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

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 °clinicaI 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 theirH ts protected?

7 Enumerate the essential documents in i i aJt als.

8 Write note on registration of clinical trials.

9 What is ICF?

10 What is blinding in clinical Trials? what is its significance?

B (5x10 = 50 Marks)

11 Explain the tools usecL n head identification and optimization.

12 Explain dosage form development process.

13 Explain the bjeñtives, design and conduct of Phase I clinical trial studied with schedule Y requiremend.

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. 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)

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.

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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)

11 Elaborate on Cost Minimization analysis with a case study.

12 a) Write in detail about adhoc 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.

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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 pharmacoenconomics and pharmacoepidemiological studies in the field of pharmacy practices. 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

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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.	
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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