



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. 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 note on 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 isoenzyme in genetic polymorphism in drug metabolism.



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. 6453

FACULTY OF PHARMACY

Pharm. D V - Year (6 YDC) (Main & Backlog) Examination, December 2020

Subject: Pharmacoepidemiology & Pharmacoeconomics

Time: 2 Hours

Max. Marks: 70

Part – A

Note: Answer any Six questions.

(6x5 = 30 Marks)

- 1 Write about need of pharmacoepidemiology and evidence based medicine.
- 2 Define cumulative incidence and prevalence.
- 3 Write a note on attributable risk.
- 4 Write about cross sectional studies and cohort studies.
- 5 What is defined daily dose and prescribed daily dose.
- 6 Give the clinical importance of drug utilization review.
- 7 Write about the importance of meta-analysis.
- 8 Discuss the applications of pharmacoepidemiology in studies of vaccine safety.
- 9 Explain the various cost factors involved in pharmacoeconomic evaluation.
- 10 Write a note on applications of pharmacoeconomic studies.

Part – B

Note: Answer any Four questions.

(4x 10 = 40 Marks)

- 11 Define the term pharmacoepidemiology and explain its outcome measurement related to prevalence and incidence rate, medication adherence management.
- 12 Define case control study. Explain the design of case control study with suitable example. Write the advantages and disadvantages, and applications of case control study.
- 13 Explain the various designs used in pharmacoepidemiological studies.
- 14 How do you express the outcome of drug use in pharmacoepidemiologic studies? Discuss briefly on meta-analysis
- 15 Discuss about the pharmacoepidemiological data bases.
- 16 Briefly explain about the significance of hospital pharmacoepidemiology
- 17 Write the applications of pharmacoeconomics with respect to case based studies.
- 18 Define the term Pharmacoeconomics. Explain the need for pharmacoeconomics in Indian scenario. Discuss the types of pharmacoeconomic evaluations.



Code No. 6453/PB

FACULTY OF PHARMACY

Pharm. D. (3 YDC) II – Year (Post Baccalaureate) (Main & Backlog)

Examination, December 2020

Subject: Pharmacoepidemiology & Pharmacoeconomics

Time: 2 Hours

Max. Marks: 70

Part – A

Note: Answer any Six questions.

(6x5 = 30 Marks)

- 1 Write about need of pharmacoepidemiology and evidence based medicine.
- 2 Define cumulative incidence and prevalence.
- 3 Write a note on attributable risk.
- 4 Write about cross sectional studies and cohort studies.
- 5 What is defined daily dose and prescribed daily dose.
- 6 Give the clinical importance of drug utilization review.
- 7 Write about the importance of meta-analysis.
- 8 Discuss the applications of pharmacoepidemiology in studies of vaccine safety.
- 9 Explain the various cost factors involved in pharmacoeconomic evaluation.
- 10 Write a note on applications of pharmacoeconomic studies.

Part – B

Note: Answer any Four questions.

(4x 10 = 40 Marks)

- 11 Define the term pharmacoepidemiology and explain its outcome measurement related to prevalence and incidence rate, medication adherence management.
- 12 Define case control study. Explain the design of case control study with suitable example. Write the advantages and disadvantages, and applications of case control study.
- 13 Explain the various designs used in pharmacoepidemiological studies.
- 14 How do you express the outcome of drug use in pharmacoepidemiologic studies? Discuss briefly on meta-analysis
- 15 Discuss about the pharmacoepidemiological data bases.
- 16 Briefly explain about the significance of hospital pharmacoepidemiology
- 17 Write the applications of pharmacoeconomics with respect to case based studies.
- 18 Define the term Pharmacoeconomics. Explain the need for pharmacoeconomics in Indian scenario. Discuss the types of pharmacoeconomic evaluations.



Code No. 6452

FACULTY OF PHARMACY

Pharm.D V-Year (6 YDC) (Main & Backlog) Examination, December 2020

Subject: Clinical Research

Time: 2 Hours

Max. Marks: 70

Part – A

Note: Answer any Six questions.

(6x5 = 30 Marks)

- 1 Write briefly the methods of target identification and validation.
- 2 What is the role of ICMR in regulation of clinical trials?
- 3 Write the limitations and regulatory requirements for the conduct of preclinical studies.
- 4 What is NDA? Mention the data which is submitted with the application.
- 5 What is CDSCO? Write its functions.
- 6 Define the terms "Source data" and "Source documents".
- 7 What is IND "clinical hold" and "clinical hold response"?
- 8 Write briefly about Data entry in clinical Data management.
- 9 Write notes on patient Information sheet.
- 10 What is PSUR?

Part – B

Note: Answer any four questions.

(4x 10 = 40 Marks)

- 11 What is "Lead molecule"? Explain in detail the Lead identification and optimization process.
- 12 Explain various functions of IEC.
- 13 Elaborate the role and responsibilities of sponsor in clinical trials as per ICH GCP.
- 14 (a) What is CRF? Write notes on CRF design.
(b) Write notes on discrepancy management in CDM.
- 15 Explain the regulatory environment for conduct of clinical trials in USA.
- 16 Write in detail various components of clinical trial "protocol". Add notes on protocol amendments.
- 17 Write in detail about Data storage and security in CDM.
- 18 (a) Explain NDA review process
(b) Explain roles and responsibilities of CRC as per ICH GCP guidelines



Code No. 6452/PB

FACULTY OF PHARMACY

Pharm. D. (3 YDC) II – Year (Post Baccalaureate) (Main & Backlog)

Examination, December 2020

Subject: Clinical Research

Time: 2 Hours

Max. Marks: 70

Part – A

Note: Answer any six questions.

