

QP Code:

Reg. No.:.....

Second Year Pharm. D (Post Baccalaureate) Degree Examinations

(Model Question Paper)

Clinical Research

Time: 3 hrs

Max. Marks: 70

- *Answer all questions*
- *Draw diagram wherever necessary*

Essays:

(3x10=30)

1. Explain clinical trial protocol as per ICH-GCP guidelines
2. Describe briefly the various phases of clinical trials.
3. Discuss the composition, responsibilities and procedures of IRB/IEC

Short notes

(8x5=40)

4. ANDA submission.
5. Explain the safety monitoring in clinical research
6. Explain the role of investigator
7. Explain the design of a patient informed consent with a suitable example
8. Pharmacological approaches to drug discovery
9. Challenges in implementing the ethical guidelines
10. Clinical trial design
11. Methods of post marketing surveillance

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Second Year Pharm. D (Post Bacculaureate) Degree Examinations

(Model Question Paper)

PHARMACOEPIDEMOLOGY AND PHARMACOECONOMICS

Time: 3 hrs

Max. Marks: 70

- *Answer all questions*
- *Draw diagram wherever necessary*

Essays:

(3x10=30)

1. Define pharmacoepidemiology. Explain the history, scope and applications of pharmacoepidemiology.
2. Define DUE and explain the steps involved in a DUE. Mention the role of pharmacist in a DUE study.
3. Explain the cost effectiveness analysis and cost utility analysis with its applications in pharmaco-economic study.

Short notes

(8x5=40)

4. Explain incidence and prevalence in pharmacoepidemiological study.
5. Explain the meta analysis models with examples.
6. Describe the various types of costs in pharmaco-economic study.
7. Explain the role of pharmaco-economics in formulary management.
8. Explain the relative risk and attributable risk in pharmacoepidemiological study.
9. Describe spontaneous reporting system.
10. Briefly explain about the pharmacoepidemiological outcome measurements.
11. Explain case control studies with suitable examples.

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(Model Question Paper)

CLINICAL PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING

Time: 3 hrs

Max. Marks: 70

- *Answer all questions*
- *Draw diagram wherever necessary*

Essays:

(3x10=30)

1. Explain therapeutic drug monitoring. Discuss the indications and protocol for TDM
2. Discuss the dosing of drugs in the elderly & children and in obese patients with suitable examples.
3. Explain the approaches of analysis of population pharmacokinetic data and mention applications.

Short notes

(8x5=40)

4. Bayesian theory of adaptive method
5. Dosage adjustment for uremic patients.
6. Effect of genetic polymorphism in drug transport and drug targets.
7. Genetic polymorphism.
8. TDM of drugs used in cardiac and seizure disorders.
9. Extracorporeal removal of drugs.
10. Drug interactions related to inhibition and induction of drug metabolism with one example.
11. Dosage adjustment in renal disease.
