Reg. No.										

MANIPAL UNIVERSITY

M. PHARM. PART–I DEGREE EXAMINATION – MAY/JUNE 2014

SUBJECT: ADVANCED PHARMACEUTICS (PCE 601)

(SPECIALIZATION: PHARMACEUTICS)

Monday, May 26, 2014

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

Answer ALL the questions.

1A. Write a note on microemulsions and characterization of disperse systems.

1B. Classify osmotic pumps. Explain any THREE with the help of diagram.

(10+10 = 20 marks)

2A. Write short notes on copyright and trademarks.

2B. Describe various out of specifications and investigations in pharmaceutical formulations.

(10+10 = 20 marks)

3A. Write a note on reverse supply chain. Discuss the distribution channel in pharmaceutical sector.

3B. Explain four quality control tests for parenterals.

(10+10 = 20 marks)

4A. Explain the preparation of ophthalmic ointment and eye drops.

4B. Describe the recent technologies in implants and infusion devices.

(10+10 = 20 marks)

5A. Explain the cleaning, filling and inspection steps for liquid orals packaging.

5B. Explain RFID and Bar coding system.

(10+10 = 20 marks)

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MANIPAL UNIVERSITY

M. PHARM. PART–I DEGREE EXAMINATION – MAY/JUNE 2014

SUBJECT: BIOPHARMACEUTICS AND PHARMACOKINETICS (PCE 602)

(SPECIALIZATION: PHARMACEUTICS/ INDUSTRIAL PHARMACY/ PHARM. QUALITY ASSURANCE)

Wednesday, May 28, 2014

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

Answer ALL the questions.

1A. Define therapeutic drug monitoring. Explain its objectives, target strategies and basic guidelines.

1B. What is scatchard plot? Give a labelled plot with a suitable example. Write its significance.

1C. Explain the influence of drug-protein binding in diseased state.

(10+5+5 = 20 marks)

2A. What are the advantages and disadvantages of a zero-order rate for drug absorption?

2B. Discuss the formulation factors that are important in drug product design.

2C. Explain the role of pKa on the drug absorption in GIT with relevant equations.

(5+10+5 = 20 marks)

3A. What is meant by feathering of blood level data? How will the individual rate constants in two compartment open model be obtained? Explain

3B. An antibiotic is to be given by IV infusion. The half life of this drug is 7 hours and Vd is 15 litres. The pharmacokinetics of this drug assumes first order process. The desired steady state plasma level for this antibiotic is 10μg/mL.

i) What is the infusion rate for this drug?

ii) Assuming no loading dose, how long after the start of the IV infusion would it take to reach 95% of the Css?

iii) What is the loading dose for this antibiotic?

3C. Explain the terms:

i) Lag time ii) Flip Flop of Ka and K

(10+5+5 = 20 marks)

4A. Explain how the rate of drug elimination may change from first order elimination to zero order elimination and the clinical implications of this occurrence.

4B. What is the Michaelis-Menten equation? How are Vmax and Km obtained? (any two methods).

4C. Describe the concept of drug accumulation in multiple dosing.

(10+5+5 = 20 marks)

5A. What do MRT, MAT and MDT indicate in noncompartment modelling? How are they obtained? How is MRT related to $t_{1/2}$?

5B. What is meant by Reference listed drug? Explain

5C. Define the term pharmacokinetic–Pharmacodynamics model and provide an equation that quantitatively simulates the time course of drug action.

5D. Briefly discuss the cross over study designs in bioequivalence testing.

(5+5+5+5 = 20 marks)

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MANIPAL UNIVERSITY

M. PHARM. PART–I DEGREE EXAMINATION – MAY/JUNE 2014

SUBJECT: ADVANCES IN DRUG DELIVERY SYSTEMS (PCE 603)

(SPECIALIZATION: PHARMACEUTICS/ INDUSTRIAL PHARMACY)

Friday, May 30, 2014

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

Answer ALL the questions.

1A. Mention different methods of microencapsulation and explain any ONE method in detail.

1B. Add a short note on feedback regulated drug delivery systems.

