(1) V Year Pharm D 20

V Pharm D

Subject: Clinical Pharmacokinetics &Pharmacotherapeutic Drug Monitoring

QUESTION BANK 2016-17

Note: Unit II, IV –Two Chapters are clubbed together

Unit I: Introduction to Clinical pharmacokinetics **No. of Hours: 3**

Short Answers **2 Marks**

1. Give the importance of clinical pharmacokinetics
2. Define apparent volume of distribution and give the mathematical equation to calculate this parameter.
3. Define non-linear pharmacokinetics
4. Describe the difference between first and zero order elimination and how each order appears graphically.
5. Define biological half-life and give it's equation with units.
6. Give the relationship between half-life and elimination rate constant.
7. What is clearance? Give the relationship between clearance, drug dose and AUC.
8. Give the assumptions of compartment model.
9. Define pharmacokinetics. Name and define three pharmacokinetic parameters that describe a typical plasma level time curve.
10. Define loading dose and maintenance dose. Give equations to calculate the same.
11. Give any four applications of clinical pharmacokinetics.

Unit II: (A. Design of Dosage Regimen + Therapeutic Drug Monitoring)

A. Design of dosage regimens **No. of Hours: 7**

Long Answers **10 Marks**

12. Explain the various factors considered in the design of dosage regimen for geriatric and obese patients.

Short Essay **5 Marks**

13. Explain the process and clinical significance of conversion from intravenous to oral dosing.
14. What are nomograms? Explain their applications in pharmacokinetic studies with examples. Give their advantages and disadvantages.
15. Explain in detail the determination of dose and dosing interval of a drug.

16. Describe the principle of superposition and how it applies to multiple drug dosing.
17. Explain the role of nomograms and tabulations in the design of dosage regimen.
18. Explain the different methods of conversion of intravenous to per oral dosing.
19. Explain various factors considered in designing the dosage regimen for geriatric patients.
20. Explain the factors considered in the design of dosage regimen for paediatric patients. Give any two formulae for the calculation of child dose.
21. Explain various factors considered in the design of dosage regimen for obese patients.
22. Why dosage adjustment is necessary in the obese patients. What are the pharmacokinetic parameters to be considered in the dosage adjustment for obese patients?
23. The elimination half-life and V_d of tobramycin was reported to be 2.15 hrs and 33.5% of body weight respectively. What is the dose for an 80 kg individual if a steady state level of 2.5 µg/ml is desired? Assume that the drug is given as iv bolus every 8 hrs.
24. The elimination half-life of an antibiotic is 3 hrs with an apparent volume of distribution equivalent to 20% of bodyweight. The usual therapeutic range of this antibiotic is between 5-15 µg/ml. Calculate the dose and dosing interval that will just maintain the therapeutic concentration.
25. Explain in detail determination of dose and dosing interval of a drug.
26. Enumerate the factors involved in calculation of drug dose in peadiatric patients.
27. Discuss the factors to be considered during the design of dosage regimen.
28. Explain the reasons for converting IV dose to oral dose. Add a note on START and STOP criteria for drugs to be used in patients.

Short Answers **2 Marks**

29. Add a note on START and STOP criteria for drugs to be used in geriatric patients.
30. Write different formulae for calculating child dose.
31. Add a note on BEER's criteria for drugs to be used in geriatric patients.
32. Write the importance of loading dose in finding drug dosing intervals.
33. Give the relationship between elimination half-life and drug dosing intervals
34. Define nomograms and tabulations.
35. Give any two advantages and disadvantages of nomograms.
36. Enumerate the methods for conversion of IV to oral dosing.
37. Give any four factors considered in dosing geriatric patients.
38. What are the factors affecting the drug absorption in geriatric patients?
39. Mention the factors affecting the drug distribution in obese patients.
40. Based on which property of drug, the drug dosage is adjusted in the obese patients and why?
41. Give any four factors considered in dosing obese patients.
42. Mention any four factors considered in dosing paediatric patients.
43. Give any two formulae for the calculation of paediatric dose.
44. Write the formula for the calculation of geriatric dose.
45. What are the factors considered in the conversion of IV to oral dosing?
46. What is the BEER's criteria for drugs to be used in geriatric patients?

