Reg. No.										

MANIPAL UNIVERSITY

FIRST YEAR M. PHARM. DEGREE EXAMINATION – MAY 2015

SUBJECT: ADVANCED PHARMACEUTICS (PCE 601T)

(SPECIALIZATION: PHARMACEUTICS)

(2014 REGULATION)

Wednesday, May 20, 2015

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

✍ **Answer ALL questions**

1. Classify osmotically controlled systems. Explain any TWO with neat labelled diagram. (10 marks)

2. Explain the various approaches implemented in development of low dose solid oral drug products to ensure safety and efficacy. (10 marks)

3. Discuss the Patent Filing system and Priority date in pharmaceutical sector. (10 marks)

4. Explain any three novel drug delivery technologies for parenterals. (10 marks)

5. Explain the manufacturing of emulsions. (10 marks)

6. Explain Microencapsulation. (10 marks)

7. Define capsules. Explain the formulation of hard gelatin capsules. (10 marks)

8. Define ophthalmic preparation and explain the formulation of eye drops and eye ointment. (10 marks)

9. **Write short notes:**

9A. Hydrocarbon Bases
9B. Ampoule filling

(5+5 = 10 marks)

10. **Write briefly on the following:**

10A. New Ophthalmic Delivery System (NODS)
10B. Evaluatory tests for plastics

(5+5 = 10 marks)

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FIRST YEAR M. PHARM. DEGREE EXAMINATION – MAY 2015

SUBJECT: ADVANCED INDUSTRIAL PHARMACY (PIP 601T)

(SPECIALIZATION: INDUSTRIAL PHARMACY)

(2014 REGULATION)

Wednesday, May 20, 2015

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

✍ **Answer ALL questions.**

1. Mention and discuss on different types of site for pharmaceutical industry.

(10 marks)

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

(10 marks)

3. Describe pilot plant scale up study with respect to tablet dosage form

(10 marks)

4. Mention different methods of Inventory control and explain any one method in detail.

(10 marks)

5. Describe the importance of proper storage and various product specific storage requirements as per regulations.

(10 marks)

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

(10 marks)

7. Discuss on causes and prevention of chemical hazards in pharmaceutical industry.

(10 marks)

8. Explain the concept of on the job training with its importance. Discuss training, training evaluation and re-training.

(10 marks)

9. **Write Short Notes:**

9A. Installation Qualification (IQ).

9B. Manufacturing procedures.

(5 marks × 2 = 10 marks)

10. **Write briefly on the following**

10A. Concurrent Process validation

10B. Any two factors to be considered in selecting a good vendor.

(5 marks × 2 = 10 marks)

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MANIPAL UNIVERSITY

FIRST YEAR M. PHARM. DEGREE EXAMINATION – MAY 2015

SUBJECT: BIOPHARMACEUTICS AND PHARMACOKINETICS (PCE 602T)

(SPECIALIZATION: PHARMACEUTICS/ INDUSTRIAL PHARMACY/ PHARM. QUALITY ASSURANCE)
(2014 REGULATION)

Friday, May 22, 2015

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

✍ **Answer ALL the questions.**

1. Explain the three compartment open model for intravenous bolus administration of drug with the required equations and graphs.

(10 marks)

2. Using various graphical methods explain the kinetics of protein binding of drugs.

(10 marks)

3. Discuss any two alternative methods of dissolution testing.

(10 marks)

4. Write a note on the various functions of clinical pharmacokinetic services.

(10 marks)

5. Explain the determination of renal clearance and discuss its relationship to biological half-life and volume of distribution.

