FACULTY OF PHARMACY

Code No: E-12367

Pharm D V Year (6 YDC) (Main & Backlog) Examination, October 2023
Subject: Clinical research

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

PART - A

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

1. Explain the toxicological approaches to drug discovery
2. Explain internal and external validity of clinical trials
3. What is a safety signal? Give the criteria for serious adverse event.
4. What is orphan drug? Explain in short clinical trial of orphan drugs.
5. Give PSUR submission timeline for USA, Europe and India.
6. Explain source data and source documents as per ICH GCP guidelines.
7. Explain selection and withdrawal of subjects in clinical trials.
8. Explain the role of DSMB in safety monitoring of clinical trials
9. Give the contents of case report form.
10. Explain data storage and security in CDM.

PART - B

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

11. Give the essential documents required before, during and after completion of clinical trial.
12. Give the composition, responsibilities and procedures of IRB/IEC.
13. Discuss the role of various stakeholders in safety monitoring in clinical trials.
14. Discuss role and responsibilities of investigator in clinical trials. Give the contents of investigators brochure.
15. Give the overview of clinical regulatory environment in USA, Europe and India.
16. Explain CDSCO statement of specific principles for epidemiology studies and vaccine trials.
17. Discuss IND application with its contents and submission.
18. Write the principles of ICH GCP guidelines. Explain the challenges and ethical issues in the implementation of these guidelines.

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Code No: E-12369

FACULTY OF PHARMACY

Pharm. D V Year (6 YDC) (Main & Backlog) Examination, October 2023
Subject: Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring

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

PART - A

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

1. Explain the role of clearance of a drug in its dosing.
2. Enumerate the advantages and disadvantages of nomograms.
3. Give examples of enzyme inducers and inhibitors.
4. Suggest ways to prevent or manage drug interactions.
5. How variability in age can affect the selection of dosage regimen?
6. Differentiate Hemodialysis and Hemoperfusion.
7. Write a short note on Hysteresis.
8. Briefly describe Genetic polymorphism in drug targets with one example
9. What are the components of protocol for TDM?
10. Explain loading dose and maintenance dose with equations.

PART - B

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

11. Discuss the genetic polymorphisms in Cytochrome P-450 Isoenzymes with examples.

12. Explain the following
    (c) Basic concept of Bayesian theory
    (d) Inhibition of MAO with examples

13. Explain the general approaches used for drug dosing in renal failure. Add a note on measurement of Glomerular filtration rate and Creatinine Clearance.

14. Discuss the effect of hepatic disease on pharmacokinetics of a drug. Describe the components of a Hemodialysis circuit.

15. Explain the procedure for Therapeutic Drug Monitoring of Sodium valproate and cyclosporin in detail.

16. (a) Describe the drug-drug interactions related to distribution with suitable examples.
    (b) Write a short note on Auto-induction and inhibition of MAO.

17. Explain the determination of dose and dosing interval. Discuss the method to estimate dosage regimens in paediatric population.

18. Explain the following
    (a) Pharmacokinetics' and PK/PD considerations
    (b) Dosing with feedback

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Code No: E-12368

FACULTY OF PHARMACY

Pharm D V Year (6 YDC) (Main & Backlog) Examination, October 2023
Subject: Pharmacoepidemiology & Pharmacoeconomics

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

PART - A

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

1. Define cohort study with an example.
2. Summarize the advantages of meta-analysis?
3. Outline time-risk relationship.
4. Discuss defined daily dose and prescribed daily dose.
5. What do you mean by case-control studies?
6. Outline systematic review and its importance.
7. Discuss quality adjusted life year.
8. Define Attributable risk and relative risk with an example.
9. What are drug-induced birth defects?
10. How are adverse effects with vaccines reported?

