Code No: G-13280

FACULTY OF PHARMACY

Pharm. D (6 YDC) V - Year (Main & Backlog) Examination, September 2025

Time: 3 Hours **Subject: Pharmacoepidemiology & Pharmacoeconomics** **Max.Marks:70**

PART–A

Note: Answer all the questions. **(10 x 2 = 20 Marks)**

1. What are QALY and VAERS?
2. Define cohort study with an example.
3. What are drug induced birth defects?
4. Write about cost effective analysis.
5. What do you mean by prescription event monitoring?
6. Write about Adhoc data sources.
7. Define morbidity and mortality.
8. Explain teratogens with example.
9. Write a short note on nested case control study.
10. Write the applications of pharmacoeconomics.

PART–B

Note: Answer any five questions. **(5 x 10 = 50 Marks)**

11. Write detailed note on vaccine safety in pharmacoepidemiology.
12. Explain the role of pharmacoeconomic evaluations in formulary management.
13. Discuss the steps for performing a decision analysis. Calculate the average costs and outcomes from a decision tree with example.
14. Compare and contrast different pharmacoeconomic evaluations
15. Discuss cost benefit analysis with the help of a case study.
16. Describe the steps involved in conducting a meta-analysis and explain different effect size measures used in meta-analysis.
17. Define medication Adherence and explain methods to evaluate medication adherence.
18. What is the origin of pharmacoepidemiology and write aims and applications of it?

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Code No: G-13281

FACULTY OF PHARMACY

Pharm. D (6 YDC) V - Year (Main & Backlog) Examination, September 2025

Subject: Clinical Pharmacokinetics & Pharmacotherapeutics Drug Monitoring

Time: 3 Hours **Max.Marks:70**

PART – A

Note: Answer all the questions. **(10 x 2 = 20 Marks)**

1. What is the role of pharmacist in clinical pharmacokinetics?
2. Write about determination of dose and dosing interval?
3. What are the indications of therapeutic drug monitoring with suitable examples?
4. Write a note on enzyme inhibition with examples?
5. Write note on drug interactions in biliary excretion?
6. Write a note on pharmacogenetics in clinical practice?
7. Write the TDM for carbamazepine?
8. Write a note on Cyp-450 enzymes?
9. Write a note on factors involved in designing drug dosage regimen?
10. Write the significance of Clearance in clinical pharmacokinetics?

PART – B

Note: Answer any five questions. **(5 x 10 = 50 Marks)**

11. Explain in detail about drug dosing in Elderly and Pediatric patients.
12. Explain various pharmacokinetic drug-drug interactions with suitable examples.
13. Explain in detail about individualization of drug dosage regimen.
14. Explain in detail about TDM of Phenytoin and Vancomycin.
15. Explain in detail the extra corporeal removal of drugs.
16. Explain briefly Bayesian theory and analysis of population pharmacokinetic data.
17. Explain in detail about the dosage adjustment in patients with hepatic disease.
18. Explain the genetic polymorphism of cytochrome p-450 in drug metabolism.

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Code No: G-13279

FACULTY OF PHARMACY

Pharm D (6 YDC) V - Year (Main & Backlog) Examination, September 2025

Subject: Clinical research

Time: 3 Hours **Max. Marks: 70**

PART - A

Note: Answer all the questions. **(10 x 2 = 20 Marks)**

1. Write a note on types of clinical trials.
2. Give the ethical issues in conduct of clinical trials.
3. Write a note on objectives of phase 3 clinical trials.
4. Write in short about statistical considerations in clinical trials as per ICH GCP guidelines.
5. Distinguish between generic and innovator drugs.
6. Differentiate NDA and ANDA application.
7. Give the regulatory action taken after identification of adverse drug reactions in post marketing surveillance.
8. Write a note on various methods of drug characterization in drug discovery.
9. Give the organisation and functions of CDSCO.
10. Explain quality assurance in clinical data management.

PART - B

Note: Answer any five questions. **(5 x 10 = 50 Marks)**

11. Explain various components of clinical trial protocol as per ICH GCP guidelines.
12. Explain methods of post marketing surveillance. Give the contents of periodic safety update report as per schedule Y requirements.
13. Explain New Drug application along with its contents and submission.
14. Explain the statement of general principles and specific principles for clinical evaluation of drugs.
15. Explain in detail clinical data management process.
16. Discuss different techniques of randomization in clinical trials. Explain ways to assess whether randomisation was successful.
17. Discuss monitoring and auditing in clinical trials.
18. Explain the design of case report form and informed consent form.

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