(6x5 = 30 Marks)

- 1 Write briefly the methods of target identification and validation.
- 2 What is the role of ICMR in regulation of clinical trials?
- 3 Write the limitations and regulatory requirements for the conduct of preclinical studies.
- 4 What is NDA? Mention the data which is submitted with the application.
- 5 What is CDSCO? Write its functions.
- 6 Define the terms "Source data" and "Source documents".
- 7 What is IND "clinical hold" and "clinical hold response"?
- 8 Write briefly about Data entry in clinical Data management.
- 9 Write notes on patient Information sheet.
- 10 What is PSUR?

Part – B

Note: Answer any four questions.

(4x 10 = 40 Marks)

- 11 What is "Lead molecule"? Explain in detail the Lead identification and optimization process.
- 12 Explain various functions of IEC.
- 13 Elaborate the role and responsibilities of sponsor in clinical trials as per ICH GCP.
- 14 (a) What is CRF? Write notes on CRF design.
(b) Write notes on discrepancy management in CDM.
- 15 Explain the regulatory environment for conduct of clinical trials in USA.
- 16 Write in detail various components of clinical trial "protocol". Add notes on protocol amendments.
- 17 Write in detail about Data storage and security in CDM.
- 18 (a) Explain NDA review process
(b) Explain roles and responsibilities of CRC as per ICH GCP guidelines



Code No. 6454

FACULTY OF PHARMACY

Pharm.D V - Year (6 YDC) (Main & Backlog) Examination, December 2020

Subject: Clinical Pharmacokinetics & Pharmacotherapeutics Drug Monitoring

Time: 2 Hours

Max. Marks: 70

Part – A

Note: Answer any Six questions.

(6x5 = 30 Marks)

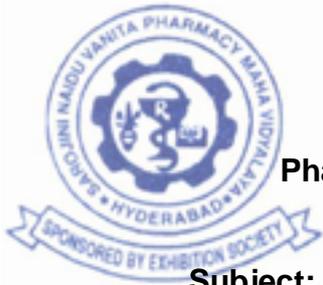
- 1 Write about the principle involved in adaptive method of dosing.
- 2 Write the Therapeutic Drug Monitoring (TDM) of carbamazepine.
- 3 Explain the importance of half-life in clinical pharmacokinetics.
- 4 What is the effect of genetic polymorphs in drug targets?
- 5 Explain enzyme inhibition with two examples.
- 6 Write the significance of population pharmacokinetics.
- 7 What is extraction ratio? Write its importance in pharmacokinetics.
- 8 Write about creatinine clearance and glomerular filtration rate.
- 9 Write the significance of nomograms in designing of dosage regimen.
- 10 Explain the Bayesian theory.

Part – B

Note: Answer any Four questions.

(4x 10 = 40 Marks)

- 11 Write in detail about various pharmacokinetics drug-drug interactions with suitable examples.
- 12 Describe in detail the Inhibition and Induction of drug metabolism.
- 13 Explain the role of cytochrome P-450 isoenzymes in genetic polymorphism.
- 14 Write in detail about individualization of drug dosage regimen.
- 15 Explain the TDM for cardiovascular diseases.
- 16 Write the pharmacokinetic and Pharmacodynamic correlation in drug therapy.
- 17 Explain in detail about the dosage adjustment in patients with renal failure.
- 18 Describe the importance of bioavailability in clinical pharmacokinetics.



Code No. 6454/PB

FACULTY OF PHARMACY

Pharm. D. (3 YDC) II – Year (Post Baccalaureate) (Main & Backlog)

Examination, December 2020

Subject: Clinical Pharmacokinetics & Pharmacotherapeutics Drug Monitoring

Time: 2 Hours

Max. Marks: 70

Part – A

Note: Answer any Six questions.

(6x5 = 30 Marks)

- 1 Write about the principle involved in adaptive method of dosing.
- 2 Write the Therapeutic Drug Monitoring (TDM) of carbamazepine.
- 3 Explain the importance of half-life in clinical pharmacokinetics.
- 4 What is the effect of genetic polymorphs in drug targets?
- 5 Explain enzyme inhibition with two examples.
- 6 Write the significance of population pharmacokinetics.
- 7 What is extraction ratio? Write its importance in pharmacokinetics.
- 8 Write about creatinine clearance and glomerular filtration rate.
- 9 Write the significance of nomograms in designing of dosage regimen.
- 10 Explain the Bayesian theory.

Part – B

Note: Answer any Four questions.