PART - B

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

11. Discuss about the origin and evolution of pharmacoepidemiology. Add a note on its applications.

12. Elaborate in detail about studies of vaccine safety.

13. Explain the concept of risk in pharmacoepidemiology. Discuss about risk management plan development.

14. Write notes on Adhoc data source and automated data system.

15. Discuss in detail about the different pharmacoeconomic methods.

16. Explain cost-benefit analysis with a case study. Add a note on its applications.

17. What is cost-effectiveness analysis? Write about the advantages, disadvantages and applications of CEA.

18. Explain cost-utility analysis? Write about the advantages, disadvantages and applications of CUA.

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Code No. D-8377/PB

FACULTY OF PHARMACY

Pharm. D II Year (3-YDC) (PB) (Main & Backlog) Examination, August 2022
Subject: Pharmacoepidemiology and Pharmacoeconomics

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

PART – A

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

1 What is the need of pharmacoepidemiology studies in India?
2 Write a note on the monetary units being used in an outcome measure.
3 Define DDD and PDD.
4 Define morbidity and mortality.
5 Write about cross sectional studies and cohort studies.
6 What do you mean by prescription event monitoring?
7 Name any two drugs induced birth defects.
8 Write about Adhoc data sources.
9 What are QALY and VAERS?
10 Write about cost effective analysis.

PART – B

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

11 Write aims and applications of pharmacoepidemiology.

12 Write about prevalence, incidence rate and medication adherence.

13 (a) Write about attributable risk and odds ratio risk with examples.
(b) Explain about significance of risk in pharmacoepidemiology.

14 (a) Explain about spontaneous reporting with different ADR forms used in reporting.
(b) Write the merits and demerits of case control and meta-analysis studies.

15 Write a note on automated data sources with examples.

16 (a) Write about hospital pharmacoepidemiology.
(b) What is Vaccine safety and write about its reporting?

17 (a) Write a note on applications of pharmacoeconomic studies.
(b) Explain the need of pharmacoeconomic evaluations in formulary management.

18 Explain about cost benefit and cost minimization evaluations in pharmacoeconomics.

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Code No. D-8376/PB

FACULTY OF TECHNOLOGY

Pharm. D (3 YDC) II Year (PB) (Main & Backlog) Examination, August - 2022
Subject: Clinical Research

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

PART – A

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

1. Distinguish between monitoring and auditing
2. What do you mean by quality assurance in clinical trials?
3. Distinguish between ADR & ADE
4. Write a note on the objectives of Phase-II clinical trials
5. What is independent data-monitoring committee (IDMC?)
6. What do you mean by essential documents & give 2 examples.
7. Distinguish between audit report and audit certificate
8. What do you mean by Investigator's Brochure (IB)
9. What is the role of impartial witness in informed consent process?
10. What do you mean by clinical hold, in US FDA regulations?

PART – B

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

11. Comment on Indian and USA regulations regarding the grant of permission to conduct clinical trials.
12. What are the responsibilities of Clinical Research Coordinator (CRC) & Clinical Research Associate (CRA).
13. Explain the role of Institutional Ethics Committee (IEC) in protecting the subjects safety, welfare and rights.
14. Write a note on the trial monitoring responsibility of sponsor.
15. Write a note on clinical data management process.
16. Write a note on ADR reporting and Periodic Safety Update Reports (PSUR).
17. Briefly explain various phases of clinical trials.
18. Write a note on informed consent process with special mention on the protection of vulnerable subjects.

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Code No. D-8378/PB

FACULTY OF PHARMACY

Pharm. D II Year (3-YDC) (PB) (Main & Backlog) Examination, September 2022
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 Write the importance of nomograms in designing of dosage.
2 Write about determination of dose and dosing interval.
3 What are the indications of therapeutic drug monitoring?
4 Write a note on microsomal enzyme inducers.
5 Explain plasma protein binding with its significance.
6 Write the TDM for lithium.
7 Add a note on Biliary Excretion.
8 Discuss the tabulations in designing dosage regimen.
9 What is the role of pharmacist in clinical pharmacokinetics?10 Write the significance of population pharmacokinetics.

PART – B

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

11 Write in detail about various pharmacokinetic drug-drug interactions with suitableexamples.

12 Explain in detail the extra corporeal removal of drugs.

13 Describe the general approach for dosage adjustment in renal disease.

14 Explain briefly Bayesian theory and analysis of population

pharmacokinetic data.15 Describe in detail about:
(a) Dosage adjustment in obese patients.
(b) TDM of carbamazepine and phenytoin sodium.

16 Explain the drug dosing in elderly, paediatric and geriatric patients.

17 Explain in detail about the dosage adjustment in patients with hepatic

disease. 18 Explain the role of cytochrome p-450 is enzyme in genetic

polymorphism in drug Metabolism.