B. Therapeutic Drug Monitoring **No. of Hours: 15**

Long Essay

47. Explain the necessity and process of TDM in patients receiving cyclosporine and carbamazepine. **10 marks**
48. List out the indications for TDM. Explain the necessity and process of TDM in patients receiving digoxin and phenytoin.
49. Explain the necessity and process of TDM in patients receiving lithium and methotrexate.
50. Enumerate and explain various factors in individualizing drug dosage regimen.
51. Explain in detail pharmacokinetic/pharmacodynamic correlation in drug therapy.

Short Essay **5 Marks**

52. Explain effect of age and bodyweight in individualization of drug dosage regimen.
53. Explain role of genetics and disease condition in the individualization of drug dosage regimen.
54. Explain role of co-existing diseases and interacting drugs in the individualization of drug dosage regimen.
55. Describe the protocol for TDM of a drug.
56. Define TDM. Discuss the indications for TDM of drugs.
57. Explain the role of clinical pharmacist in TDM.
58. Explain the relationship between dose and pharmacological effect of a drug.
59. Explain the relationship between dose and duration of activity of a drug.
60. Explain with suitable examples how elimination half life of a drug influence the duration of activity.
61. Write about Emax model
62. Explain the sigmoidal Emax model in PK/PD correlation

Short Answers **2 Marks**

63. Enlist various types of samples used for analysis in TDM
64. What do you understand by drug tolerance and physical dependency?
65. Define narrow therapeutic index with suitable examples.
66. Define TDM. Name any four drugs that require TDM.
67. Write the protocol for TDM of a drug.
68. Give any four indications for TDM.
69. Why is TDM necessary for digitoxin.
70. Why is TDM necessary for methotrexate.
71. Explain the necessity of monitoring cyclosporine.
72. Give the necessity for TDM of lithium.
73. Why is TDM necessary for phenytoin.
74. Explain the reasons for monitoring drug levels.

Unit III: Pharmacokinetics of drug interactions **No. of Hours: 5**

Short Essay **5 Marks**

75. Explain the various pharmacokinetic drug interactions with suitable examples*.
76. Explain the influence of drug interaction on drug absorption with examples
77. Discuss drug interactions related to protein binding and metabolism.

78. Describe the role of cytochrome P-450 enzymes in drug interactions. Add a note with suitable examples and their clinical significance.
79. Explain the influence of drug interaction on drug metabolism with respect to enzyme induction and enzyme inhibition.
80. Explain the effect of inhibition of biliary excretion of drugs and list out the drug interactions which influence the biliary excretion.

Unit IV: (A. Dosage adjustment in renal and hepatic disease + B. Pharmacogenetics)

A. Dosage adjustment in renal and hepatic disease

No. of Hours: 10

Long Essay

10 Marks

81. Explain in detail the general approaches for dosage adjustment in renal diseases.
82. Explain in detail the different methods of extracorporeal removal of drugs.
83. Discuss various markers used in the measurement of glomerular filtration rate along with their advantages and disadvantages. Enumerate the various formulae used for the measurement of creatinine clearance.
84. Enumerate various causes for renal impairment. Discuss in detail the pharmacokinetic considerations in the renal failure patients.
85. List out various factors for hepatic impairment. Discuss in detail the pharmacokinetic considerations in the hepatic disease patients.

Short Essay5 Marks

86. List various formulae for measurement of glomerular filtration rate.
87. Explain the various pharmacokinetic changes observed in the renally impaired patients.
88. How do you adjust dosage regimen in renal failure patients based on elimination half life of drug?
89. How do you adjust dosage regimen in renal failure patients based on total body clearance of drug?
90. Give the ideal characteristics of a marker to be used in the measurement of GFR.
91. Explain various markers used in the measurement of glomerular filtration rate along with their advantages and disadvantages.
92. Define creatinine clearance. Enumerate various formulae used for the measurement of creatinine clearance.
93. Explain the effect of hepatic disease on pharmacokinetics of drugs.
94. Describe peritoneal dialysis with its advantages and disadvantages.
95. Explain the Giusti-Hayton method for the dosage adjustment in uremic patients.
96. Describe the Wagner method for the dose adjustment in uremic patients.
97. The maintenance dose of gentamicin is 80mg every 6hrs for a patient with normal renal function. Calculate the maintenance dose for a uremic patient with creatinine clearance of 20ml/min. Assume a normal creatinine clearance of 100ml/min.
98. What is the creatinine clearance for a 25 year old male patient with a serum creatinine of 1mg/dL? The patient is 5 ft, 4inches in height and weighs 103 Kg.
99. An adult male patient (52 years old, 75 kg) whose serum creatinine is 2.4 mg/dL is to be given gentamicin sulphate. The usual dose of gentamicin in adult patients with normal renal

function is 1 mg/kg every 8 hours by multiple IV bolus injections. Calculate the appropriate dosage regimen of gentamicin sulfate for this patient.