(4x 10 = 40 Marks)

- 11 Write in detail about various pharmacokinetics drug-drug interactions with suitable examples.
- 12 Describe in detail the Inhibition and Induction of drug metabolism.
- 13 Explain the role of cytochrome P-450 isoenzymes in genetic polymorphism.
- 14 Write in detail about individualization of drug dosage regimen.
- 15 Explain the TDM for cardiovascular diseases.
- 16 Write the pharmacokinetic and Pharmacodynamic correlation in drug therapy.
- 17 Explain in detail about the dosage adjustment in patients with renal failure.
- 18 Describe the importance of bioavailability in clinical pharmacokinetics.



Code No. 6201

FACULTY OF PHARMACY

Pharm D (6 – YDC) V – Year (Instant) Examination, February 2020

Subject: Pharmacoepidemiology & Pharmacoeconomics

Time: 3 Hours

Max.Marks: 70

Note: Answer all questions from Part – A. Any Five questions from Part – B.

PART – A (10x2 = 20 Marks)

- 1 Write the applications of pharmacoepidemiology.
- 2 Define incidence and incidence rate.
- 3 Define number of prescriptions.
- 4 What are defined daily doses and prescribed daily doses?
- 5 What is medication adherence measurement?
- 6 Write about time-risk relationship.
- 7 What do you mean by case-cohort studies?
- 8 What are Ad Hoc data sources?
- 9 What is vaccine safety?
- 10 What is cost-minimization method of pharmacoeconomics?

PART – B (5 X 10 = 50 Marks)

- 11 Elaborate on the evaluation and aim of pharmacoepidemiology with suitable example. [10]
- 12 a) Explain about outcome measure in pharmacoepidemiology. [5]
b) Write about various types of risk in Pharmacoepidemiology. [5]
- 13 a) Explain the role of pharmacist in drug utilization review. [5]
b) Write a note on WHO programme for ADR reporting. [5]
- 14 a) Write a note on prescription event monitoring. [5]
b) Write a note on record linkage system. [5]
- 15 Write the merits and demerits of case control and meta-analysis studies. [10]
- 16 Elaborate various types of bias involved in pharmacoepidemiology. [10]
- 17 Explain the need of pharmacoeconomic evaluations in formulary management. [10]
- 18 Write the applications of pharmacoeconomics with respect to case based studies. [10]



Code No. 6201 / PB

FACULTY OF PHARMACY

Pharm D (3-YDC) II-Year (Instant) (Post Baccalaureate) Examination, February 2020

Subject: Pharmacoepidemiology & Pharmacoeconomics

Time: 3 Hours

Max.Marks: 70

Note: Answer all questions from Part – A. Any Five questions from Part – B.

PART – A (10x2 = 20 Marks)

- 1 Write the applications of pharmacoepidemiology.
- 2 Define incidence and incidence rate.
- 3 Define number of prescriptions.
- 4 What are defined daily doses and prescribed daily doses?
- 5 What is medication adherence measurement?
- 6 Write about time-risk relationship.
- 7 What do you mean by case-cohort studies?
- 8 What are Ad Hoc data sources?
- 9 What is vaccine safety?
- 10 What is cost-minimization method of pharmacoeconomics?

PART – B (5 X 10 = 50 Marks)

- 11 Elaborate on the evaluation and aim of pharmacoepidemiology with suitable example. [10]
- 12 a) Explain about outcome measure in pharmacoepidemiology. [5]
b) Write about various types of risk in Pharmacoepidemiology. [5]
- 13 a) Explain the role of pharmacist in drug utilization review. [5]
b) Write a note on WHO programme for ADR reporting. [5]
- 14 a) Write a note on prescription event monitoring. [5]
b) Write a note on record linkage system. [5]
- 15 Write the merits and demerits of case control and meta-analysis studies. [10]
- 16 Elaborate various types of bias involved in pharmacoepidemiology. [10]
- 17 Explain the need of pharmacoeconomic evaluations in formulary management. [10]
- 18 Write the applications of pharmacoeconomics with respect to case based studies. [10]



Code No. 6202

FACULTY OF PHARMACY

Pharm D (6 – YDC) V – Year (Instant) Examination, February 2020

Subject: Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring

Time: 3 Hours

Max.Marks: 70

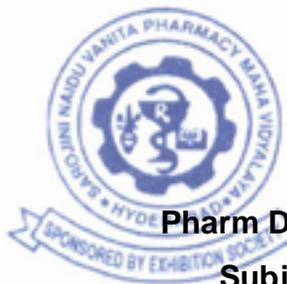
Note: Answer all questions from Part – A. Any Five questions from Part – B.

PART – A (10x2 = 20 Marks)

- 1 Write about determination of dose and dosing interval.
- 2 Write the TDM for phenytoin sodium.
- 3 Explain about inulin clearance.
- 4 Write a note on enzyme inhibition with examples.
- 5 Add a note on Biliary Excretion.
- 6 Give a brief account on dosage adjustment in uremic patients
- 7 Brief about pharmacogenetics and its applications.
- 8 Write a brief note on dosing with feedback.
- 9 What is the role of pharmacist in clinical pharmacokinetics?
- 10 Write the significance of population pharmacokinetics.

