail the various phases of clinical trial

SHORT ESSAYS 05 MARKS

1. Briefly explain phase 1 and phase 2 clinical trials
2. write short note on clinical trial design
3. objectives of phase 1/2/3/4
4. methods of randomization
5. difference between phase 2a and phase 2b

SHORT ANSWERS 02 MARKS

1. note on randomized clinical trial
2. define phase Zero
3. Note on open labeled clinical trails
4. Methods of sample size calculations in clinical trials
5. what are the objectives of phase 2 studies
6. Use of Placebo in clinical trials
7. Principles of trial subject sampling.

2.3 METHODS OF POST MARKETING SURVELLEINCE

LONG ANSWERS 10 MARKS

1. Discuss about the different methods of post marketing surveillance

SHORT ESSAYS 05 MARKS

1. write a note on case control studies
2. difference between retrospective and prospective study
3. observational studies
4. write a note on meta analysis

SHORT ANSWERS 02 MARKS

1. note on cohort studies
2. differentiate ADR and ADE
3. retrospective study
4. cross sectional study
5. Epidemiological study
6. Define false positive result with an example.

2.4 ABBREVIATED NEW DRUG APPLICATION

LONG ANSWERS 10 MARKS

1. explain briefly about ANDA submission
2. Explain in detail NDA submission

SHORT ESSAYS 05 MARKS

1. write a note on ANDA
2. basic methodology and study designs of BA/BE studies

SHORT ANSWERS 02 MARKS

1. limitations of post marketing surveillance

2.5 GOOD CLINICAL PRACTICE

LONG ANSWERS 10 MARKS

1. discuss the principles of ICH-GCP guidelines
2. Explain clinical trial protocol as per ICH-GCP guidelines
3. Explain Clinical trials and monitoring. Discuss different types ofmonitoring visits in detail
4. What do you mean by expedited reporting in clinical trial?Discuss the safety reporting as per schedule Y
5. discuss the recent amendments in schedule Y with special reference to ethics committee

SHORT ESSAYS 05 MARKS

1. what the note on ICH-GCP guidelines
2. essential documents in conducting clinical trials
3. Discuss in detail about CDSCO guidelines
4. Write a short note on new amendments to Schedule Y
5. what are medical devices and classify with suitable examples
6. statistical design in clinical trails
7. write a note on Clinical Study Reports
8. Premature Termination or Suspension of a Study
9. Selection and recruitment of Study Subjects
10. Clinical Trials with Surgical Procedures / Medical devices

SHORT ANSWERS 02 MARKS

1. Role of ICMR in clinical research
2. list the guidelines and acts that govern the conduct of clinical trials in India
3. selection and withdrawal of subjects in clinical trail
4. multicentre trails
5. preparative termination of clinical trail
6. Unblinding
7. drug master file
8. subject identification code

9. Note on CIOMS
10. ICH E6
11. contract research
12. clinical trial registries
13. clinical trial insurance
14. comparative studies
15. coding of investigation products
16. importance of confidentiality statement in IB
17. Phases of Vaccine Trials
18. Non-Therapeutic Study
19. Validation of clinical study

2.6 CHALLENGES IN THE IMPLEMENTATION OF GUIDELINES

SHORT ESSAYS 05 MARKS

1. Comment on the challenges in the implementation of ethicalguidelines

2.7 ETHICAL GUIDELINESIN CLINICAL RESEARCH

LONG ANSWERS 10 MARKS

1. write a note on clinical data management in clinical trials

SHORT ESSAYS 05 MARKS

1. explain clinical trials for vaccines
2. pregnant women as research participant
3. Explain the ethical guidelines for clinical research
4. write a note on compensation for clinical Trial subjects as perethical guidelines
5. Conflict of interest in clinical trials

SHORT ANSWERS 02 MARKS

1. research involving children
2. Inclusion of pregnant women and nursing mothers in CT?
3. vulnerable subject
4. define Ethics
5. Ethical issues involved in Genetic Screening

2.8 COMPOSITION, RESPONSIBILITIES, PROCEDURE OF IRB/ IEC

SHORT ESSAYS 05 MARKS

1. explain composition and responsibilities of IRB
2. Discuss in detail about institutional review board

