Code No: F–7308

FACULTY OF PHARMACY

Pharm. D V - Year (6 YDC) (Main & Backlog) Examination, September 2024

Subject: Clinical research

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

PART–A

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

1. What is a safety signal? What are the criteria for serious adverse event?
2. Explain the role of auditors as per ICH GCP Guidelines.
3. Explain database lock in clinical data mangement.
4. Write the role of Participant identification centre in clinical research.
5. Explain PSUR and PBRER as per ICH-GCP guidelines.
6. What is ICH? Give the responsibilities of ICH.
7. Differentiate innovator and generic drugs.
8. Give the organization and function of CDSCO.
9. Give ethical issues in clinical research.
10. Explain importance of Impartial witness in Informed consent process.

PART–B

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

11. Write a brief note on centralized procedure of marketing authorization, in Europe.

12. Explain objectives, design and conduct of Phase 3 and phase 4 clinical trials with schedule Y requirements.

13. Explain Case report form design, discrepancy management, data storage and security in Clinical data management.

14. Explain the statement of specific principles for epidemiological studies as per ICMR guidelines.

15. Explain in detail IEC Review procedure of a research proposal.

16. What are the contents of INDA? How IND application is reviewed?

17. Discuss safety monitoring in clinical trials.

18. Explain the role of sponsor and investigator as per ICH-GCP guidelines.

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Code No: F-7309

FACULTY OF PHARMACY

Pharm. D V - Year (6 YDC) (Main & Backlog) Examination, October 2024
Subject: Pharmacoepidemiology & Pharmacoeconomics

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

PART–A

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

1. Define incidence and prevalence with an example.
2. Elaborate the importance of meta-analysis.
3. Outline time-risk relationship.
4. Explain odds ratio.
5. What do you mean by case-control studies?
6. Outline systematic review and its importance.
7. Discuss quality adjusted life year.
8. What are the sources of Ad Hoc data in pharmacoepidemiology?
9. Outline Cochrane review.
10. Summarize the advantages of cost-minimization analysis?

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 the significance of hospital pharmacoepidemiology.
13. Explain the concept of risk in pharmacoepidemiology. Discuss about risk management plan development.
14. Classify different types of data and its source in pharmacoepidemiology. Add a note on automated data linkage systems.
15. Analyze in detail about drug induced birth defects. How can you prevent birth defects?
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. Define cost-utility analysis. Explain the methods for assessing utility.

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Code No: F-7310/PB

FACULTY OF PHARMACY

Pharm. D II - Year (3 YDC) (PB) (Main & Backlog) Examination, October 2024

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. Write the importance of nomograms in designing of dosage?
2. Write about determination of dose and dosing interval?
3. Write a note on protocol of therapeutic drug monitoring?
4. Write a note on enzyme induction with examples?
5. Explain plasma protein binding with its significance?
6. Write the TDM for Digoxin?
7. Write a note on GFR and Creatinine?
8. Write a note on Cyp-450 enzymes involved in metabolism?
9. Write a note on conversion of IV to Oral route of drug administration?
10. Write a note on Population pharmacokinetics?

PART–B

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

11. Write in detail pharmacokinetic drug-drug interactions with suitable examples.
12. Explain in detail the extra corporeal removal of drugs.
13. Explain in detail about the dosage adjustment in patients with hepatic disease.
14. Explain briefly Bayesian theory and analysis of population pharmacokinetic data.
15. Explain the drug dosing in pediatrics and elderly population.
16. Explain in detail pk/pd correlation in drug therapy.
17. Explain genetic polymorphism of cytochrome p-450 isoenzyme in drug metabolism.
18. Describe in detail about
    (a) Drug interaction in Biliary excretion
    (b) TDM of phenytoin sodium

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Code No: F-7155

FACULTY OF PHARMACY

Pharm.D (6 - YDC) V - Year (Instant) Examination, August 2024

Subject: Clinical Research

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

PART-A

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

1. Distinguish between quality assurance & quality control in clinical trials.
2. What are the objectives of Phase-I clinical trials?
3. What are the objectives of Phase-III clinical trials?
4. What are the functions of independent data monitoring committee (IDMC)?
5. What are microdosing trials?
6. Distinguish between audit report and audit certificate.
7. Comment on the importance of impartial witness in IC process.
8. What do you mean by post-trial access of investigational new drug?
9. What is treatment IND?
10. Comment on permitting Phase-I clinical trials in India.