100. Explain hemodialysis.
101. Explain methods of determining creatinine clearance.
102. Describe the methods of measurement of GFR and their significance.

Short Answers **2 Marks**

103. Enumerate the factors influencing dialyzability of drugs.
104. Enumerate the causes for renal failure
105. Give any four pharmacokinetic parameter changes observed in the renal failure patients.
106. List the markers used in the measurement of GFR.
107. Give any four ideal characteristics of the marker drugs to be used for GFR measurement.
108. Give two advantages and disadvantages of inulin as a marker for GFR measurement.
109. Give the Jellife's equation for the measurement of creatinine clearance.
110. Give the Cockraft and Gault's equation for the measurement of creatinine clearance.
111. Give the formula for the calculation of creatinine clearance in children.
112. Give the MDRD equation for the measurement of creatinine clearance.
113. Name the methods for the extracorporeal removal of drugs.
114. Give any two advantages and disadvantages of peritoneal dialysis.
115. Give any two advantages and disadvantages of haemodialysis.
116. Define intrinsic clearance of drugs with its clinical significance.
117. Calculate creatinine clearance for a 30 year old female patient with a serum creatinine value of 0.8 mg/dl. The patient is 5 ft 1 inch tall and weighs 69 kgs.
118. Name the metabolic markers used in liver function test with their normal values.
119. Define hepatic clearance
120. Give the importance of extra corporeal removal of drugs.
121. Calculate creatinine clearance for a 23 year old male patient with a serum creatinine value of 1.2 mg/dl. The patient is 5 ft 5 inch tall and weighs 98 kgs.
122. Using the method of Cockroft and Gault, Calculate creatinine clearance for a 36 year old female patient with a serum creatinine value of 1.8 mg/dl. The patient is 5 ft 5 inch tall and weighs 58 kgs.

B. Pharmacogenetics **No. of Hours: 5**

Long Essay **10 Marks**

123. Discuss the role and clinical significance of genetic polymorphism in drug transports and drug targets with suitable examples.
124. Discuss the importance of genetic polymorphism of cytochrome P-450 isozymes on drug metabolism with suitable examples.

Short Essay **5 Marks**

125. Describe the role of genetic polymorphism in drug targets.
126. Describe the genetic polymorphism in CYP2D6 and 2C9 isozymes.

Short Answers **2 Marks**

127. Define pharmacogenetics
128. Describe genetic polymorphism in CYP2D6 isozymes
129. Describe genetic polymorphism in CYP2C9 isozymes
130. How do efflux transporters affect the bioavailability of the drugs
131. Give any two examples for clinically important genetic polymorphism of drug targets.
132. Give any two examples for clinically important genetic polymorphism of drug transporters.
133. Describe the role of genetic polymorphism in drug targets.
134. Define pharmacogentics and with suitable examples.
135. With suitable examples, enumerate drug dosing in genetic dependent fast acetylators.

Unit V: Population Pharmacokinetics **No. of Hours: 5**

Short Essay **5 Marks**

136. Describe Bayesian theory
137. Explain dosing with feedback.
138. Discuss population pharmacokinetic analysis using NONMEM method.
139. Discuss analysis of population pharmacokinetic data.
140. Discuss about the methods used to obtain the estimates of fixed effects and variability
141. Describe the two-stage approach in population pharmacokinetic analysis
142. Explain non-linear mixed effects modeling approach
143. Give the applications of population pharmacokinetics.
144. Explain the sampling design used in population pharmacokinetic study
145. Describe how population pharmacokinetic data analysis is carried out.
146. Give the reasons for conducting population pharmacokinetic study
147. What are the limitations of population pharmacokinetic approach
148. Explain the difference between traditional pharmacokinetics and population pharmacokinetics.