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Code No. D-8048

FACULTY OF PHARMACY

Pharm.D V-Year (6-YDC) (Instant) Examination May 2022

Subject: Pharmacoepidemiology & Pharmacoeconomics

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

PART – A

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

1 What are drug induced birth defects?
2 Explain hospital pharmacoepidemiology.
3 Explain time trade off and standard gamble method.
4 Explain incremental cost effectiveness ratio and willingness to pay in pharmacoeconomics.
5 Describe sensitivity analysis in pharmacoeconomics.
6 Give the criteria for causal nature of association in pharmacoepidemiology.
7 Explain the role of case reports in pharmacoepidemiology.
8 Explain teratogens with examples.
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 Describe the available methods for medication adherence measurement. Add a note on analysis of medication adherence data.

12 Describe the steps involved in conducting a meta-analysis. Explain the different effect size measures used in meta-analysis.

13 Discuss in detail vaccine safety in pharmacoepidemiology.

14 Compare and contrast case-control, cohort and cross sectional studies.

15 Explain the role of pharmacoeconomic evaluations in formulary management.

16 Discuss cost-benefit analysis with the help of a case study.

17 Elaborate different types of costs and outcome measurement units in pharmacoeconomic studies.

18 Compare and contrast different pharmacoeconomic evaluations.

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Code No. D-8048/PB

FACULTY OF PHARMACY

Pharm.D II-Year (3-YDC) (Instant) (Post-Baccalaureate) Examination, May 2022

Subject: Pharmacoepidemiology & Pharmacoeconomics

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

PART – A

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

1 What are drug induced birth defects?
2 Explain hospital pharmacoepidemiology.
3 Explain time trade off and standard gamble method.
4 Explain incremental cost effectiveness ratio and willingness to pay in pharmacoeconomics.
5 Describe sensitivity analysis in pharmacoeconomics.
6 Give the criteria for causal nature of association in pharmacoepidemiology.
7 Explain the role of case reports in pharmacoepidemiology.
8 Explain teratogens with examples.
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 Describe the available methods for medication adherence measurement. Add a note on analysis of medication adherence data.

12 Describe the steps involved in conducting a meta-analysis. Explain the different effect size measures used in meta-analysis.

13 Discuss in detail vaccine safety in pharmacoepidemiology.

14 Compare and contrast case-control, cohort and cross sectional studies.

15 Explain the role of pharmacoeconomic evaluations in formulary management.

16 Discuss cost-benefit analysis with the help of a case study.

17 Elaborate different types of costs and outcome measurement units in pharmacoeconomic studies.

18 Compare and contrast different pharmacoeconomic evaluations.

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Code No. 12474

FACULTY OF PHARMACY

Pharm.D V Year (6-YDC) (Main & Backlog) Examination, October 2021

Subject: Clinical Pharmacokinetics & Pharmacotherapeutics Drug Monitoring

Time: 2 Hours **Max. Marks: 70**

PART – A

Note: Answer any six questions. **(6 x 5 = 30 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?
4 Write a note on enzyme inhibition with examples.
5 Write any one method dosage conversion from I.V. to oral dosing.
6 Define pharmacogenetics and write its applications.
7 Write the TDM for carbamazepine.
8 Write a not eon Cyp-450 enzymes.
9 What is the role of pharmacist in clinical pharmacokinetics?
10 Write the significance of population pharmacokinetics.

PART – B

Note: Answer any four questions. **(4 x 10 = 40 Marks)**

11 Explain in detail about drug dosing in Elderly and Pediatric patients.

12 Explain various pharmacokinetic drug-drug interactions with suitable examples.

13 Describe the general approach for dosage adjustment in renal disease.

14 Explain in detail about individualization of drug dosage regimen.

15 Explain in detail the extra corporeal removal of drugs.

16 Explain briefly Bayesian theory and analysis of population pharmacokinetic c data.

17 Explain in detail about the dosage adjustment in patients with hepatic disease.

18 Explain the role of cytochrome p-450 isoenzyme in genetic polymorphism in drug metabolism.

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Code No. 12474/PB

FACULTY OF PHARMACY

Pharm.D II Year (3-YDC) (Post Baccalaureate) (Main & Backlog) Examination, October 2021

Subject: Clinical Pharmacokinetics & Pharmacotherapeutics Drug Monitoring

Time: 2 Hours **Max. Marks: 70**

PART – A

Note: Answer any six questions. (6 x 5 = 30 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?
4 Write a note on enzyme inhibition with examples.
5 Write any one method dosage conversion from I.V. to oral dosing.
6 Define pharmacogenetics and write its applications.
7 Write the TDM for carbamazepine.
8 Write a not eon Cyp-450 enzymes.
9 What is the role of pharmacist in clinical pharmacokinetics?
10 Write the significance of population pharmacokinetics.