PART – B (5x10 = 50 Marks)

- 11 Describe the following:
 - a) Pharmacokinetic correlation in drug therapy. [5]
 - b) Bayesian theory [5]
- 12 Explain in detail about the role of genetic polymorphism in drug metabolism and target with examples. [10]
- 13 a) Explain various diseases where TDM is applicable. [4]
b) Dosage variability with respect to genetics, disease and age. [6]
- 14 Write a note on drug dosing in elderly and pediatric patients. [10]
- 15 Add a note on:
 - a) Induction of drug metabolism. [5]
 - b) Dosage adjustment in hepatic disease. [5]
- 16 Explain various pharmacokinetic drug-drug interactions with suitable examples. [10]
- 17 Explain about the following:
 - a) GFR and creatinine clearance. [5]
 - b) Adaptive method with feedback. [5]
- 18 Write in brief about clinical pharmacokinetics. [10]



Code No. 6202 / PB

FACULTY OF PHARMACY

Pharm D (3 –YDC) II–Year (Instant) (Post Baccalaureate) Examination, February 2020

Subject: Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring

Time: 3 Hours

Max.Marks: 70

Note: Answer all questions from Part – A. Any Five questions from Part – B.

PART – A (10x2 = 20 Marks)

- 1 Write about determination of dose and dosing interval.
- 2 Write the TDM for phenytoin sodium.
- 3 Explain about inulin clearance.
- 4 Write a note on enzyme inhibition with examples.
- 5 Add a note on Biliary Excretion.
- 6 Give a brief account on dosage adjustment in uremic patients
- 7 Brief about pharmacogenetics and its applications.
- 8 Write a brief note on dosing with feedback.
- 9 What is the role of pharmacist in clinical pharmacokinetics?
- 10 Write the significance of population pharmacokinetics.

PART – B (5x10 = 50 Marks)

- 11 Describe the following:
 - a) Pharmacokinetic correlation in drug therapy. [5]
 - b) Bayesian theory [5]
- 12 Explain in detail about the role of genetic polymorphism in drug metabolism and target with examples. [10]
- 13
 - a) Explain various diseases where TDM is applicable. [4]
 - b) Dosage variability with respect to genetics, disease and age. [6]
- 14 Write a note on drug dosing in elderly and pediatric patients. [10]
- 15 Add a note on:
 - a) Induction of drug metabolism. [5]
 - b) Dosage adjustment in hepatic disease. [5]
- 16 Explain various pharmacokinetic drug-drug interactions with suitable examples. [10]
- 17 Explain about the following:
 - a) GFR and creatinine clearance. [5]
 - b) Adaptive method with feedback. [5]
- 18 Write in brief about clinical pharmacokinetics. [10]

FACULTY OF PHARMACY

Pharm D (3 – YDC) II – Year (Instant) (Post Baccalaureate) Examination, January 2020

Subject: Clinical Research

Time: 3 Hours

Max.Marks: 70

Note: Answer all questions from Part – A. Any Five questions from Part – B.

PART – A (10x2 = 20 Marks)

- 1 What is drug discovery? Write basic approaches to drug discovery.
- 2 What is IND "clinical hold"? Explain the basis for clinical hold.
- 3 List out various functions of CDSCO.
- 4 What is ANDA?
- 5 Write briefly the roles and responsibilities of CRC as per ICH GCP.
- 6 What is vulnerable population? How are their rights protected?
- 7 Enumerate the essential documents in clinical trials.
- 8 Write note on registration of clinical trials.
- 9 What is ICF?
- 10 What is blinding in clinical trials? What is its significance?

PART – B (5x10 = 50 Marks)

- 11 Explain the tools used in lead identification and optimization.
- 12 Explain dosage form development process.
- 13 Explain the objectives, design and conduct of Phase I clinical trial studied with schedule Y requirements.
- 14 Explain NDA review process with contents and submission.
- 15 a) Explain the IEC review procedure of a research proposal.
b) Explain informed consent process.
- 16 Explain the role and responsibilities of sponsor in clinical trials as per ICH GCP.
- 17 Explain in detail the regulatory environment in USA.
- 18 a) Write note on clinical data storage and security.
b) Explain randomization in clinical trials.



Code No. 1264

FACULTY OF PHARMACY

Pharm D (6–YDC) V-Year (Main & Backlog) Examination, July 2018

Subject: Clinical & Pharmacokinetics Pharmacotherapeutic Drug Monitoring

Time: 3 Hours

Max.Marks: 70

Note: Answer all questions from Part – A. Any Five questions from Part – B.

PART – A (10x2 = 20 Marks)

- 1 What is the role of pharmacist in clinical pharmaceutics?
- 2 What type of drugs should be monitored?
- 3 Why is creatinine clearance used in renal disease?
- 4 Write the TDM of digoxin.
- 5 Write the significance of population pharmacokinetics.
- 6 Write a note on indications for TDM.
- 7 Write a note on effect of hepatic disease on pharmacokinetics.
- 8 Name and contrast any two methods adjusting drug dose in renal disease.
- 9 Write any one method of dosage conversion from IV to oral dosing.
- 10 Define pharmacogenetics and write its applications.