Short Answers **2 Marks**

149. Define adaptive method in population pharmacokinetics study.
150. Define population pharmacokinetics.
151. Define adaptive method in population pharmacokinetics study.
152. Define population pharmacokinetics.
153. What are the advantages of population pharmacokinetic study over traditional pharmacokinetic study?
154. Define interindividual variation
155. Define within subject variation
156. What is random error?
157. What is residual error?
158. What do you understand by typical value?
159. Define theta, omega, sigma in NONMEM method of analysis
160. List the methods used for the population pharmacokinetic model evaluation
161. What is difference between observed and predicted concentrations?
162. What do you understand by over-estimation?
163. List various softwares used for conducting population pharmacokinetic analysis

164. Give Bayesian equation.
165. What do you understand by Goodness of Fit plot
166. Define FO and FOCE.
167. What do you understand by nested models?
168. What is naïve pool data?
169. Give the advantages of Bayesian method in population pharmacokinetic study
170. What is interoccasion variation?

V Year Pharm D 13

QUESTION BANK

PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS

LONG ESSAYS 10 MARKS

1. Define risk & enlist the various factors influencing risk in pharmacoepidemiology. Explain relative risk and Odd's ratio with suitable examples.
2. What is bias. Explain the different types of bias in pharmacoepidemiology with examples.
3. What is medication adherence. Explain the methods used to assess medication adherence.
4. Identify and explain the two major pharmacoepidemiological models used to test the relationship between drug exposure and patient outcomes.
5. Explain the applications of pharmacoeconomics.
6. Define DUE. Explain the steps involved in a DUE and mention the pharmacist role in DUE cycle.
7. Explain the merits and demerits of Cohort and case controlled study.
8. Define pharmacoepidemiology and explain history and scope of pharmacoepidemiology.
9. What is cost utility analysis. Explain with suitable examples how the outcome measured using cost utility analysis.
10. What is cost effective analysis. Explain with suitable examples how the outcome measured using cost effective analysis.
11. Explain criteria for causal nature of an association in pharmacoepidemiology study.
12. Define pharmacoepidemiology. Explain case control and cohort studies with suitable examples.
13. Explain in detail the measurement of outcomes in PE studies and explain in detail the drug use measures?
14. Explain in detail the concept of risk and measurement of risk of an ADR with respect to
15. Attributable risk Relative riskTime risk relationship Odds ratio
16. .Explain in detail the methods of Pharmacoeconomic evaluation. (a) Cost of illness evaluation. (b) Cost of minimization analysis. (c) Cost of benefit analysis. (d) Cost effective analysis. (e) cost utility analysis
17. Explain in detail the cohort studies in Pharmacoepidemological study designs and explain in detail the cohort classification?
18. Define record linkage system and explain the process of record linkage system and also explain the probabilistic and deterministic approach in record linkage system?
19. Define Pharmaco-economics and write the applications of Pharmacoeconomics and explain the types of Pharmacoeconomic evaluations. a) CMA b) CBA c) CEA d) CUA?
20. What is bias? Explain the different types of bias with examples in pharmacoepidemiology?
21. Define DUE. Explain the steps involved in a DUE and mention the pharmacists role in DUE cycle.
22. Explain the merits and demerits of cohort and case controlled study.
23. Explain and mention merits and demerits of cohort and case-control studies.(2)
24. Explain and mention the steps involved in a DUE and mention the pharmacists' role in DUE study.
25. Define DUE. Explain the steps involved in a DUE and mention the pharmacists' role in DUE study.
26. Identify two major pharmacoepidemological models used to test the relationship between drug exposure and patients outcomes and explain
27. Explain few important pharmacoepidemiological studies involving drug induced birth defects.