PART-B

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

11. What are the functions of IEC? Comment on the quorum requirements of IEC, to take decisions.
12. Distinguish between monitoring, auditing & inspections in clinical trials. Give a note ontheir purpose & significance.
13. What are essential documents in clinical trials? Write a note on the principles of ICH-GCP.
14. What is clinical data management? Give a brief note on discrepancy management.
15. Who are the stakeholders in clinical trials? Write about investigator's responsibilities.
16. Explain various considerations involved in the design of clinical trial protocol.
17. Explain the NDA & ANDA approval process.
18. Explain the preclinical data requirements in new drug development process.

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Code. No: F-7157

FACULTY OF PHARMACY

Pharm. D (6 YDC) V - Year (Instant) Examination, August 2024

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. 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 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 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. 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.

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Code. No: F-7156

FACULTY OF PHARMACY

Pharm.D V- Year (6 - YDC) (Instant) Examination, August 2024

Subject: Pharmacoepidemiology & Pharmacoeconomics

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

PART-A

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

1. Discuss defined daily dose and prescribed daily dose.
2. Summarize the advantages of meta-analysis?
3. Classify the types of risk in pharmacoepidemiology?
4. Analyse ECHO model of assessing outcomes in pharmacoepidemiology?
5. Define cohort study with an example.
6. Explain spontaneous reporting in pharmacoepidemiology.
7. What are drug-induced birth defects?
8. Outline Cochrane review?
9. Classify different costs involved in pharmacoeconomics.
10. Identify the advantages of cost-benefit analysis?

PART-B

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

11. Define pharmacoepidemiology. Write about its origin, scope and applications.
12. Elaborate in detail about studies of vaccine safety.
13. What is meta-analysis? Elaborate the steps involved in conducting meta-analysis?
14. Classify different sources of data in pharmacoepidemiology? Add a note on Ad-hoc data sources and its advantages.
15. Discuss in detail about the different pharamacoeconomic methods
16. What is cost-minimization analysis? Add a note on its applications.
17. Define cost-effectiveness analysis. Write about the steps involved in conducting CEA and its applications.
18. Explain cost-utility analysis? Write about the advantages, disadvantages and applications of CUA.

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Code No: E-12367

FACULTY OF PHARMACY

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-12367

FACULTY OF PHARMACY

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) Pharmacogenetics 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

FACULTY OF PHARMACY

Pharm. D V Year (6-YDC) (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-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

FACULTY OF TECHNOLOGY

Pharm. D (6 YDC) V Year (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-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

FACULTY OF PHARMACY

Pharm. D V Year (6-YDC) (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 suitable examples.

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 isoenzyme in genetic polymorphism in drug metabolism.

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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 suitable examples.

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 isoenzyme 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 pharmacokineti 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 isoenzyme 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.

* * *

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.

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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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Code No. 12186

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 ofpharmacoepidemiology.

12 Discuss vaccine safety in pharmacoepidemiology.

13 (a) Discuss the outcome measurement units inpharmacoepidemiology.
(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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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 trails 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

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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 pharmacoepidenological 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 pharmacoecconomics in Indian scenario. Discuss the types of pharmacoeconomic evaluations.

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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-cohert 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]

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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-cohert 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]

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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 innulin 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 innulin 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. 6200 / PB

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 head 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.

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Code No. 13299

FACULTY OF PHARMACY

Pharm D (6 – YDC) V – Year (Main & Backlog) Examination, June 2019

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 development? What are the steps involved in the process?

2 Write different methods of lead identification.

3 List out the key players in clinical drug development.

4 What is NDA? How is it filed as per guidelines of schedule Y?

5 What is waiver of consent in clinical research?

6 What is IEC? Write the composition and basic responsibilities of IEC..

7 What is Regulatory Authority? Write the general roles and responsibilities of Regulatory Authority.

8 Write advantages of electronic data capture in CDM.

9 Explain the responsibilities of monitor in clinical trials.

10 What are the types of control treatments in Phase III of clinical trials?

PART – B (5x10 = 50 Marks)

11 Explain the types of preclinical studies with regulatory requirements for conduct of studies. Discuss variou8s animal pharmacology testing required for discovery of new drugs.