SHORT ANSWERS 02 MARKS

1. Describe members of ICH

2.9 OVERVIEW OF REGULATORY ENVIRONMENT IN USA, EUROPE AND INDIA

LONG ANSWERS 10 MARKS

1. Write a note on pharmaceutical regulations in regard toclinical trials in European union
2. Write a note on Centralized procedure and Decentralized Mutual Recognition Procedure in European union
3. write a note on Accelerated Approval, Fast Track, and Priority review

SHORT ESSAYS 05 MARKS

1. what are different regulator system in USA, europe and India
2. give an overview of regulatory environment in India
3. expand forms of the following MHRA, CRO, CRF, MAH, EMEA,CTA, GLP, CFR
4. write a note on regulations for OFF-Label Use
5. write a note on Accelerated Approval
6. write a note on Fast Track, and Priority Review

SHORT ANSWERS 02 MARKS

1. write on European Clinical Directive
2. function of dcgi
3. Note on 21CFR Part 312
4. Note on Marketing Authorization Holder (MAH)
5. note on centralized marketing and decentralized marketing
6. Note on Clinical Trial Document (CTD)
7. What is MHRA
8. What is EMEA
9. What is USFDA

2.10 ROLE AND RESPONSIBILITIES OF CLINICAL TRIAL PERSONNEL AS PER ICH GCP

LONG ANSWERS 10 MARKS

1. Explain in detail the role and responsibilities of a) investigator b) Clinical research associate c) Regulatory authority as per ICH-GCP

2. explain about clinical trials audit and inspection with special emphasis on national regulatory authorities

SHORT ESSAYS 05 MARKS

1. Write a note on CRA
2. What is an Investigators brochure and explain its content?
3. Role and responsibilities of auditors
4. explain the role of investigators I clinical trials
5. Role and responsibilities of sponsor in clinical trials
6. explain designing of CRF with a suitable example
7. Discuss about designing of inform consent form for clinical study?

SHORT ANSWERS 02 MARKS

1. Expand the following: IND, DCGI, PvPI, BPO
2. role of CRC
3. Role of auditor In clinical data
4. criterias for selection of an investigator/s
5. define protocol
6. explain confidentiality and impartial witness

2.11 DESIGNING OF CLINICAL STUDY DOCUMENTS (PROTOCOL, CRF, ICF, PIC WITH ASSIGNMENT)

SHORT ESSAYS 05 MARKS

1. Explain in detail the informed consent process

SHORT ANSWERS 02 MARKS

1. difference between consent and assent forms
2. explain Waiver of consent

2.12 INFORMED CONSENT PROCESS

SHORT ESSAYS 05 MARKS

1. Explain in detail the informed consent process
2. Discuss about designing of informed consent form for clinical study

SHORT ANSWERS 02 MARKS

1. explain confidentiality and impartial witness
2. difference between consent and assent forms
3. explain Waiver of consent

2.13 DATA MANAGEMENT AND ITS COMPONENTS

SHORT ESSAYS 05 MARKS

1. write a note on QA and QC
2. Discuss data management and its component
3. Write the application of computers in clinical data management
4. write a note on clinical data archive
5. Discuss Electronic Data Processing

SHORT ANSWERS 02 MARKS

1. What is ANOVA?
2. Role of DSMB in safety monitoring
3. Components of documentation form

2.1.4 SAFETY MONITORING IN CLINICAL TRIALS

LONG ANSWERS 10 MARKS

1. Explain the monitoring visits in initiation, conduction and closing of clinical trial
2. Explain spontaneous reporting of ADR with suitable examples. What are the merits and demerits of spontaneous reporting

SHORT ESSAYS 05 MARKS

1. write about safety monitoring in clinical trails
2. Explain the purpose of the clinical trial monitoring and the responsibilities of monitors in clinical monitoring
3. write a note on Active Surveillance in ADR reporting
4. Role of Eudravigilance in safety monitoring