SHORT ESSAYS 05 MARKS

1. Explain the different types of cost in pharmacoeconomic study.
2. What is Markov model. Explain with examples.
3. Describe studies of vaccine safety.
4. Explain the steps involved in cost minimization analysis study.
5. Explain the role of pharmacoeconomics in formulary management.
6. Explain the factors to determine cost of illness study.
7. How is confidence interval measured for an odds ratio.
8. Explain any three important methods of determining medication adherence.
9. What is Markov model. Explain the features.
10. What is decision tree. With an example explain the use of decision tree in clinical decision analysis.
11. Describe the steps involved in formulating a study decision in pharmacoepidemiology.
12. What are the requirements of an ideal database. Write the strength and weakness of automated database.
13. Identify two common statistics used to describe the relationship between drug exposure and outcomes.
14. Explain CMA and give its applications.
15. Explain the benefits and limitations of a automated database.
16. Describe a typical DUE cycle.
17. Write a note on prescription event monitoring.
18. Explain the different types of cost in pharmacoeconomic study.
19. Explain Markov model with a suitable example.
20. Define a Cohort study with an example.
21. Define spontaneous reporting system.
22. Write a note on studies on vaccine safety.
23. Discuss the applications of pharmacoeconomics.
24. What are meta analysis models. Give examples with strengths and weakness.
25. Explain different types of costs in pharmacoeconomic study.
26. Explain the types of errors that can occur in a pharmacoepidemiological study.
27. What are the steps involved in formulating a study design in pharmacoepidemiology.
28. Explain methods, advantages and disadvantages of cross sectional study.
29. Explain the significance of relative risk and attributable risk.
30. Explain few important pharmacoepidemiological studies involving drug induced birth defects
31. Write a note on case reports with its advantages and disadvantages?
32. Write a note on case series with its advantages and disadvantages?
33. Explain Multi Attribute Utility Theory (MAUT) and System of Objectified Judgement Analysis (SOJA)?
34. Explain in detail various costs involved in acquisition of health care facility
35. What are the possible outcomes of a well-defined pharmacoeconomic study and what are the steps involved in planning a pharmacoeconomic study with pharmacoeconomic evaluation?

36. Define drug formulary? Explain various parameters which are analysed in formulary decision making process
37. What are the general operational principles for conducting an ad-hoc study?
38. Define: a) Attributable risk b) Relative risk c) Odds ratio?
39. Define pharmacoepidemology and explain the difference between PE and CP?
40. Explain the potential contributions of PE?
41. Explain the overview of scientific method to investigate a research question along with three stage process?
42. Explain in detail the types of errors one can make in performing a study?
43. Explain the approaches to controlling confounding variables?
44. Explain the criteria for causal nature of an association?
45. Give the advantages and disadvantages of epidemiologic study designs?
46. Explain in detail case reports?
47. Explain in detail case series?
48. What is analysis of secular trends on ecological studies?
49. Explain case control studies?
50. Explain cohort studies?
51. Compare between case control and cohort studies?
52. Explain randomised clinical trial?
53. Enlist the national and international post marketing safety databases?
54. What are reporting ratios?
55. Explain signal detection and approach for detecting signals from a post marketing safety database?
56. Explain about national pharmacovigilance system?
57. Explain the strengths and limitations of post marketing safety reporting system?
58. Define Odds ratio and data mining?
59. Explain about the claims and other administrative database?
60. What are the strengths and weakness of computerised database?
61. What are MRDBs?
62. What are electronic medical records (EMRs)?
63. Discuss the health maintenance organisations/ health plans?
64. Enlist the current and past multisite multiproject research programs within HMORN?
65. Explain about Cancer research network (CRN), Cardiovascular research network (CVRN), Vaccine safety database (VSD)? Explain the data structure of Medicaid database?
66. What are the strengths and weakness of Medicaid, Medicare, and department of Veterans Affairs?
67. Explain the prescription drug database in Canadian provincial database?
68. Explain record linkage, patient router files in pharmacy based medical record linkage system?
69. Define Ad-Hoc studies and enumerate the strength of Ad-Hoc studies?
70. What are the essential steps to be taken prior to selection of a design for in ad-hoc studies?
71. Explain protocol development in ad-hoc studies?
72. Explain the three key aspects in set up of ad-hoc studies?
73. What are the operational principles in conducting PE trend studies
74. Explain the different types of cost in a pharmacoeconomic study.
75. What is Markov model? Explain with examples.
76. Describe studies of vaccine safety.
77. Explain the steps involved in Cost Minimisation Analysis Study.
78. Explain the role of pharmacoeconomics in formulary management.
79. Explain the factors to determine cost of illness study.