PART – B (50 Marks)

- 11 Describe the effect of genetic polymorphism in drug transport and drug targets.
- 12 Explain TDM of drugs used in cardiovascular and organ transplantations.
- 13 Explain the drug dosing in elderly, pediatrics and obese patients.
- 14 Explain the measurement of glomerular filtration rate and creatinine clearance.
- 15 Explain various pharmacokinetic drug – drug interactions along with suitable examples.
- 16 Write a note on protocols for TDM and explain how TDM will affect individualization of drug dosage regime.
- 17 a) Explain briefly extracorporeal removal of drugs. 5
b) Write a note on dosage adjustment in renal disease. 5
- 18 Explain briefly Bayesian theory and analysis of population pharmacokinetic data.



Code No. 1262

FACULTY OF PHARMACY

Pharm D (6–YDC) V-Year (Main & Backlog) Examination, July 2018

Subject: Clinical Research

Time: 3 Hours

Max.Marks: 70

Note: Answer all questions from Part – A. Any Five questions from Part – B.

PART – A (10x2 = 20 Marks)

- 1 What is drug discovery? Write basic approaches to drug discovery.
- 2 Write note on registration of clinical trials.
- 3 Write different methods of lead identification.
- 4 List out various functions of data management team.
- 5 What is periodic and interim review by EC?
- 6 What is waiver of consent in clinical research?
- 7 What is a target molecule? Write briefly the different approaches to target identification.
- 8 What are different control treatments in clinical trial design?
- 9 Explain the responsibilities of monitor in clinical trials.
- 10 What are “equivalence”, “superiority” and “non-inferiority” trials?

PART – B (50 Marks)

- 11 Explain the term “lead molecule”. Describe in detail the lead identification and optimization process.
- 12 List out various responsibilities of IRB. Explain review procedures of a research proposal by IRB.
- 13 Explain post marketing surveillance methods.
- 14 Explain the components of clinical trial design.
- 15 Discuss various animal pharmacology testing required for discovery of new drugs.
- 16 a) Give an overview of regulatory environment in USA.
b) Write detailed note on selection of special groups as research participants.
- 17 Explain the statement of general principles and specific principles for clinical evaluation of drugs.
- 18 a) Explain data capture in CDM.
b) Write note on ICF and PIC.



Code No. 1263

FACULTY OF PHARMACY

Pharm. D. (6 YDC) V – Year (Main & Backlog) Examination, July 2018

Subject : Pharmacoepidmiology and Pharmacoeconomics

Time : 3 hours

Max. Marks : 70

Note: Answer all questions from Part-A & answer any Five questions from Part-B.

Part - A (10 x 2 = 20 Marks)

- 1 Write a note on the units of drug dispensed as an outcome measure.
- 2 Define Risk.
- 3 What is Pharmacoepidemiology?
- 4 Write a brief note on Incidence density.
- 5 Write a short note on case series and its significance.
- 6 Write the applications of Pharmacoeconomics.
- 7 Write a brief note on Time trade off method and Standard Gamble method.
- 8 Write a note on formulary and its use.
- 9 Give two examples of automated data sources.
- 10 Name any two drugs induced birth defects.

Part - B (5 x 10 = 50 Marks)

- 11 Elaborate on cost benefit analysis with a case study. 10
- 12 a) Write the advantages and disadvantages of adhoc data base systems. 5
b) Vaccine safety and its reporting. 5
- 13 a) What are the various types of costs in Pharmacoeconomic evaluations? 5
b) Write a note on the origin and need of Pharmacoepidemiology. 5
- 14 a) Discuss in detail the newer methods of measuring adherence. 5
b) Write in detail about relative risk with an example. 5
- 15 a) Write a note on the strengths and weaknesses of spontaneous reporting system. 5
b) Role of a pharmacist in Formulary decision making. 5
- 16 a) Write in detail regarding the case control studies, their strengths and weaknesses. 5
b) Explain modified prescription event monitoring and its use in pharmacoepidemiology. 5
- 17 a) Differentiate between systematic reviews and meta analysis. 5
b) Discuss regarding hospital pharmacoepidemiology studies. 5
- 18 a) Discuss about cost minimization analysis with an example. 5
b) Write a short note on QALY. 5



Code No. 1125

FACULTY OF PHARMACY
Pharm. D (6 YDC) V-Year (Instant) Examination, March 2018

Subject : Clinical Research

Time : 3 Hours

Max. Marks: 70

Note: Answer all questions from Part – A, answer any five questions from Part-B.

PART – A (10 x 2 = 20 Marks)

- 1 What is Drug discovery? What are the steps involved in the process?
- 2 What is IND “clinical hold”? Explain the basis for clinical hold.
- 3 What is ANDA? Write note on its submission.
- 4 What is PMS and PSUR?
- 5 Write briefly the roles and responsibilities of CRC as per ICH GCP.
- 6 Write note on registration of clinical trials.
- 7 Enumerate the essential documents in clinical trials.
- 8 Write briefly about query management in CDM.
- 9 What is Patient information sheet?
- 10 What is blinding in clinical trials? What is its significance?

PART – B (5 x 10 = 50 Marks)

- 11 Explain the tools used in Lead identification and optimization.
- 12 Explain toxicity studies carried out in preclinical drug development.
- 13 Explain the objective, design and conduct of phase I clinical trial studies with schedule Y requirements.
- 14 Explain NDA review process with contents and format requirements.
- 15 Explain the IEC Review procedure of a research proposal.
- 16 Explain in detail the regulatory environment in USA.
- 17 (a) Explain Data Entry methods.
(b) Write about clinical trials database lock.
- 18 Explain the role and responsibilities of sponsor in clinical trials as per ICH GCP.



