Reg. No.										

MANIPAL UNIVERSITY

M. PHARM. PART–I DEGREE EXAMINATION – MAY/JUNE 2010

SUBJECT: MODERN PHARMACEUTICAL ANALYSIS (PQA 601)

(SPECIALIZATION: PHARMACEUTICS / PHARMACOLOGY / PHARM. QUALITY ASSURANCE / PHARM. BIOTECHNOLOGY)

Thursday, May 27, 2010

Time: 10:00 – 13:00 Hrs. Max. Marks: 100

- **Answer ALL questions.**
- **Draw neatly labelled diagrams wherever necessary.**

1A. Define Lamberts-Beer's law and derive an expression for the same.

1B. Explain the construction and working of any two detectors used in UV Visible spectrophotometer.

1C. Discuss the factors influencing vibrational frequencies of molecules.

1D. Explain the solid sampling technique in IR spectroscopy.

(5×4 = 20 marks)

2A. Explain with suitable examples, the effect of solvent and temperature on absorption spectra.

2B. Explain the factors affecting quenching of fluorescence.

2C. Discuss the inductive effect and diamagnetic effect.

2D. Explain the steps involved in NMR data interpretation.

(5×4 = 20 marks)

3A. Write a note on size exclusion chromatography.

3B. Explain the construction and working of electrochemical detector. Explain the advantages in terms of sensitivity and specificity.

3C. Write a note on solvent selection in HPLC.

3D. Explain the meaning of split, splitless an on column injection. Explain various sample injection systems in brief.

(5×4 = 20 marks)

4A. With suitable example discuss about chemical ionization.

4B. Discuss in detail about MALDI-TOF.

4C. Discuss the principle, various methods and applications of capillary electrophoresis.

(5+5+10 = 20 marks)

5A. Write a note on triple quadrupole mass analyzer.

5B. Discuss the applications of ELISA and RIA.

5C. Compare HPTLC and TLC.

5D. Explain derivative spectroscopy with suitable examples.

(5×4 = 20 marks)

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MANIPAL UNIVERSITY

M. PHARM. PART–I DEGREE EXAMINATION – MAY/JUNE 2010

SUBJECT: QUALITY ASSURANCE AND MANAGEMENT (PQA 602)

(SPECIALIZATION: PHARMACEUTICAL QUALITY ASSURANCE)

Friday, May 28, 2010

Time: 10:00 – 13:00 Hrs. Max. Marks: 100

✍ **Answer ALL questions.**

1A. What is ISO 9000 and 14000? Explain in detail.

1B. Write in brief personnel training and hygiene for the pharmaceutical industry.

(15+5 = 20 marks)

2A. Explain in detail about master formula record and batch manufacturing record.

2B. Define labeling. Explain label issuance and line clearance in brief.

2C. Write a note on good warehouse practice.

(10+5+5 = 20 marks)

3A. Explain the term distribution and distribution record.

3B. Define product recall. Explain in detail about product recall classification and strategies of the same.

3C. Write in detail about the waste disposal procedure and records.

(5+10+5 = 20 marks)

4A. Write in detail about Statistic Quality Control Charts.

4B. Define 't' test. Enlist the situations in which the unpaired and paired 't' test are applied.

4C. Write a short note on equipment design qualification.

(10+5+5 = 20 marks)

5A. Explain the validation of moist heat sterilizer.

5B. Explain in detail about construction and working of HVAC system.

(10+10 = 20 marks)

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MANIPAL UNIVERSITY

M. PHARM. PART–I DEGREE EXAMINATION – MAY/JUNE 2010

SUBJECT: BIOPHARMACEUTICS AND PHARMACOKINETICS (PCE 602)

(SPECIALIZATION: PHARMACEUTICS/ PHARM. QUALITY ASSURANCE)

Saturday, May 29, 2010

Time: 10:00 – 13:00 Hrs. Max. Marks: 100

✍ **Answer ALL questions.**

1A. Discuss the biological factors affecting drug absorption.