80. How is confidence interval measured for an odds ratio?
81. Explain any three important methods of determining medication adherence.
82. Describe cohort study with an example.
83. Explain the strength and weakness of automated databases
84. Write a note on studies of vaccine safety.
85. Describe a typical DUE cycle
86. Give the strengths and weakness of meta-analysis
87. Explain the various measurements of outcome in pharmacoepidemology study...
88. Identify 2 common statistics used to describe the relationship between drug exposure and outcomes.
89. What are the ideal requirements of ideal databases? Write the strengths and weakness of automated databases.
90. Describe a case control study. Give its advantages and limitations
91. Describe spontaneous reporting systems
92. Write about prescription even monitoring
93. What are meta-analysis models? Give examples
94. Describe different type of error that occur in pharmacoepdemolgical study?

SHORT ANSWERS 02 MARKS

1. Define prevalence.
2. What is signal generation. Explain its significance.
3. What is outcome research.
4. Name four computerized databases used for pharmacoepidemiological research.
5. What is willingness to pay.
6. Mention the limitations of pharmacoeconomic study.
7. What is case series.
8. Define sensitivity analysis.
9. Define attributable risk.
10. Define pharmacoeconomics and outcome research.
11. Define spontaneous reporting systems.
12. What is QALY.
13. Give advantages of Cohort study.
14. What is ICER and ACER.
15. List meta analysis models.
16. Define prevalence and incidence.
17. Define "Defined daily dose"and "Prescribe daily dose".
18. Give examples of intangible cost involved in pharmacoeconomic study.
19. Define monetary units.
20. Explain confounding.
21. What is record linkage system.
22. Give the applications of cost benefit analysis.
23. Define term outcome research.
24. List out steps involved in creating a study design for pharmacoeconomic study.
25. What are ad-hoc data sources.
26. Explain selection bias.
27. What is case report.What are limitations.
28. What is opportunity cost.
29. What is the need of post marketing surveillance.
30. Define attributable risk?
31. Define relative risk?
32. Define time risk relationship?
33. Define odds ratio?
34. Define outcomes research Cost Conequences.
35. Define incidence, prevalence?
36. What is bias? Explain its different types?
37. Write a note on VAERS?
38. Define confounding?
39. Explain QOL and QALY?

40. Give the advantage of cohort study
41. What is outcome research.
42. What is record linkage system
43. Name any 4 computerized data base used in pharmacoepidemological study
44. What are case series?
45. What are ad hoc data sources?
46. Explain the selection of bias?
47. Define term outcome research?
48. Mention two drug products recalled with associated adverse events
49. What are case reports and give its significant
50. Explain "cofounding"
51. List meta-analysis models
52. List out the purpose of meta analysis
53. Define prevalence.
54. What is signal generation? Explain its significance.
55. What is outcome research?
56. Name four computerised database used for pharmacoepidemiological research.
57. What is willingness to pay?
58. Mention the limitations for pharmacoeconomic study.
59. What is case series?
60. Define sensitivity analysis.
61. Define attributive risk?
62. Define pharmacoecomics and outcome research.
63. Explain the potential contributions of PEY studies.
64. Define Ad-Hoc studies and enumerate the strength of Ad-Hoc studies?
65. Explain the need of pharmacoeconomics.
66. Write two applications of CMA.
67. Enlist types of errors
68. Define QALY & QOL
69. Define DUE
70. Define risk in PEY.
71. Define vaccine safety.
72. Role of pharmacist in essential drug concept.
73. Write the objectives of pharmacoepidemiology.
74. What are the strengths and weakness of Medicaid and Medicare.
75. Define Pharmacoeconomics.
76. Write two applications of Cost of illness analysis.
77. Define case reports.
78. Define cost utility analysis.
79. Define prescribed daily dose.
80. Define time risk relationship.
81. Define hospital pharmacoepidemiology.
82. Write a note on rational use of drugs.
83. Write the advantages of PEY studies.
84. What are the strengths and weakness of computerised database.
85. Write the aims of pharmacoeconomic studies.
86. Write the applications of cost utility analysis.
87. What is the significance of post marketing surveillance?

88. Define direct costs
89. Define DDD.
90. Enumerate the difference between relative risk and attributable risk.
91. Enlist two birth defects.
92. What do you mean by essential drug list.

