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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