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SHORT ANSWERS 02 MARKS

1. List global ADR reporting Forms?
2. Define unexpected ADR
3. Minimum criteria to report ADR
4. List various criterias to classify a serious ADR
5. What is PVPI
6. What is PSUR
7. What is SUSAR
8. Role of Uppsala monitoring centre (UMC) in safety Monitoring

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Pharmacoepidemiology

&

Pharmacoeconomics

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1. Define risk & enlist the various factors influencing risk in pharmacoepidemiology. Explain relative risk and Odd's ratio with suitable examples.
2. What is bias. Explain the different types of bias in pharmacoepidemiology with examples.
3. What is medication adherence. Explain the methods used to assess medication adherence.
4. Identify and explain the two major pharmacoepidemiological models used to test the relationship between drug exposure and patient outcomes.
5. Explain the applications of pharmacoeconomics.
6. Define DUE. Explain the steps involved in a DUE and mention the pharmacist role in DUE cycle.
7. Explain the merits and demerits of Cohort and case controlled study.
8. Define pharmacoepidemiology and explain history and scope of pharmacoepidemiology.
9. What is cost utility analysis. Explain with suitable examples how the outcome measured using cost utility analysis.
10. What is cost effective analysis. Explain with suitable examples how the outcome measured using cost effective analysis.
11. Explain criteria for causal nature of an association in pharmacoepidemiology study.
12. Define pharmacoepidemiology. Explain case control and cohort studies with suitable examples.
13. Explain in detail the measurement of outcomes in PE studies and explain in detail the drug use measures?
14. Explain in detail the concept of risk and measurement of risk of an ADR with respect to
15. Attributable risk Relative riskTime risk relationship Odds ratio
16. .Explain in detail the methods of Pharmacoeconomic evaluation. (a) Cost of illness evaluation. (b) Cost of minimization analysis. (c) Cost of benefit analysis. (d) Cost effective analysis. (e) cost utility analysis
17. Explain in detail the cohort studies in Pharmacoepidemological study designs and explain in detail the cohort classification?
18. Define record linkage system and explain the process of record linkage system and also explain the probabilistic and deterministic approach in record linkage system?
19. Define Pharmaco-economics and write the applications of Pharmacoeconomics and explain the types of Pharmacoeconomic evaluations. a) CMA b) CBA c) CEA d) CUA?

20. What is bias? Explain the different types of bias with examples in pharmacoepidemiology?

21. Define DUE. Explain the steps involved in a DUE and mention the pharmacists role in DUE cycle.

22. Explain the merits and demerits of cohort and case controlled study.

23. Explain and mention merits and demerits of cohort and case-control studies.(2)

24. Define DUE. Explain the steps involved in a DUE and mention the pharmacists' role in DUE study.

25. Identify two major pharmacoepidemological models used to test the relationship between drug exposure and patients outcomes and explain

26. Explain few important pharmacoepidemiological studies involving drug induced birth defects.

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Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring

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UNIT-I: Introduction to Clinical Pharmacokinetics

SHORT ANSWERS 02 MARKS

1. Give the importance of clinical pharmacokinetics
2. Define apparent volume of distribution and give the mathematical equation to calculate this parameter.
3. Define non-linear pharmacokinetics
4. Describe the difference between first and zero order elimination and how each order appears graphically.
5. Define biological half-life and give it's equation with units.
6. Give the relationship between half-life and elimination rate constant.
7. What is clearance? Give the relationship between clearance, drug dose and AUC.
8. Give the assumptions of compartment model.
9. Define pharmacokinetics. Name and define three pharmacokinetic parameters that describe a

typical plasma level time curve.