12 What is INDA? Explain the review process of IND application.

13 Explain various elements of clinical trial study design.

14 Explain in detail the different methods of post marketing surveillance.

15 Give an overview of regulatory environment in Europe.

16 What is ICMR code? Explain the statement of specific principles for drug trials.

17 a) Explain various data entry methods.

b) Write note on CRF design.

18 a) Explain various aspects of safety monitoring in clinical trials.

b) Write note on quality assurance in CDM.

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Code No. 13300

FACULTY OF PHARMACY

Pharm D (6 – YDC) V – Year (Main & Backlog) Examination, June 2019

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. Applications of pharmacoepidemiology and pharmacoeconomics.
2. Write about units of drug use.
3. Write a note on measurement of risk and relative risk.
4. Write about case control studies.
5. Explain in detail about prescription event monitoring.
6. Discuss odds ratio.
7. Write a note on spontaneous reporting.
8. Significance of hospital pharmacoepidemiology.
9. What are drug-induced birth defects?
10. Write about cost-benefit analysis of pharmacoeconomics.

PART – B (5 x 10 = 50 Marks)

11. Write a note on origin, aims and applications of Pharmacoepidemiology. [10]
12. a)Define medication adherence. Explain the methods to evaluate medication adherence. [5]
    b) Discuss the significance and steps of drug utilization review. [5]
13. Elaborate the cross-sectional, cohort, case- control studies of pharmacoepidemiological methods. [10]
14. Write about Ad Hoc data sources available for pharmacoepidemiological studies. [10]
15. Explain the pharmacoepidemiological methods used to study drug induced birth defects.[10]
16. Briefly discuss about the significance of relative and attributable risk. [10]
17. Explain the need of pharmacoeconomic evaluations in formulary management. [10]
18. Write a brief note on cost-benefit, cost-effectiveness study parameters with the help of case studies. [10]

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Code No. 13301

FACULTY OF PHARMACY

Pharm D (6 – YDC) V – Year (Main & Backlog) Examination, June 2019

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 the importance of nomograms in designing of dosage regimen.

2 What is TDM? Write the indications for TDM.

3 Add a note on PK-PD correlation in drug therapy.

4 Write a note on Cyp-450 enzymes.

5 Write the significance of half life in clinical pharmacokinetics.

6 Explain enzyme induction with examples.

7 What are the methods involved in the conversion of IV to oral dose?

8 Write the TDM of digoxin.

9 Give two examples of genetic polymorphism in drug transport.

10 Write the importance of bioavailability in pharmacokinetics.

PART – B (5x10 = 50 Marks)

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

12 Write a note on:
   a) Bayesian theory
   b) Analysis of population pharmacokinetic data.

13 Describe the role of genetic polymorphism in drug action.

14 Explain in detail about individualization of drug dosage regimen.

15 Write in detail about various pharmacokinetic drug-drug interactions with suitable examples.

16 Describe in detail about
   a) Dosage adjustment in obese patients.
   b) TDM of carbamazepine and phenytoin sodium.

17 Explain in detail the extra corporeal removal of drugs.

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

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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)

10 Describe the effect of genetic polymorphism in drug transport and drug targets.

11 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.

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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.

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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

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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.

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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 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)

10 Elaborate on Cost Minimization analysis with a case study.

11 a) Write in detail about adhoc data base systems.
b) Special issues in vaccine safety.

12 a) What are the various types of outcomes in pharmacoeconomic evaluations?
b) Write a note on the aims and potential applications of Pharmacoepidemiology.

13 a) Discuss in detail the various methods of measuring adherence.
b) Write in detail about relative risk and odds ratio.

14 a) Write a note on the strengths and weaknesses of spontaneous reporting system.
b) Role of a pharmacist in formulary decision making.

15 a) Write in detail regarding the cohort studies, their strengths and weaknesses.
b) Explain prescription event monitoring and its use in pharmacoepidemiology.

16 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?

17 a) What are the various methods to measure utility?
b) Write a short note on ICER.

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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.

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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 pharma-coepidemiological 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?

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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.

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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 fo carhamadepine.
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 different 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 the 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.

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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 trails 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

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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: i) Case report ii) Case series.	2
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. (b) Short note on teratology reports.	7 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

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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

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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

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