

# Question Paper

Exam Date & Time: 12-Jul-2022 (10:00 AM - 01:00 PM)



## MANIPAL ACADEMY OF HIGHER EDUCATION

SECOND YEAR PHARM D (POST BACCALAUREATE PROGRAMME) / FIFTH YEAR PHARM. D DEGREE EXAMINATION  
- JULY 2022

SUBJECT: PPR 5.1T: CLINICAL RESEARCH  
(REVISED REGULATIONS 2014)

Marks: 70

Duration: 180 mins.

### Long Essay Questions:

- 1) Explain the role of sponsor in trial management, data handling and record keeping. (10)
- 2) Discuss the principles and applications of schedule Y in clinical trials. (10)
- 3) Explain the objectives and procedures in the conduct of clinical trials Phase I to IV. (10)

### 4. Short Essay Questions:

- 4A) Explain the role of clinical investigator in clinical trials. (5)
- 4B) Outline briefly various components of clinical data management. (5)
- 4C) Discuss IND application process. (5)
- 4D) Describe the various toxicity studies during preclinical drug development program. (5)
- 4E) Explain the role of auditors in clinical trials. (5)
- 4F) Explain the Abbreviated New Drug Application process. (5)

### 5. Give Reasons for the following:

- 5A) Transdermal drug delivery systems are associated with many advantages and disadvantages. (2)
- 5B) Vulnerable Subjects participation could be unduly influenced during clinical trials. (2)
- 5C) 1979 Belmont Report is a cornerstone document related to clinical trials. (2)
- 5D) High throughput screening is an important step in drug discovery development. (2)
- 5E) Acid labile drugs are formulated as enteric coated tables. (2)

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# Question Paper

Exam Date & Time: 18-Jul-2022 (10:00 AM - 01:00 PM)



## MANIPAL ACADEMY OF HIGHER EDUCATION

SECOND YEAR PHARM D (POST BACCALAUREATE) / FIFTH YEAR PHARM D. DEGREE EXAMINATION - JULY 2022  
SUBJECT: PPR 5.3T: CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTICS DRUG MONITORING  
(REVISED REGULATIONS 2014)

Marks: 70

Duration: 180 mins.

### Long Essay Questions:

- 1) Explain the genetic polymorphism of G6PD and N-Acetyltransferase and its effect on drug metabolism. (10)
- 2) Explain the indications for Therapeutic Drug Monitoring and explain TDM of digoxin, amiodarone and valproate (10)
- 3) Explain direct and indirect link models for pharmacokinetic and pharmacodynamic correlation. (10)

### 4. Short Essay Questions :

- 4A) Describe extracorporeal elimination techniques with their applications. (5)
- 4B) Mention all the formula used in dosage calculation for pediatrics. (5)
- 4C) Explain the patient selection criteria for IV to oral conversion and describe any one method of conversion (5)
- 4D) Describe the pharmacokinetic factors which govern dosage adjustment in geriatric population (5)
- 4E) Explain the concept of nomograms and their applications with examples (5)
- 4F) Describe the difference between traditional and population pharmacokinetics. (5)

### 5. Give reasons for the following :

- 5A) CYP2C9 genetic polymorphism screening helps in warfarin dosing (2)
- 5B) Protein binding interactions causes pharmacokinetic changes (2)
- 5C) Drug transporters' pharmacogenetics reduces plasma concentration of drugs (2)
- 5D) Highly water soluble drugs have larger volume of distribution in infants (2)
- 5E) Nomograms are useful in dosage individualization (2)

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