PART – B

Note: Answer any four questions. (4 x 10 = 40 Marks)

11 Explain in detail about drug dosing in Elderly and Pediatric patients.

12 Explain various pharmacokinetic drug-drug interactions with suitable examples.

13 Describe the general approach for dosage adjustment in renal disease.

14 Explain in detail about individualization of drug dosage regimen.

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 role of cytochrome p-450 is enzyme in genetic polymorphism in drug metabolism.

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Code No. 12472

FACULTY OF PHARMACY

Pharm. D (6 YDC) V Year (Main & Backlog) Examination, October 2021 Subject: Clinical Research

Time: 2 Hours **Max. Marks: 70**

Part – A

Note: Answer any six questions. **(6 x 5 = 30 Marks)**

1 What are the differences between monitoring & auditing?
2 What do you mean by quality assurance & quality control in clinical trials?
3 What do you mean by ANDA?
4 Write a note on the objectives of Phase-I clinical trials.
5 What is Data Safety Monitoring Board (DSMB)?
6 What are essential documents in clinical trials?
7 Distinguish between audit report and audit certificate.
8 Give a brief note on investigator's brochure.
9 Comment on the importance of impartial witness in IC process.
10 What do you know about post trial access of investigational new drug.

Part – B

Note: Answer any four questions. **(4 x 10 = 40 Marks)**

11 Write a note on the principles of ICH-GCP.
12 Write a brief note on centralized procedure of marketing authorization, in Europe.
13 Write a note on the investigator's responsibility in the conduct of clinical trials.
14 Describe the procedure of communicating ADR reports & Periodic Safety Update Reports (PSUR).
15 What is the process for obtaining permission to conduct clinical trials, in India & USA?
16 Explain the role of clinical research coordinator (CRC) & Clinical Research Associate (CRA).
17 Explain the objectives of various phases of clinical trials and criteria for approval of new drug by regulatory agencies.
18 Give salient features of informed consent process & mention how vulnerable subjects are protected.

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Code No. 12473

FACULTY OF PHARMACY

Pharm.D V Year (6-YDC) (Main & Backlog) Examination, October 2021

Subject: Pharmacoepidemiology and Pharmacoeconomics

Time: 2 Hours **Max. Marks: 70**

PART – A

Note: Answer any six questions. **(6 x 5 = 30 Marks)**

1 Define pharmacoepidemiology.
2 What are prevalence and incidence rate?
3 Define time risk relationship and odds ratio risk.
4 What is teratogenicity and give two example drugs?
5 Define (a) Case Report
(b) Case Series.
6 What are Adhoc data sources?
7 Write about significance of hospital pharmacoepidemiology.
8 What is the role of pharmacist in hospital formulary decision making?
9 Write a note on Spontaneous Reporting.
10 Write a brief note on cost utility evaluation.

PART – B

Note: Answer any four questions. **(4 x 10 = 40 Marks)**

11 What is the origin of pharmacoepidemiology and write aims and applications of it?

12 Define Medication Adherence and explain methods to evaluate medication adherence.

13 (a) Write about relative risk and attributable risk with example.
(b) Explain about defined daily doses and prescribed daily doses.

14 (a) What is the role of record linkage in pharmacoepidemiology?
(b) Describe about prescription event monitoring.

15 (a) What is DUR and classify DUR and write steps in drug use evaluation?
(b) What is cohort study and explain it with the help of case studies.

16 Write a note on Adhoc data sources available for pharmacoepidemiological studies.

17 (a) What are different kinds of cost involved in pharmacoeconomics and explain them?
(b) Write about application of pharmacoeconomics.

18 Explain about cost effective, cost benefit and cost minimization evaluations in pharmacoeconomics.

Code No. 12185

FACULTY OF PHARMACY

Pharm D V Year (6-YDC) (Instant) Examination, July 2021

Subject: Clinical Research

Time: 2 Hours **Max. Marks: 70**

Note: Answer any six questions from Part A; Answer any four questions from Part B.