(10+10 = 20 marks)

2A. Explain matrix tablets and ion-exchange resin based oral controlled drug delivery systems.

2B. Discuss important approaches for delivery of peptide and protein drugs.

(10+10 = 20 marks)

3A. What are different ocular controlled drug delivery systems? Explain any TWO systems in detail.

3B. Explain various transdermal drug delivery systems.

(10+10 = 20 marks)

4A. Write a note on hormone releasing IUDs.

4B. Mention different methods of preparation of liposomes and explain any two methods.

(10+10 = 20 marks)

5A. Explain different buccal drug delivery systems.

5B. Write a note nasal drug delivery systems.

(10+10 = 20 marks)

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MANIPAL UNIVERSITY

M. PHARM. PART–I DEGREE EXAMINATION – MAY/JUNE 2014

SUBJECT: PHARMACEUTICAL PRODUCT DEVELOPMENT (PCE 604)

(SPECIALIZATION: PHARMACEUTICS/ INDUSTRIAL PHARMACY)

Monday, June 02, 2014

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

✍ **Answer ALL the questions.**

1A. In the generic product development of solid oral dosage form what is the importance of analytical methods development and methods validation?

1B. With suitable graphical representation explain simplex method of optimization technique.

(10+10 = 20 marks)

2A. In the generic product development of solid oral dosage form what is the importance of analytical methods development and methods validation?

2B. Discuss hydrotropy & dielectric constant modification approaches to enhance the solubility of drugs.

(10+10 = 20 marks)

3A. Explain the various random sampling procedures.

3B. Discuss hydrolysis & oxidation pathways of degradation of drugs.

(10+10 = 20 marks)

4A. What are the general storage conditions recommended by ICH for drug products for various studies?

4B. Write a short note on DSC.

4C. Explain the effect of solubility and surfactant on the dissolution of drug.

4D. Find the Karl Pearson's coefficient of correlation between the drug concentration and absorbance from the following data:

Drug Concentration	0	1	2	3	4	5	6
Absorbance	0	0.099	0.198	0.299	0.402	0.495	0.606

4E. Write Noyes-Whitney and Hixson-Crowell cube root equations.

(5+5+4+4+2 = 20 marks)

5A. What is projected diameter? Explain optical microscopy for the determination of particles size.

5B. How the dissolution data can be computed to find zero-order and first-order kinetics of the pharmaceutical dosage forms? Write the applications of zero-order and first-order kinetics.

5C. Give the limitations of sedimentation method used for particle size determination.

5D. Write the short note on polymorphism.

5E. Why the tablet takes more time for dissolution in comparison of powder?

(6+6+3+3+2 = 20 marks)

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MANIPAL UNIVERSITY

M. PHARM. PART–I DEGREE EXAMINATION – MAY/JUNE 2014

SUBJECT: ADVANCED INDUSTRIAL PHARMACY (PIP 601)
(SPECIALIZATION: INDUSTRIAL PHARMACY)

Monday, May 26, 2014

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

Answer ALL questions.

1A. Mention any EIGHT factors affecting site selection for pharmaceutical Industry and explain the advantages and disadvantages of URBAN SITES for pharmaceutical industry.

1B. Explain pilot plant scale up technique in pharmaceutical industry.

(10+10 = 20 marks)

2A. Explain vendor development procedure in pharmaceutical industry.

2B. Explain mechanical hazards and its prevention in pharmaceutical industry.

(10+10 = 20 marks)

3A. Define plant layout and explain plant layout procedure with respect to pharmaceutical plant.

3B. Define Design Qualification (DQ). With the help of suitable example, discuss DQ in detail.

(10+(1+9) = 20 marks)

4A. Identify important critical process parameters and explain its control during manufacturing of Tablets by wet granulation method.

4B. What is ICH? Mention any EIGHT quality guidelines as per ICH. Explain ICH stability guidelines in detail.

(10+(1+4+5) = 20 marks)

5A. What is the importance of training and development for new recruits? Explain types of training as per current industry standards.

5B. What is a market complaint? Mention various types with examples. Explain investigation procedure in detail.

((3+7)+(1+2+7) = 20 marks)