10. Define loading dose and maintenance dose. Give equations to calculate the same.
11. Give any four applications of clinical pharmacokinetic

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UNIT II: A. Design of Dosage Regimen + B. Therapeutic Drug Monitoring

A. Design of dosage regimens

LONG ANSWERS 10 MARKS

1. Explain the various factors considered in the design of dosage regimen for geriatric and
2. obese patients.
3. Short Essay 5 Marks
4. Explain the process and clinical significance of conversion from intravenous to oral dosing.
5. What are nomograms? Explain their applications in pharmacokinetic studies with examples.
6. Give their advantages and disadvantages.
7. Explain in detail the determination of dose and dosing interval of a drug.
8. Describe the principle of superposition and how it applies to multiple drug dosing.
9. Explain the role of nomograms and tabulations in the design of dosage regimen.
10. Explain the different methods of conversion of intravenous to per oral dosing.
11. Explain various factors considered in designing the dosage regimen for geriatric patients.
12. Explain the factors considered in the design of dosage regimen for paediatric patients. Give any two formulae for the calculation of child dose.
13. Explain various factors considered in the design of dosage regimen for obese patients.
14. Why dosage adjustment is necessary in the obese patients. What are the pharmacokinetic parameters to be considered in the dosage adjustment for obese patients?
15. The elimination half-life and Vd of tobramycin was reported to be 2.15 hrs and 33.5% of body weight respectively. What is the dose for an 80 kg individual if a steady state level of 2.5 μg/ml is desired? Assume that the drug is given as iv bolus every 8 hrs.

16. The elimination half-life of an antibiotic is 3 hrs with an apparent volume of distribution equivalent to 20% of bodyweight. The usual therapeutic range of this antibiotic is between 5-15 µg/ml. Calculate the dose and dosing interval that will just maintain the therapeutic concentration.
17. Explain in detail determination of dose and dosing interval of a drug.
18. Enumerate the factors involved in calculation of drug dose in peadiatric patients.
19. Discuss the factors to be considered during the design of dosage regimen.
20. Explain the reasons for converting IV dose to oral dose. Add a note on START and STOP riteria for drugs to be used in patients.

SHORT ANSWERS 02 MARKS

1. Add a note on START and STOP criteria for drugs to be used in geriatric patients.
2. Write different formulae for calculating child dose.
3. Add a note on BEER's criteria for drugs to be used in geriatric patients.
4. Write the importance of loading dose in finding drug dosing intervals.
5. Give the relationship between elimination half-life and drug dosing intervals
6. Define nomograms and tabulations.
7. Give any two advantages and disadvantages of nomograms.
8. Enumerate the methods for conversion of IV to oral dosing.
9. Give any four factors considered in dosing geriatric patients.
10. What are the factors affecting the drug absorption in geriatric patients?
11. Mention the factors affecting the drug distribution in obese patients.
12. Based on which property of drug, the drug dosage is adjusted in the obese patients and why?
13. Give any four factors considered in dosing obese patients.
14. Mention any four factors considered in dosing paediatric patients.
15. Give any two formulae for the calculation of paediatric dose.
16. Write the formula for the calculation of geriatric dose.
17. What are the factors considered in the conversion of IV to oral dosing?
18. What is the BEER's criteria for drugs to be used in geriatric patients?

B. Therapeutic Drug Monitoring

LONG ESSAY 10 MARKS

1. Explain the necessity and process of TDM in patients receiving cyclosporine and carbamazepine.
2. List out the indications for TDM. Explain the necessity and process of TDM in patients receiving digoxin and phenytoin.
3. Explain the necessity and process of TDM in patients receiving lithium and methotrexate.
4. Enumerate and explain various factors in individualizing drug dosage regimen.
5. Explain in detail pharmacokinetic/pharmacodynamic correlation in drug therapy.

SHORT ESSAY 05 MARKS

6. Explain effect of age and bodyweight in individualization of drug dosage regimen.
7. Explain role of genetics and disease condition in the individualization of drug dosage regimen.
8. Explain role of co-existing diseases and interacting drugs in the individualization of drug dosage regimen.
9. Describe the protocol for TDM of a drug. Define TDM. Discuss the indications for TDM of drugs.
10. Explain the role of clinical pharmacist in TDM.
11. Explain the relationship between dose and pharmacological effect of a drug.
12. Explain the relationship between dose and duration of activity of a drug.
13. Explain with suitable examples how elimination half life of a drug influence the duration of activity.Write about Emax model
14. Explain the sigmoidal Emax model in PK/PD correlation

SHORT ANSWERS 02 MARKS

15. Enlist various types of samples used for analysis in TDM
16. What do you understand by drug tolerance and physical dependency?
17. Define narrow therapeutic index with suitable examples.
18. Define TDM. Name any four drugs that require TDM.
19. Write the protocol for TDM of a drug.
20. Give any four indications for TDM.
21. Why is TDM necessary for digitoxin.

