Question Paper

Exam Date & Time: 04-May-2022 (10:00 AM - 01:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

SECOND YEAR PHARM D-POST BACCALAUREATE / FIFTH YEAR PHARM. D DEGREE EXAMINATION - MAY 2022
SUBJECT: PPR 5.1T: CLINICAL RESEARCH
(REVISED REGULATIONS 2014)

Answer ALL questions.

Marks: 70 **Duration: 180 mins.**

Long essay questions.

1)	Explain the objectives and procedures in the conduct of clinical trials Phase I to Phase III.	(10)
2)	Discuss the features of essential documents for the conduct of a clinical trials.	(10)
3)	Explain New Drug application (NDA) process. Draw a typical algorithm for NDA submission.	(10)

4. **Short essay questions.**

4A)	Write a brief note on data validation process.	(5)
4B)	Discuss the importance of schedule Y in clinical trials.	(5)
4C)	Discuss role and responsibilities of regulatory authority for conducting clinical trial in India.	(5)
4D)	Define the terms bioavailability, bioequivalence, informed consent, suspected adverse reactions and investigator.	(5)
4E)	Explain the significance of Post marketing surveillance and Periodic Safety Update Reports (PSUR).	(5)
4F)	Discuss premature termination or suspension of a trial in detail.	(5)

5. **Give Reasons for the following:**

5A)	Biological characterization of new chemical entity is mandatory before clinical trials.	(2)
5B)	Sponsor should have special SOPs for Vulnerable Subjects.	(2)
5C)	Data security is compulsory for trial subjects.	(2)
5D)	Compensation to the trial participants is a complicated process.	(2)
5E)	India is a less known for New drug discovery development.	(2)

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Question Paper

Exam Date & Time: 06-May-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 - MAY 2022
SUBJECT: PPR 5.2T: PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS
(REVISED REGULATION 2014)

Marks: 70 **Duration: 180 mins.**

Long Essay Questions.

1)	Discuss the important considerations while performing a meta-analysis.	(10)
2)	Discuss the types of pharmacoeconomic evaluations. Briefly explain about role of pharmacoeconomic evaluations in formulary management decisions.	(10)
3)	What is medication adherence? Explain the methods used to assess medication adherence.	(10)

4. **Short Essay Questions.**

4A)	Define Prescription Event Monitoring (PEM) and explain the method of PEM in general medical practice.	(5)
4B)	Explain case control studies with examples.	(5)
4C)	Describe Ad-hoc data sources and automated data systems.	(5)
4D)	Describe record linkage system.	(5)
4E)	Explain Defined Daily Dose and Prescribed Daily Dose with suitable examples.	(5)
4F)	What are time-risk relationship? Explain with examples.	(5)

5. **Give Reasons for the following:**

5A)	Cohort study is different from case cohort study.	(2)
5B)	Major considerations of meta-analysis include publication bias.	(2)
5C)	Case reports are considered as the least evidence among evidence based medicine.	(2)
5D)	Drug-induced birth defect studies may have various clinical problems.	(2)
5E)	Automated data base systems are useful in data mining.	(2)

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Question Paper

Exam Date & Time: 09-May-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 - MAY 2022
SUBJECT: PPR 5.3T: CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEAUTICS DRUG MONITORING (REVISED REGULATIONS 2014)

Marks: 70 **Duration: 180 mins.**

Long Essay Questions.

1)	Explain the genetic polymorphism in G6PD, CYP 3A4 and 2C9 isozymes in drug metabolism.	(10)
2)	Explain the indications for Therapeutic Drug Monitoring and explain TDM of carbamazepine, digoxin and lithium.	(10)
3)	Describe Naive Pooled approach and Non-linear Mixed effect Model approach of population pharmacokinetic data analysis.	(10)

4. **Short Essay Questions.**

4A)	Describe the patient selection criteria and advantages of IV to oral conversion.	(5)
4B)	Describe the pharmacokinetic factors which govern dosage adjustment in elderly.	(5)
4C)	Describe the process of assigning probability for a diagnosis using Bayesian approach.	(5)
4D)	Describe nomograms and their applications in designing dosage regimen.	(5)
4E)	Define enzyme inhibition, its consequences and describe any one mechanism.	(5)
4F)	Describe the salient features that differentiates conventional and population pharmacokinetics.	(5)

5. **Give reasons for the following.**

5A)	N-Acetyl transferase metabolism is different in different ethnic group.	(2)
5B)	Cockcroft-Gault formula does not calculate GFR effectively in obese patients.	(2)
5C)	Poor metabolizers of certain drugs tend to develop toxicity.	(2)
5D)	Bayesian theory concept is different from deterministic statistics.	(2)
5E)	Dosage nomograms are useful in dosing regimen designs.	(2)

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