(b) V year Pharm D 6

CLINICAL RESEARCH CHAPTERWISE QUESTION BANK

Chapter No	Topics	Questions	Marks
		Drug Development Process	
1	Introduction	With schematic representation, discuss integrated drug development process.	5
1.1	Pharmacological approach	Define therapeutic index	2
		Short note on Helsinki declaration	2
		What is LD50? and ED50	2
		What is Human Equivalent Dose (HED)? How to convert animal dose to HED?	2
		Explain the different pharmacological action studies in the drug development process	5
		explain pre-clinical trials	5
		write a note ADME profiling	5
		Define Proof of Concept	2
		define maximum tolerated dose	2
		Write a note on lead selection and optimization drug development process.	5
1.2	Toxicological approach	Importance of chronic toxicity	2
		Explain the toxicological approach to drug development process	5
		mutagenecity and carcinogenicity	2
		Sub acute toxicity	2
1.3	IND Application	Discuss in detail the IND application	10
		What is IND? Enlist the different criteria for IND application	5
1.4	Drug characterization	Discuss various drug characterization techniques in drug development process	5
1.5	Dosage form	biopharmaceutical classification of drugs	2
		name the critical Pharmacokinetic parameter in drug development	2
		drug bioavailability	2
		Fixed dose combinations	2
		Explain the importance of dosage form design in pre-clinical and clinical stages	5
		Clinical Development of Drug	
2.1	Introduction to Clinical trials	Requirements to conduct clinical trials as per schedule Y	10
		What is clinical trail	2
		define single blind method	2

		explain inclusion and exclusion criteria in selection of clinical trial subjects	5
		define double blind method	2
		name different types of clinical trials	2
		investigation product/drug	2
		What is Belmont report?	2
		Nuremberg trials	2
		Explain the role of BPOs in conducting clinical research in India	5
		what is 'The Orange Book'	2
		Note on Non-inferiority clinical study	2
		define bias	2
		Regulations for orphan drugs	2
		Regulations for Counterfeit drugs	2
		drug labeling requirement in clinical studies	2
		What is scurvy trail?	2
2.2	Various phases of clinical trial	Discuss in detail the various phases of clinical trial	10
		note on randomized clinical trial	2
		Briefly explain phase 1 and phase 2 clinical trials	5
		write short note on clinical trial design	5
		define phase Zero	2
		objectives of phase 1/2/3/4	5
		methods of randomization	5
		Note on open labeled clinical trails	2
		Methods of sample size calculations in clinical trials	2
		difference between phase 2a and phase 2b	5
		what are the objectives of phase 2 studies	2
		Use of Placebo in clinical trials	2
		principles of trial subject sampling	2
2.3	Methods of post marketing surveillance	Discuss about the different methods of post marketing surveillance	10
		write a note on case control studies	5
		difference between retrospective and prospective study	5
		observational studies	5
		write a note on meta analysis	5
		note on cohort studies	2
		differentiate ADR and ADE	2
		retrospective study	2
		cross sectional study	2
		Epidemiological study	2
		Define false positive result with an example	2

		Non-Therapeutic Study	
		Validation of clinical study	2
		Selection and recruitment of Study Subjects	2
		Clinical Trials with Surgical Procedures / Medical devices.	5
2.6	Challenges in the implementation of guidelines	comment on the challenges in the implementation of ethical guidelines	5
2.7	Ethical guidelines in Clinical Research	write a note on clinical data management in clinical trials	5
		research involving children	10
		Inclusion of pregnant women and nursing mothers in CT?	2
		vulnerable subject	2
		define Ethics	2
		Ethical issues involved in Genetic Screening	2
		explain clinical trials for vaccines	2
		pregnant women as research participant	5
		Explain the ethical guidelines for clinical research	5
		write a note on compensation for clinical Trial subjects as per ethical guidelines	5
		Conflict of interest in clinical trials	5
2.8	Composition, responsibilities, procedures of IRB / IEC	members of ICH	2
		explain composition and responsibilities of IRB	5
		Discuss in detail about institutional review board	5
2.9	Overview of regulatory environment in USA, Europe and India	write on European Clinical Directive	2
		function of dcgi	2
		Note on 21CFR Part 312	2
		Note on Marketing Authorization Holder (MAH)	2
		note on centralized marketing and decentralized marketing	2
		Note on Clinical Trial Document (CTD	2
		MHRA	2
		EMEA	2
		USFDA	2
		what are different regulator system in USA, europe and India	5
		give an overview of regulatory environment in India	5
		expand forms of the following MHRA, CRO, CRF, MAH, EMEA, CTA, GLP, CFR	5
		write a note on regulations for OFF-Label Use	5
		Write a note on pharmaceutical regulations in regard to clinical trials in European union	10