22. Why is TDM necessary for methotrexate.
23. Explain the necessity of monitoring cyclosporine.
24. Give the necessity for TDM of lithium.
25. Why is TDM necessary for phenytoin.
26. Explain the reasons for monitoring drug levels.

Unit III: Pharmacokinetics of drug interactions

SHORT ESSAY 05 MARKS

1. Explain the various pharmacokinetic drug interactions with suitable examples*.
2. Explain the influence of drug interaction on drug absorption with examples
3. Discuss drug interactions related to protein binding and metabolism.
4. Describe the role of cytochrome P-450 enzymes in drug interactions. Add a note withmsuitable examples and their clinical significance.
5. Explain the influence of drug interaction on drug metabolism with respect to enzyme induction and enzyme inhibition.
6. Explain the effect of inhibition of biliary excretion of drugs and list out the drug interactions which influence the biliary excretion.

UNIT IV: (A. Dosage adjustment in renal and hepatic disease + B. Pharmacogenetics)

A. Dosage adjustment in renal and hepatic disease

LONG ESSAY 10 MARKS

1. Explain in detail the general approaches for dosage adjustment in renal diseases.
2. Explain in detail the different methods of extracorporeal removal of drugs.
3. Discuss various markers used in the measurement of glomerular filtration rate along with their advantages and disadvantages. Enumerate the various formulae used for the measurement of creatinine clearance.
4. Enumerate various causes for renal impairment. Discuss in detail the pharmacokinetic considerations in the renal failure patients.
5. List out various factors for hepatic impairment. Discuss in detail the pharmacokinetic considerations in the hepatic disease patients.

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SHORT ESSAY 05 MARKS

1. List various formulae for measurement of glomerular filtration rate.
2. Explain the various pharmacokinetic changes observed in the renally impaired patients.
3. How do you adjust dosage regimen in renal failure patients based on elimination half life of drug?
4. How do you adjust dosage regimen in renal failure patients based on total body clearance of drug?
5. Give the ideal characteristics of a marker to be used in the measurement of GFR.
6. Explain various markers used in the measurement of glomerular filtration rate along with their advantages and disadvantages.
7. Define creatinine clearance. Enumerate various formulae used for the measurement of creatinine clearance.
8. Explain the effect of hepatic disease on pharmacokinetics of drugs.
9. Describe peritoneal dialysis with its advantages and disadvantages.
10. Explain the Giusti-Hayton method for the dosage adjustment in uremic patients.
11. Describe the Wagner method for the dose adjustment in uremic patients.
12. The maintenance dose of gentamicin is 80mg every 6hrs for a patient with normal renal function. Calculate the maintenance dose for a uremic patient with creatinine clearance of 20ml/min. Assume a normal creatinine clearance of 100ml/min.
13. What is the creatinine clearance for a 25 year old male patient with a serum creatinine of 1mg/dL? The patient is 5 ft, 4inches in height and weighs 103 Kg.
14. An adult male patient (52 years old, 75 kg) whose serum creatinine is 2.4 mg/dL is to be given gentamicin sulphate. The usual dose of gentamicin in adult patients with normal renal function is 1 mg/kg every 8 hours by multiple IV bolus injections. Calculate the appropriate dosage regimen of gentamicin sulfate for this patient.
15. Explain hemodialysis.
16. Explain methods of determining creatinine clearance.
17. Describe the methods of measurement of GFR and their significance.

