Reg. No.										

MANIPAL ACADEMY OF HIGHER EDUCATION

SECOND YEAR PHARM D (POST BACCALAUREATE)/FIFTH YEAR PHARM D. DEGREE EXAMINATION – MAY 2019

SUBJECT: PPR 5.1T/PD 5.1: CLINICAL RESEARCH
(COMMON FOR 2014 & OLD REGULATION)

Monday, May 06, 2019

Time: 10:00 – 13:00 Hrs. Max. Marks: 70

✍ **Answer ALL the questions.**

SECTION – A

✍ **Long essay questions:**

1. Explain the principles of ICH GCP guidelines.
2. Define informed consent. Explain the informed consent process while enrolling patients into a clinical study.
3. Discuss the concepts and processes of safety monitoring during clinical trials.

(10 marks × 3 = 30 marks)

SECTION – B

4. **Short essay questions:**

4A. Explain the role and responsibilities of clinical research associate and clinical research coordinator.
4B. Discuss in detail on lead optimization stage of drug development.
4C. Describe the IND application process.
4D. Explain the subacute and chronic toxicity studies of preclinical drug development program.
4E. Describe the components of a clinical trial protocol.
4F. Discuss the challenges in the implementation of clinical trial guidelines.

(5 marks × 6 = 30 marks)

SECTION – C

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

5A. Nuremberg Code of 1947 is perhaps the most important document in the history of medical ethics.
5B. The confidentiality of records should be in accordance with the applicable regulatory requirement(s).
5C. Randomization of subjects is important during clinical trials.
5D. Audit Trail allows the reconstruction of the course of events.
5E. Data from chemical characterization of NCE is vital.

(2 marks × 5 = 10 marks)

Reg. No.										

MANIPAL ACADEMY OF HIGHER EDUCATION

SECOND YEAR PHARM D (POST BACCALAUREATE)/FIFTH YEAR PHARM D. DEGREE EXAMINATION – MAY 2019

SUBJECT: PPR 5.2T/PD 5.2: PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS

Wednesday, May 08, 2019

Time: 10:00 – 13:00 Hrs. Max. Marks: 70

✍ **Answer ALL the questions.**

SECTION – A

✍ **Long essay questions:**

1. Define meta-analysis. Explain the steps involved in conducting a meta-analysis with an example.
2. Briefly explain the steps of pharmacoeconomic evaluations and explain the role of pharmacoeconomic evaluations in formulary management decisions.
3. Define spontaneous reporting and Record Linkage System (RLS). Explain in detail the strengths and limitations of spontaneous ADR reporting and information flow in RLS.

(10 marks × 3 = 30 marks)

SECTION – B

4. **Short essay questions:**

4A. Explain role and responsibility of WHO in Global drug surveillance.
4B. Explain about the merits and demerits of software applications of pharmacoeconomics.
4C. Briefly explain about the significance of hospital pharmacoepidemiology.
4D. Explain and differentiate cross sectional and cohort studies.
4E. Explain about Quality-Adjusted Life Year (QALY) measure of health outcome for economic evaluation in pharmacoeconomic module.
4F. Write a note on studies of vaccine safety.

(5 marks × 6 = 30 marks)

SECTION – C

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

5A. Deterministic record linkage system is different from probabilistic record linkage system.
5B. Case-Control studies are retrospective in nature.
5C. Relative risk can be calculated for prospective study.
5D. Medication adherence can be improved by patient information leaflets.
5E. Pharmacoeconomic analysis is important in formulary management.

(2 marks × 5 = 10 marks)

Reg. No.										

MANIPAL ACADEMY OF HIGHER EDUCATION

SECOND YEAR PHARM D (POST BACCALAUREATE)/FIFTH YEAR PHARM D. DEGREE EXAMINATION – MAY 2019

SUBJECT: PPR 5.3T/PD 5.3: CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTICS DRUG MONITORING

Friday, May 10, 2019

Time: 10:00 – 13:00 Hrs. Max. Marks: 70

✍ **Long essay questions:**

1. Explain methods for analysis of population pharmacokinetic data.

2. Explain Bayesian theory and adaptive dosing or dosing with feedback.

3. Explain the indications for Therapeutic Drug Monitoring (TDM) and explain TDM of digoxin, theophylline and sodium valproate.

(10 marks × 3 = 30 marks)

4. **Short essay questions:**

4A. Explain Child-Pugh scoring system and its relevance to hepatic dosage adjustment
4B. Describe four mechanisms in enzyme induction
4C. Explain drug-drug interactions in absorption and distribution processes.
4D. Explain the pharmacokinetic changes, which affect drug dosage in children
4E. Explain the process of Hemodialysis and its applications
4F. Describe nomograms and their applications in designing dosage regimen.

(5 marks × 6 = 30 marks)

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

5A. Ideal body weight is used to dose certain drugs.
5B. Indirect link PK-PD model has time lag.
5C. Dosing interval is altered in renal failure patients.
5D. Population pharmacokinetic study methodology is different from conventional pharmacokinetic study methodology.
5E. Pediatric subjects have different volume of distribution compared to adults.

(2 marks × 5 = 10 marks)