PART - A (6 x 5 = 30 Marks)

1 What is ANDA? Write note on its submission.
2 Define double blind method in clinical trials.
3 Write briefly the roles and responsibilities of CRC as per ICH GCP.
4 What is drug discovery? What are the steps involved in the process?
5 What is IND “clinical hold”? Explain the basis for clinical hold.
6 What is regulatory authority? Write the general roles and responsibilities of regulatory authority.
7 Explain the responsibilities of monitor in clinical trials.
8 What are “stopping rules” in clinical trials?
9 What is vulnerable population? How are their rights protected?
10 What is electronic signature? Write its significance.

PART - B (4 x 10 = 40 Marks)

11 Explain the objectives, design and conduct of phase I and II clinical trial studies with schedule requirements.

12 Explain NDA review process with contents and submission.

13 Explain the IEC review procedure of a research proposal and the methods of review process adopted by IEC.

14 Explain toxicity studies carried out in preclinical drug development.

15 Discuss various components of a protocol for conduct of clinical trials according to schedule Y and its approval.

16 Give an overview of regulatory environment in Europe.

17 a) Write note on quality assurance in CDM.
b) Explain various data entry methods.

18 Explain the roles and responsibilities of sponsor in clinical trials as per ICH GCP.

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Code No. 12187

FACULTY OF TECHNOLOGY

Pharm.D V-Year (6 YDC) (Instant) Examination, July 2021

Subject: Clinical & Pharmacokinetics Pharmacotherapeutic Drug

Monitoring Time: 2 Hours **Max. Marks: 70**

Note: Answer any six questions from Part-A. Answer any four questions from Part-B.

PART- A (6x5=30 Marks)

1 Explain about the measurement of GFR.
2 What are the indications of therapeutic drug monitoring?
3 Write a note on microsomal enzyme inducers.
4 Explain plasma protein binding with its significance.
5 What are the factors involved in conversion of IV to oral dosing?
6 Write a note on binary excretion.
7 Write the importance of nomograms in designing of dosage regimen.
8 Explain in brief about first pass metabolism.
9 Write about insulin clearance.
10 Write the significance of bioavailability in clinical pharmacokinetics.

PART- B (4x10=40 Marks)

11 Describe the role of genetic polymorphism in drug action with examples.

12 Write about renal impairment, and the importance of GFR and creatinine clearance in dosage adjustment.

13 Describe Bayesian theory and analysis of population pharmacokinetic data.

14 Explain in detail about TDM of vancomycin and lithium carbonate.

15 Describe the importance of adaptive method in population pharmacokinetics.

16 Explain the role of cyp450 isoenzymes in genetic polymorphism.

17 Describe in detail about:
(a) Dosage adjustment of uremic patients
(b) Extra corporeal removal of drugs

18 Describe about drug dosing in obese patients and elderly.

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FACULTY OF PHARMACY
Pharm.D V-Year (6-YDC) (Instant) Examination,

July 2021 Subject: Pharmacoepidemiology &

Pharmacoeconomics

Time: 2 Hours **Max. Marks: 70**

PART – A

Note: Answer any six questions. **(6 x 5 = 30 Marks)**

1 Differentiate between incidence and prevalence.
2 Discuss incremental cost effectiveness ratio with example.
3 Explain defined daily dose and prescribed daily dose.
4 Explain odds ratio.
5 Describe a case control study.
6 Elaborate cost minimization analysis.
7 Explain the concept of risk in pharmacoepidemiology.
8 Explain record linkage system.
9 Write a short note on quality adjusted life year.
10 Explain spontaneous reporting in pharmacoepidemiology.

PART – B

Note: Answer any four questions. **(4 x 10 = 40 Marks)**

11 Discuss the origin, evolution, aims and applications of Pharmacoepidemiology.

12 Discuss vaccine safety in pharmacoepidemiology.

13 (a) Discuss the outcome measurement units in Pharmacoepidemiology.
(b) Elaborate the different types of costs in Pharmacoeconomic analysis.

14 Explain cost-effectiveness analysis. Illustrate the cost-effectiveness grid and cost-effectiveness plane in Pharmacoeconomic analysis.

15 (a) Describe the cost-utility analysis.
(b) Discuss the different methods in estimating utilities.

16 Discuss in detail steps in conducting a meta-analysis. Explain the significance of Cochrane reviews.

17 Discuss the steps for performing a decision analysis. Calculate the average costs and outcomes from a decision tree with example.

18 (a) Describe drug utilization evaluation with its applications.
(b) Discuss automated data systems with examples.

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