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SHORT ANSWERS 02 MARKS

1. Enumerate the factors influencing dialyzability of drugs.
2. Enumerate the causes for renal failure
3. Give any four pharmacokinetic parameter changes observed in the renal failure patients.
4. List the markers used in the measurement of GFR.
5. Give any four ideal characteristics of the marker drugs to be used for GFR measurement.
6. Give two advantages and disadvantages of inulin as a marker for GFR measurement.
7. Give the Jellife's equation for the measurement of creatinine clearance.
8. Give the Cockraft and Gault's equation for the measurement of creatinine clearance.
9. Give the formula for the calculation of creatinine clearance in children.
10. Give the MDRD equation for the measurement of creatinine clearance.
11. Name the methods for the extracorporeal removal of drugs.
12. Give any two advantages and disadvantages of peritoneal dialysis.
13. Give any two advantages and disadvantages of haemodialysis.
14. Define intrinsic clearance of drugs with its clinical significance.
15. Calculate creatinine clearance for a 30 year old female patient with a serum creatinine value of 0.8 mg/dl. The patient is 5 ft 1 inch tall and weighs 69 kgs.
16. Name the metabolic markers used in liver function test with their normal values
17. Define hepatic clearance
18. Give the importance of extra corporeal removal of drugs.
19. Calculate creatinine clearance for a 23 year old male patient with a serum creatinine value of 1.2 mg/dl. The patient is 5 ft 5 inch tall and weighs 98 kgs.
20. Using the method of Cockroft and Gault, Calculate creatinine clearance for a 36 year old female patient with a serum creatinine value of 1.8 mg/dl. The patient is 5 ft 5 inch tall and weighs 58 kgs.

B. Pharmacogenetics

LONG ESSAY 10 MARKS

1. Discuss the role and clinical significance of genetic polymorphism in drug transports and drug targets with suitable examples.
2. Discuss the importance of genetic polymorphism of cytochrome P-450 isozymes on drug metabolism with suitable examples.

SHORT ESSAY 05 MARKS

1. Describe the role of genetic polymorphism in drug targets.
2. Describe the genetic polymorphism in CYP2D6 and 2C9 isozymes

SHORT ANSWERS 02 MARKS

1. Define pharmacogenetics
2. Describe genetic polymorphism in CYP2D6 isozymes
3. Describe genetic polymorphism in CYP2C9 isozymes
4. How do efflux transporters affect the bioavailability of the drugs
5. Give any two examples for clinically important genetic polymorphism of drug targets.
6. Give any two examples for clinically important genetic polymorphism of drug transporters.
7. Describe the role of genetic polymorphism in drug targets.
8. Define pharmacogentics and with suitable examples.With suitable examples, enumerate drug dosing in genetic dependent fast acetylators.

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Unit V: Population Pharmacokinetics

SHORT ESSAY 05 MARKS

1. Describe Bayesian theory
2. Explain dosing with feedback.
3. Discuss population pharmacokinetic analysis using NONMEM method.
4. Discuss analysis of population pharmacokinetic data.
5. Discuss about the methods used to obtain the estimates of fixed effects and variability
6. Describe the two-stage approach in population pharmacokinetic analysis
7. Explain non-linear mixed effects modeling approach
8. Give the applications of population pharmacokinetics.
9. Explain the sampling design used in population pharmacokinetic study
10. Describe how population pharmacokinetic data analysis is carried out.
11. Give the reasons for conducting population pharmacokinetic study
12. What are the limitations of population pharmacokinetic approach
13. Explain the difference between traditional pharmacokinetics and population pharmacokinetics.

SHORT ANSWERS 02 MARKS

1. Define adaptive method in population pharmacokinetics study.
2. Define population pharmacokinetics.
3. Define adaptive method in population pharmacokinetics study.
4. Define population pharmacokinetics.
5. What are the advantages of population pharmacokinetic study over traditional pharmacokinetic study?
6. Define interindividual variation
7. Define within subject variation
8. What is random error?
9. What is residual error?
10. What do you understand by typical value?
11. Define theta, omega, sigma in NONMEM method of analysis
12. List the methods used for the population pharmacokinetic model evaluation
13. What is difference between observed and predicted concentrations
14. What do you understand by over-estimation?

15. List various software's used for conducting population pharmacokinetic analysis
16. Give Bayesian equation.
17. What do you understand by Goodness of Fit plot
18. Define FO and FOCE.
19. What do you understand by nested models?
20. What is naïve pool data?
21. Give the advantages of Bayesian method in population pharmacokinetic study
22. What is interoccasion variation?

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**.