Code No. 1126

FACULTY OF PHARMACY

Pharm D (6–YDC) V-Year (Instant) Examination, March 2018

Subject: Pharmacoepidemiology & Pharmacoeconomics

Time: 3 Hours

Max.Marks: 70

Note: Answer all questions from Part – A. Any Five questions from Part – B.

PART – A (10x2 = 20 Marks)

- 1 Write a note on the monetary units being used as an outcome measure.
- 2 Write a brief note on time – risk relationship.
- 3 Define morbidity.
- 4 Write a brief note on incidence.
- 5 Write a short note on case reports and its significance.
- 6 Write the applications of pharmacoeconomics.
- 7 Define serious adverse event.
- 8 What is QALY?
- 9 Define teratogenesis. Give two examples of teratogens.
- 10 How are adverse effects with vaccines reported?

PART – B (50 Marks)

- 11 Elaborate on Cost Minimization analysis with a case study.
- 12 a) Write in detail about ad hoc data base systems.
b) Special issues in vaccine safety.
- 13 a) What are the various types of outcomes in pharmacoeconomic evaluations?
b) Write a note on the aims and potential applications of Pharmacoepidemiology.
- 14 a) Discuss in detail the various methods of measuring adherence.
b) Write in detail about relative risk and odds ratio.
- 15 a) Write a note on the strengths and weaknesses of spontaneous reporting system.
b) Role of a pharmacist in formulary decision making.
- 16 a) Write in detail regarding the cohort studies, their strengths and weaknesses.
b) Explain prescription event monitoring and its use in pharmacoepidemiology.
- 17 a) Write briefly about meta-analysis and their role in PE studies.
b) What are the methodological issues to be addressed by pharmacoepidemiologic research in the studies on birth defects?
- 18 a) What are the various methods to measure utility?
b) Write a short note on ICER.



Code No. 1127

FACULTY OF PHARMACY
Pharm. D (6 YDC) V-Year (Instant) Examination, March 2018

Subject : Clinical Pharmacokinetics and Pharmacotherapeutic Drug Monitoring

Time : 3 Hours

Max. Marks: 70

Note: Answer all questions from Part – A, answer any five questions from Part-B.

PART – A (10 x 2 = 20 Marks)

- 1 What is TDM? Write the Indications for TDM.
- 2 Write a note on drug interactions at elimination site.
- 3 Write about Cytochrome P-450 isoenzymes.
- 4 Write about determination of Dose and Interval.
- 5 Explain enzyme induction with examples.
- 6 Explain plasma protein binding with its significance.
- 7 Explain Biological half life.
- 8 What are the factors involved in conversion of Intra Venous to oral dosing?
- 9 What is Pharmacogenetics?
- 10 Write the TDM protocol for vancomycin.

PART – B (5 x 10 = 50 Marks)

- 11 Explain the TDM for cardiovascular diseases.
- 12 Describe the pharmacodynamic drug interaction in detail.
- 13 Explain in detail about the dosage adjustment in patients with hepatic disease.
- 14 Write about Renal impairment. Write the importance of GFR and Creatinine clearance in dose adjustment.
- 15 (a) Describe the Bayesian-theory.
(b) Pharmacokinetic correlation in drug therapy.
- 16 Explain in detail genetic polymorphism in (a) Drug metabolism (b) Drug absorption
- 17 How do you fix the dose for Obese, pediatric and geriatric patients?
- 18 Explain the extracorporeal removal of drugs.



Code No. 4276

FACULTY OF PHARMACY
Pharm. D (6 YDC) V-Year (Main) Examination, July 2017

Subject : Pharmacoepidemiology and Pharmacoeconomics

Time : 3 Hours

Max. Marks: 70

Note: Answer all questions from Part - A and answer any five questions from Part-B.

PART – A (10 x 2 = 20 Marks)

- 1 What is the need for Pharmacoepidemiologic studies in India?
- 2 Write briefly on defined daily dose and its significance.
- 3 What are the various methods to measure drug use?
- 4 Write the cost effective analysis plane.
- 5 How is odds ratio calculated? Give an example.
- 6 What is a decision tree?
- 7 What is ACER?
- 8 Define a formulary.
- 9 What is VAERS?
- 10 Define teratogenesis. Give two examples of teratogens.

PART – B (5 x 10 = 50 Marks)

- 11 (a) What are the methodologic problems to be addressed by Meta-analysis?
(b) Studies on drug induced birth defects.
- 12 Write in detail the concept and measurement of risk and their significance in pharmacoepidemiology.
- 13 Write in detail the concept of defined and prescribed daily doses and the other units of presentation of volume.
- 14 (a) Write a short note on surveys of drug use and its significance in pharmacoepidemiological studies.
(b) Write a note on record linkage system and its need in pharmaco epidemiological studies.
- 15 (a) Discuss regarding the automated data systems with examples.
(b) Write in detail regarding the DUE along with its applications.
- 16 Describe the Cost benefit analysis, their applications, advantages and disadvantages with the help of a case study.
- 17 (a) Elaborate on the role of pharmacoeconomics in formulary management decisions.
(b) Write a note on methods to measure indirect and intangible benefits.
- 18 (a) Write a brief note on ECHO model.
(b) What are the various types to costs in pharmacoeconomics study?



