

MANIPAL UNIVERSITY**SECOND YEAR PHARM D (POST BACCALAUREATE) DEGREE EXAMINATION – MAY 2011****SUBJECT: PD 5.1: CLINICAL RESEARCH**

Monday, May 23, 2011

Time: 10:00 – 13:00 Hrs.

Max. Marks: 70

✍ Long Essay Questions:

1. Explain the designing of clinical trial protocol.
2. Define informed consent and explain the informed consent process for enrolling patients into a clinical study.
3. Discuss the features of essential documents for the conduct of a clinical trials.

(10×3 = 30 marks)

4. Short Essay Questions:

- 4A. Discuss the contents of IND application.
- 4B. Outline the procedures for acute and chronic toxicity studies.
- 4C. Discuss composition and responsibilities of independent ethics committee (IEC).
- 4D. Explain the methods of post marketing surveillance.
- 4E. What are the roles and responsibilities of Clinical Investigators in a clinical trial?
- 4F. Describe the role of sponsors in clinical trials as per ICH GCP guidelines.

(5×6 = 30 marks)

5. Short Answer Questions.

- 5A. Outline the procedure for conducting the Ame's test.
- 5B. Discuss the advantages and disadvantages of transdermal drug delivery systems.
- 5C. Outline the procedure for subacute toxicity studies.
- 5D. What are orphan drugs? Explain with examples.
- 5E. List the parameters of biological characterization of a new drug.

(2×5 = 10 marks)



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SECOND YEAR PHARM D (POST BACCALAUREATE) DEGREE EXAMINATION – MAY 2011

SUBJECT: PD 5.2: PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS

Wednesday, May 25, 2011

Time: 10:00 – 13:00 Hrs.

Max. Marks: 70

✍ **Long Essay Questions:**

1. Describe the various methods for measuring medication adherence. What are the major predictors of poor adherence to medication?
2. Explain the steps involved in establishing a drug utilization review program in a hospital setup.
3. Explain different steps involved in the development of patient-reported outcome instrument.

(10×3 = 30 marks)

4. **Short Essay Questions:**

- 4A. Define and explain the process for prescription event monitoring (PEM).
- 4B. Explain attributable risk and relative risk with suitable examples.
- 4C. Explain case control studies and case –cohort studies with suitable examples.
- 4D. Explain clinical problems and methodological problems to be addressed in risk management.
- 4E. Explain cost- benefit and cost – effectiveness analysis with suitable examples.
- 4F. Explain role and responsibility of WHO in international drug monitoring.

(5×6 = 30 marks)

5. **Short Answer Questions:**

- 5A. Enumerate the functions of ATC/DDD system.
- 5B. Explain signal strengthening and its importance in ADR reporting.
- 5C. Define meta analysis.
- 5D. Enlist various automated data base systems.
- 5E. Write a short note on PSUR.

(2×5 = 10 marks)



MANIPAL UNIVERSITY**SECOND YEAR PHARM D (POST BACCALAUREATE) DEGREE EXAMINATION – MAY 2011****SUBJECT: PD 5.3: CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTICS DRUG MONITORING**

Friday, May 27, 2011

Time: 10:00 – 13:00 Hrs.

Max. Marks: 70

Long Essay Questions:

1. Explain the indications for Therapeutic Drug Monitoring and explain TDM of digoxin, theophylline and sodium valproate.
(10 marks)
2. Explain various models for pharmacokinetic and pharmacodynamic correlation.
(10 marks)
- 3A. Explain Bayesian theory with an example.
- 3B. Explain adaptive dosing or dosing with feedback.
(5+5 = 10 marks)

4. Short Essay Questions:

- 4A. Explain the conversion of dosage regimen from Intravenous to oral administration.
- 4B. Explain the mechanisms of enzyme induction.
- 4C. Describe nomograms and their applications in designing dosage regimen.
- 4D. Explain the pharmacokinetic changes, which affect drug dosage in pediatrics.
- 4E. Explain the factors affecting dialyzability of a drug.
- 4F. Describe Nonlinear Mixed Effect Modeling of population pharmacokinetic data.
(5×6 = 30 marks)

5. Short Answer Questions.

- 5A. Mention the indications for TDM.
- 5B. Explain the formulae to calculate the loading dose and maintenance dose.
- 5C. Mention any four drugs metabolized by CYP2D6.
- 5D. Define direct link model for pharmacokinetic and pharmacodynamic correlation.
- 5E. Mention two drug interactions due to alteration of protein binding.
(2×5 = 10 marks)



MANIPAL UNIVERSITY

M. Sc. PART – I (ADVANCED PHARMACEUTICAL STUDIES)
DEGREE EXAMINATION – MAY 2011SUBJECT: ADVANCED PHARMACEUTICAL ANALYSIS (MQA 601)
(BRANCH: NEUTRACEUTICAL AND COSMECEUTICAL SCIENCES)

Tuesday, May 24, 2011

Time: 10:00 – 13:00 Hrs.

Max. Marks: 100

✍ Answer ALL the questions. Draw neatly labeled diagrams wherever necessary.

- 1A. Explain detectors used in UV-Vis spectrophotometers in brief.
1B. Explain the principle and applications of CD spectra.
1C. Explain the effect of pH and solvent on absorption spectra with suitable examples.
1D. Explain the differences between Raman and IR spectra. (5×4 = 20 marks)
- 2A. Classify and explain differential scanning calorimetry.
2B. Write a note on agar gel, starch gel, and polyacrylamide gel used in gel electrophoresis.
2C. Explain the reverse phase TLC and dual phase TLC giving their advantages.
2D. Explain the principle and procedure for the quantitative estimation using in situ densitometry. (5×4 = 20 marks)
- 3A. What are packed and capillary columns in GC? Give their comparative specifications and advantages.
3B. Explain the importance of the following parameters in chromatography with necessary equations.
i) Retention factor
ii) Number of theoretical plates
3C. Explain the construction, working and advantages of a refractive index detector for HPLC with the help of a schematic diagram.
3D. Write a short note on Supercritical fluid chromatography. (5×4 = 20 marks)
- 4A. Explain in brief the detectors used in IR spectrophotometer.
4B. Write a note on ^{13}C NMR spectroscopy and its applications in structural analysis.
4C. Explain the significance of the reference standard used in NMR spectroscopy. (10+5+5 = 20 marks)
- 5A. Explain in detail the fragmentation rules in electron impact mass spectroscopy with suitable examples.
5B. Explain with examples spin spin coupling.
5C. What are mass analysers? Explain. (10+5+5 = 20 marks)