1B. Explain carrier mediated and pore transport mechanisms of drug absorption.

(10+10 = 20 marks)

2A. Mention the methods to measure bioavailability of a drug and explain invitro dissolution testing.

2B. Give the elements of a typical protocol in the bioequivalence study.

(10+10 = 20 marks)

3A. Explain the pharmacokinetics of a drug given intravenously as a bolus dose and give equations for calculating relevant pharmacokinetic parameters. (Assume one compartment model).

3B. An I.V. bolus administration of 100 mg of a drug gave AUC as 67.43 mcg.hr Ml^{-1} and AUMC as 553.21 $mcg.hr^2$ ml^{-1}. Calculate the mean residence time, elimination rate constant, clearance and volume of distribution.

(12+8 = 20 marks)

4A. Explain the tissue permeability and perfusion rate limited distribution of drug.

4B. Explain the steps in the cytochrome P-450 oxidation and glutathione conjugation reactions.

(12+8 = 20 marks)

5A. Explain the role of drug p^{Ka} and Urine p^{H} in the reabsorption of drugs.

5B. Explain biliary excretion of drugs.

5C. Define dose dependent Kinetics. Write simple tests to detect nonlinearity in a rate process.

5D. Write the advantages and disadvantages of compartment modeling.

(5+5+4+6 = 20 marks)

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MANIPAL UNIVERSITY

M. PHARM. PART–I DEGREE EXAMINATION – MAY/JUNE 2010

SUBJECT: REGULATORY AFFAIRS (PQA 603)

(SPECIALIZATION: PHARMACEUTICAL QUALITY ASSURANCE)

Monday, May 31, 2010

Time: 10:00 – 13:00 Hrs. Max. Marks: 100

Answer ALL questions.

1A. Discuss the salient features of ICH-GCP guidelines.

1B. Discuss the FDA guideline for drug master file.

(10+10 = 20 marks)

2A. Discuss the principles of toxicokinetic studies.

2B. Discuss in detail about types of patents.

(10+10 = 20 marks)

3A. Write note on trade related aspects of intellectual property rights.

3B. Discuss biowaviers in BA/BE studies in detail.

(10+10 = 20 marks)

4A. Discuss the dissolution profile comparison.

4B. What are the general principles of chronic toxicity studies?

4C. Discuss the decision tree for identification and quantification of impurities in new drug substances.

(5+5+10 = 20 marks)

5A. Write about Drug substance permeability class.

5B. Write a note on SUPAC-IR guideline with regard to changes in batch size.

5C. Discuss the EUDRA guidelines about the pharmacokinetic studies in the safety evaluation of new medicinal products in animals.

(5+5+10 = 20 marks)

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M. PHARM. PART–I DEGREE EXAMINATION – MAY/JUNE 2010

SUBJECT: PHARMACEUTICAL ANALYSIS & PRODUCT DEVELOPMENT (PQA 604)

(SPECIALIZATION: PHARMACEUTICAL QUALITY ASSURANCE)

Tuesday, June 01, 2010

Time: 10:00 – 13:00 Hrs. Max. Marks: 100

Answer ALL questions.

1A. What is polarography? Explain the different types of polarography.

1B. Discuss about different methods of drug extraction from plasma.

(10+10 = 20 marks)

2A. Explain in detail "one level assay with standard curve" for microbial assay of antibiotics.

2B. Describe the principle and applications of gel electrophoresis.

(10+10 = 20 marks)

3A. Explain the techniques of fingerprinting.

3B. Discuss the principle and procedure involved in the determination of:

i) Optical rotation

ii) Clarity and Color of solution

(10+5+5 = 20 marks)

4A. Describe the evaluation of plastic containers.

4B. Explain various levels of IVIVC, and how a correlation can be achieved. What is the relevance of dissolution testing and IVIVC?

(10+10 = 20 marks)

5A. Describe the various methods of determination of partition coefficient.

5B. Discuss in detail about accelerated stability studies.

(10+10 = 20 marks)