Code No. 4275

FACULTY OF PHARMACY
Pharm. D (6 YDC) V-Year (Main) Examination, July 2017

Subject : Clinical Research

Time : 3 Hours

Max. Marks: 70

Note: Answer all questions from Part - A and answer any five questions from Part-B.

PART – A (10 x 2 = 20 Marks)

- 1 Mention different types of preclinical studies.
- 2 What are the requirements to conduct clinical trials as per schedule Y?
- 3 What is ANDA? How is it filed ?
- 4 Explain briefly the steps involved in CDM.
- 5 What is PIC? Explain its role.
- 6 What is ICMR code?
- 7 Define the terms “protocol” and “protocol amendments”.
- 8 What is a regulatory authority? Write the general roles and responsibilities of regular authority.
- 9 What is “subject identification code” in clinical trials?
- 10 Write the composition of IRB and explain quorum for meetings.

PART – B (5 x 10 = 50 Marks)

- 11 Explain Dosage form development process.
- 12 (a) Explain the principles of CDSCO GCP guidelines.
(b) Explain the roles and responsibilities of Auditors as per ICH GCP.
- 13 What are the contents of INDA ? How IND application is reviewed?
- 14 Who is a sponsor? Enumerate sponsor’s responsibilities as per ICH GCP.
- 15 (a) Explain randomization in clinical trials.
(b) Write notes on multicentre trials.
- 16 Discuss various toxicological testing required for discovery of new drugs.
- 17 (a) Explain various Data Entry methods.
(b) Write about safety monitoring in clinical Trials.
- 18 (a) Explain in detail responsibilities of investigator as per ICH GCP.
(b) Give an overview of Regulatory Environment in Europe.



Code No. 4277

FACULTY OF PHARMACY
Pharm. D (6 YDC) V-Year (Main) Examination, July 2017

Subject : Clinical Pharmacokinetics and Pharmacotherapeutic Drug Monitoring

Time : 3 Hours

Max. Marks: 70

Note: Answer all questions from Part - A and answer any five questions from Part-B.

PART – A (10 x 2 = 20 Marks)

- 1 What is the role of pharmacist in clinical pharmacokinetics?
- 2 Write the significance of population pharmacokinetics.
- 3 What are the major considerations in TDM?
- 4 What are the main factors that influence drug design in renal disease?
- 5 Why is creatinine clearance difficult to predict? Explain.
- 6 Define pharmacogenetics and write its applications.
- 7 Write the TDM for carbamazepine.
- 8 What are the pharmacokinetic considerations in designing a dosage regime?
- 9 Write a note on pharmacokinetic drug – drug interactions with suitable examples.
- 10 Write any one method dosage conversion from I.V. to oral dosing.

PART – B (5 x 10 = 50 Marks)

- 11 Explain TDM drugs used in cardiovascular and seizure disorders.
- 12 (a) Explain dosage adjustment for uremic patients.
(b) Write a note on effect of hepatic disease on pharmacokinetics.
- 13 Explain briefly Bayesian theory and analysis of population pharmacokinetic data.
- 14 Explain the role of cytochrome p-450 isoenzyme in genetic polymorphism in drug metabolism.
- 15 Explain drug dosing in elderly, pediatrics and obese patients.
- 16 Describe inhibition and induction of drug metabolism.
- 17 Explain measurement of glomerular filtration rate and creatinine clearance.
- 18 Explain how TDM will affect individualization of drug dosage Regime.



Code No. 7309

FACULTY OF PHARMACY

Pharm. D. (6 YDC) V Year (Instant) Examination, January 2014

Subject: Clinical Research

Time: 3 Hours

Max. Marks: 70

Note: Answer all questions from Part A. Answer any five questions from Part B.

PART – A (10 x 2 = 20 Marks)

- 1 Write briefly about different types of masking designs in clinical trials. 2
- 2 Define IND and explain when IND application is not required. 2
- 3 What are the advantages of randomized clinical trials? 2
- 4 Explain the importance of drug characterization in drug discovery. 2
- 5 Write about the role of regulatory authority in clinical trials. 2
- 6 Explain briefly about phase II clinical trials. 2
- 7 Write briefly about pharmacological approach in drug development. 2
- 8 What is meant by informed consent process and explain the contents in document? 2
- 9 Explain the procedures of IRB. 2
- 10 Define ADR, write briefly about the monitoring of ADR. 2

PART – B (5 x 10 = 50 Marks)

- 11 Explain in detail about CDSCO guidelines in maintaining good clinical practice. 10
- 12 (a) Explain about phase III clinical trials guidelines. 5
(b) Write about various methods of post marketing surveillance. 5
- 13 Explain in detail about the design of clinical trials. 10
- 14 (a) Write about safety measures in ADR. 5
(b) Explain the components of data management in clinical trials. 5
- 15 Write in detail about the submission of ANDA. 10
- 16 Explain about composition, responsibilities and procedures of IEC. 10
- 17 (a) Write about regulatory authority in India. 5
(b) Explain the responsibilities of investigators and auditors in clinical trial. 5
- 18 (a) Write about methods of safety monitoring in clinical trials. 6
(b) Write a note on ethical guidelines in clinical research. 4



Code No. 7310

FACULTY OF PHARMACY

Pharm. D. (6 YDC) V-Year (Instant) Examination, January 2014

Subject: Pharmaco epidemiology and Pharmacoeconomics

Time: 3 Hours

Max.Marks: 70

Note: Answer all questions from Part A. Answer any five questions from Part B.

