QP Code: **Reg. No…….**

FifthYear Pharm. D Degree Examinations

(Model Question Paper)

Clinical Pharmacokinetics and Pharmacotherapeutic Drug Monitoring

Time: 3 hrsMax. Marks: 70

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

Essays **3x10=30**

1. Discuss in detail the dose adjustment in patients with renal failure.

2. Define therapeutic drug monitoring. Discuss various steps and pharmacokinetic evaluations in therapeutic drug monitoring process

3. Classify and explain pharmacokinetic drug-drug interactions with suitable examples

Short notes **8 x 5 = 40**

4. Analysis of Population pharmacokinetic data

5. Nomograms.

6. Individualization of dosage regimen with respect to age

7. What are cytochrome P-450 isoenzymes and Add a note on genetic polymorphism in drug metabolism

8. Drug dosing in 3Neonates

9. Explain the basic principles of clinical pharmacokinetics

10. Genetic polymorphism in drug transport.

11. Explain the conversion of drug dose from intravenous infusion to oral dosing.

****

QP Code: **Reg. No…….**

FifthYear Pharm. D Degree Examinations

(Model Question Paper)

Clinical Research.

Time: 3 hrs **Max. Marks: 70**

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

Essays: **3x10=30**

1List out the different phases of clinical trials. Explain Phase -1 and Phase II of clinical trials.

2. Discuss the different stages of drug development.

3. Explain the role of ICH-GCP guidelines in the conduct of clinical trials

Short notes **8x5=40**

4. Enumerate informed consent process

5. Describe the composition and responsibilities of IEC.

6. Protocol design in clinical trials

7. Describe briefly about the regulatoryenvironmentt of clinical trials in India

8. Explain the significance of nuremberg code in clinical trial

9 Explain the different methods in post marketing surveillance

10. Describe the role and responsibilities of sponsor as per ICH- GCP.

11. Explain the ANDA filing in clinical trials

****

QP Code: **Reg. No…….**

Fifth Year Pharm. D Degree Examinations

(Model Question Paper)

PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS

Time: 3 hrs **Max. Marks: 70**

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

ESSAYS **3x10=30**

1. Define DUE and explain the steps involved in DUE Mention the role of pharmacist in DUE study.
2. Explain briefly on cohort study and case control study with its merits and demerits.
3. Discuss the various methods of pharmacoeconomic evaluations with its advantages and disadvantages.

Short notes **8 x 5 = 40**

4. Pharmacoepidemiological outcome measurements.
5. Prevalence in pharmacoepidemiological study.
6. Explain odds ratio and hazards ratio.
7. Explain the meta analysis models with examples.
8. Describe the various types of costs and outcomes in pharmacoeconomic study.
9. Explain the role of pharmacoeconomics in formulary management.
10. Explain the relative risk and attributable risk in pharmacoepidemiological study.
11. Describe Spontaneous reporting system.

****