V Pharm D

MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES
MANIPAL
(A constituent unit of MAHE, Manipal)

Manipal Academy of Higher Education
Fifth Year PharmD and II PharmD PB Degree Examination- July 2021
Subject Code: PPR 5.1T Subject: Clinical Research

Date: 26-07-2021 **Duration: 2 Hour (Time: 2.30 to 4.30 PM)** **Max. Marks:** 50

Instructions:

- **Answer ALL questions.**
- **Draw diagrams wherever necessary.**
- **In each page students must write class, registration no, Name, signature with date.**
- **Students should view before writing and press turn in button after uploading answer before due time or close time.**

Section A: Long Answer Questions (2 x 10 marks = 20 marks)		**Marks**
1.	Explain various types of IND application. Explain regulatory process for IND application to the FDA.	10 KK
2.	Discuss human pharmacology trials and therapeutic confirmatory trials in detail.	10KK
Section B: Short Answer Questions (6x 5 marks = 30 marks)		**Marks**
1.	Explain the role of sponsor in trial initiation, auditing and monitoring of clinical trial.	5 MR
2.	Explain various challenges faced during the conduct of a Clinical Trial according to ICH – GCP guidelines.	5 MR
3.	Explain various responsibilities of Institutional Review Board/Independent Ethics Committee as per ICH GCP guidelines.	5 MR
4.	Define informed consent and explain the informed consent process for enrolling patients into a clinical study.	5 MR
5.	Discuss in detail the quality assurance of data management during the process of clinical trial.	5 KK
6.	Compare regulatory environment for conducting clinical trials in India and US.	5 KK

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Manipal Academy of Higher Education
Fifth Year Pharm D/ II Pharm D (PB) Degree Examination- July 2021
Subject Code: PPR. 5.2T Pharmacoepidemiology and Pharmacoeconomics

Date: 28-07-2021 **Duration: 2 Hour (Time: 2.30 pm to 4.30 pm)** **Max. Marks:** 50

Instructions:

- **Answer ALL questions.**
- **Draw diagrams wherever necessary.**
- **In each page students must write class, registration no, Name, signature with date.**
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Section A: Long Answer Questions (2 x 10 marks = 20 marks)		**Marks**
1.	Enumerate different types of pharmacoepidemiological study designs and describe cohort study in detail.	10 marks
2.	Explain cost-effectiveness grid and cost-minimization analysis.	10 marks

Section B: Short Answer Questions (6x 5 marks = 30 marks)		**Marks**
1.	Explain defined daily dose (PDD) and prescribed daily dose (DDD)	5 marks
2.	Explain why the PRISMA statement is important when conducting a meta-analysis.	5 marks
3.	What does spontaneous ADR reporting imply, and explain the strengths and limitations of spontaneous ADR reporting?	5 marks
4.	What is meant by automated databases? Explain claim database.	5 marks
5.	Enlist the different types of cost categories in pharmacoeconomic studies and explain any two.	5 marks
6.	Mention the types of software used in pharmacoeconomic analysis and briefly describe any two.	5 marks

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Reg. No.									

Manipal College of Pharmaceutical Sciences
Manipal Academy of Higher Education, Manipal
University Examination –July/August 2021
V Year PharmD/ II Year PharmD (PB)
Subject: PPR 5.3 T : CPKTDM

Date: 30-07-2021 Time: 02:30 pm - 04:30 pm Max. Marks: 50

Instructions: Answer ALL questions.

Long Answer Questions **2X10=20 Marks**

1. Discuss about the TDM of Phenytoin, Carbamazepine and Digoxin
2. Explain genetic polymorphism in drug metabolism of CYP2C9, CYP2C19 and CYP2D6

Short Answer Questions **6X5=30 Marks**

3. Explain pharmacokinetic drug interactions
4. Discuss about extracorporeal elimination of drugs
5. Discuss about non-liner mixed effect model of population pharmacokinetic approach
6. Explain direct link and direct response model in PKPD correlation
7. Discuss about the Bayesian theory with an example
8. Discuss about the nomograms and tabulations for dosage adjustment

"End of the question paper."