PART – A (10 x 2 = 20 Marks)

- 1 Define cost utility analysis. 2
- 2 What do you mean by cost effectiveness analysis? 2
- 3 What do you mean prescription event monitoring? 2
- 4 Define formulary. 2
- 5 Mention pharmacoeconomic principles. 2
- 6 Write short notes on: 2
 - i) Case report
 - ii) Case series.
- 7 Write a note on meta analysis. 2
- 8 Mention two applications of pharmacoeconomics. 2
- 9 Write a note on spontaneous reporting. 2
- 10 What do you mean by decision analysis? 2

PART – B (5 x 10 = 50 Marks)

- 11 Describe in detail need and applications of pharmacoeconomics and pharmacoepidemiological studies in the field of pharmacy practice. 10
- 12 Write notes on attributable risk, relative risk and odds ratio. 10
- 13 Describe in detail, theoretical pharmacoepidemiological methods with the help of case studies. 10
- 14 Write notes on Adhoc data source and automated data system. 10
- 15 (a) Explain in detail developing a formulary list and formulary management. 7
(b) Short note on teratology reports. 3
- 16 Explain in detail cost minimization, cost benefit and cost effectiveness analysis with the help of case studies. 10
- 17 Explain health economics, health outcome research and health related quality of life. 10
- 18 Write short note on DDD, PDD and medication adherence measurement. 10



Code No. 2746 / M

FACULTY OF PHARMACY

Pharm. D. (6YDC) V Year (Main) Examination, Sept/Oct 2013

Subject: Clinical Research

Time: 3 Hours

Max.Marks: 70

Note: Answer all questions from Part A. Answer any five questions from Part B.

PART – A (10x2 = 20 Marks)

1. Write about the responsibilities of IRB. 2
2. Define IND and write its applications. 2
3. What is the role of dosage form in drug development process? 2
4. What is the role of auditor's in clinical trials? 2
5. Write about the protocol design in clinical study document. 2
6. Write in brief about safety monitoring in clinical trials. 2
7. Write about different methods of randomization in clinical trials. 2
8. Define informed consent process and when the documents of ICP are revised. 2
9. Write about methods of reporting ADR. 2
10. Write about the advantages of double-blind design in clinical trials. 2

PART – B (5x10 = 50 Marks)

11. Explain in detail about GCP according to ICH guidelines. 10
- 12.(a) Write the responsibilities of sponsor and clinical research associate in clinical trial. 7
(b) Write a note on CRF. 3
13. Define clinical trial and explain various phases of clinical trials. 10
14. Explain about regulatory environment in USA and India. 10
- 15.(a) Write about data management in clinical trials. 5
(b) Explain how the challenges can be overcome in implementation of guidelines. 5
16. Explain in detail how a clinical trial can be designed. 10
17. Write in detail about submission of ANDA. 10
- 18.(a) Define ADR and explain how it can be monitored. 5
(b) Write the composition and responsibilities of IEC. 5



Code No. 2747 / M

FACULTY OF PHARMACY

Pharm. D. (6 YDC) V Year (Main) Examination, September 2013

Subject: Pharmacoepidemiology and Pharmacoeconomics

Time: 3 Hours

Max.Marks: 70

Note: Answer all questions from Part A. Answer any five questions from Part B.

PART – A (10x2 = 20 Marks)

1. Define cost of illness. 2
2. What do you mean by cost minimization analysis? 2
3. Define cost utility analysis. 2
4. What do you mean by pharmacoepideomiology? 2
5. Mention various factors to be considered in evaluating pharmacoepideomiological study. 2
6. What do you mean by Cochrane reviews? 2
7. How do you measure medication adherence? 2
8. Write a note on meta analysis. 2
9. Define teratology reports. 2
10. Mention major quality of life domains. 2

PART – B (5x10 = 50 Marks)

11. Describe aims, applications of pharmacoepidemiology. Add a note on the origin and evolution. 10
12. Describe in detail medication adherence measurement. Add a note on DDD. 10
13. Write notes on measurement of risk, attributable risk and relative risk. 10
14. Explain various pharmacoepiemiological methods with the help of case studies. 10
- 15.(a) Explain in detail developing a formulary list and formulary management? 7
(b) Short note on teratology reports. 3
16. What are the sources of data for pharmacoepidemiological studies? 10
17. What do you mean by pharmacoepidemiological studies in hospital setup and add a note on vaccine safety? 10
18. What are various pharmacoeconomic methods of evaluation and explain in detail with the help of case studies. 10