2.4	Abbreviated New Drug Application submission	explain briefly about ANDA submission	10
		Explain in detail NDA submission	10
		write a note on ANDA	5
		basic methodology and study designs of BA/BE studies	5
		limitations of post marketing surveillance	2
2.5	Good Clinical Practice – ICH, GCP, Central drug standard control organization (CDSCO) guidelines	discuss the principles of ICH-GCP guidelines	10
		explain clinical trial protocol as per ICH-GCP guidelines	10
		Explain Clinical trials and monitoring. Discuss different types of monitoring visits in detail	10
		What do you mean by expedited reporting in clinical trial? Discuss the safety reporting as per schedule Y	10
		discuss the recent amendments in schedule Y with special reference to ethics committee	10
		what the note on ICH-GCP guidelines	5
		essential documents in conducting clinical trials	5
		Discuss in detail about CDSCO guidelines	5
		Role of ICMR in clinical research	2
		list the guidelines and acts that govern the conduct of clinical trials in India	2
		selection and withdrawal of subjects in clinical trail	2
		multicentre trails	2
		Write a short note on new amendments to Schedule Y.	5
		what are medical devices and classify with suitable examples	5
		preparative termination of clinical trail	2
		statistical design in clinical trails	5
		unblinding	2
		drug master file	2
		subject identification code	2
		write a note on Clinical Study Reports	5
		Note on CIOMS	2
		Premature Termination or Suspension of a Study	5
		ICH E6	2
		contract research	2
		clinical trial registries	2
		clinical trial insurance	2
		comparative studies	2
		coding of investigation products	2
		importance of confidentiality statement in IB	2
		Phases of Vaccine Trials	2

		Write a note on Centralized procedure and Decentralized Mutual Recognition Procedure in European union	10
		write a note on Accelerated Approval	5
		write a note on Accelerated Approval, Fast Track, and Priority Review	10
		write a note on Fast Track, and Priority Review	5
2.10	Role and responsibilities of clinical trial personnel as per ICH GCP a. Sponsor b. Investigators c. Clinical research associate d. Auditors e. Contract research coordinators f. Regulatory authority	write a note on CRA	5
		Explain in detail the role and responsibilities of a)investigator b) clinical research associate c) Regulatory authority as per ICH-GCP	10
		explain about clinical trials audit and inspection with special emphasis on national regulatory authorities	10
		Expand the following: IND, DCGI, PvPI, BPO	2
		role of CRC	2
		Role of auditor In clinical data	2
		What is an Investigators brochure and explain its content?	5
		role and responsibilities of auditors	5
		explain the role of investigators I clinical trials	5
		criterias for selection of an investigator/s	2
		Role and responsibilities of sponsor in clinical trials	5
2.11	Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment)	Explain in detail the process of designing study protocol in clinical trials. Add a note on importance of CRF	10
		explain designing of CRF with a suitable example	5
		define protocol	2
2.12	Informed consent Process	Discuss about designing of inform consent form for clinical study?	5
		explain confidentiality and impartial witness	2
		Explain in detail the informed consent process	5
		difference between consent and assent forms	2
		explain Waiver of consent	2
2.13	Data management and its components	write a note on QA and QC	5
		Discuss data management and its component	5
		write the application of computers in clinical data management	5
		write a note on clinical data archive	5
		What is ANOVA?	2

		Role of DSMB in safety monitoring	2
		Components of documentation form	2
		Discuss Electronic Data Processing	5
2.14	Safety monitoring in clinical trials	Explain the monitoring visits in initiation, conduction and closing of clinical trial	10
		List global ADR reporting Forms?	2
		Define unexpected ADR	2
		Minimum criteria to report ADR	2
		List various criterias to classify a serious ADR	2
		write about safety monitoring in clinical trails	5
		Explain the purpose of the clinical trial monitoring and the responsibilities of monitors in clinical monitoring	5
		PVPI	2
		PSUR	2
		SUSAR	2
		write a note on Active Surveillance in ADR reporting	5
		Role of Eudravigilance in safety monitoring	5
		Role of Uppsala monitoring centre (UMC) in safety Monitoring	2
		Explain spontaneous reporting of ADR with suitable examples. What are the merits and demerits of spontaneous reporting	10