(10 marks)

6. What are the drawbacks of Wagner Nelson method to compute Ka?
The plasma profile of a 300 mg dose of a drug is described by the equation $C = 42.7e^{-0.03t} - 42.7e^{-0.15t}$. Calculate t_{max}, C_{max} and the concentration of the drug in plasma at t= 4 hours

(10 marks)

7. Explain the concept of drug accumulation on repetitive i.v dosing.

(10 marks)

8. Describe the characteristics of Nonlinear pharmacokinetics. Explain any two methods to obtain K_m and V_{max}

(10 marks)

9. **Write short notes on:**

9A. Flip flop kinetics

9B. Criteria for obtaining a waiver for in vivo BE studies.

(5+5 = 10 marks)

10. **Write briefly on the following:**

10A. Comparison of Sigma minus and Excretion rate method for calculating excretion rate constant

10B. Evaluation of pharmacokinetic parameters from non-compartment model

(5+5 = 10 marks)

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MANIPAL UNIVERSITY

FIRST YEAR M. PHARM. DEGREE EXAMINATION – MAY 2015

SUBJECT: ADVANCES IN DRUG DELIVERY SYSTEMS (PCE 603T)

(SPECIALIZATION: PHARMACEUTICS / INDUSTRIAL PHARMACY)

(2014 REGULATION)

Monday, May 25, 2015

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

Answer ALL questions.

1. Enlist different system parameters useful in controlled release drug delivery and explain any TWO parameters.

(10 marks)

2. Explain the principle and composition of matrix tablets in detail.

(10 marks)

3. Discuss different pathways for nasal absorption of drugs.

(10 marks)

4. Explain different theories of transmucosal penetration of drug molecules.

(10 marks)

5. Classify injectable controlled release formulations and explain any two of them.

(10 marks)

6. Briefly explain different components of Transdermal drug delivery systems.

(10 marks)

7. Mention different methods of preparation of microspheres and explain two important methods in detail.

(10 marks)

8. What is the rationale for developing enteric coated tablets? Explain the principle and composition of these tablets.

(10 marks)

9. **Write short notes:**

9A. Classification of polymers with examples
9B. Two approaches for the delivery of peptide and protein drugs

(5+5 = 10 marks)

10. **Write briefly on the following:**

10A. Ocuserts
10B. Drug targeting approaches in cancer therapy

(5+5 = 10 marks)

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FIRST YEAR M. PHARM. DEGREE EXAMINATION – MAY 2015

SUBJECT: PHARMACEUTICAL PRODUCT DEVELOPMENT (PCE 604T)

(SPECIALIZATION: PHARMACEUTICS/ INDUSTRIAL PHARMACY)

(2014 REGULATION)

Wednesday, May 27, 2015

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

Answer ALL the questions.

1. Discuss on pre-formulation study of derived properties in the development of solid dosage form. (10 marks)

2. How selection of excipients becomes important in tablet dosage forms? Explain. (10 marks)

3. Explain two methods for the determination of solubility of drugs. (10 marks)

4. How in vivo bioequivalence assessment of generic product is performed when it is developed? Explain. (10 marks)

5. Explain reciprocating cylinder and flow through cell apparatus for dissolution of drugs. (10 marks)

6. Explain any five methods by which physical degradation of pharmaceutical products is possible. Suggest the preventive methods for the same. (5+5 = 10 marks)

7. Explain in brief the parametric and non-parametric tests. (10 marks)

8. Discuss on Lagrangian method of optimization. (10 marks)

9. **Write short notes on:**

9A. The Glass-Transition temperature in DSC curve

9B. Drug stability studies for generic product development (5+5 = 10 marks)

10. **Write briefly on the following:**

10A. Oxidative decomposition of drugs

10B. Importance of experimental design (5+5 = 10 marks)

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FIRST YEAR M. PHARM. DEGREE EXAMINATION – JULY 2015

SUBJECT: MODERN PHARMACEUTICAL ANALYSIS (PQA 601T)

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

(2014 REGULATION)

Monday, July 20, 2015

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

1. Write the qualitative and quantitative applications of double beam UV/Visible spectroscopy with examples in brief.

(10 marks)

2A. Explain the principle and advantages of FT-IR spectrometer.

2B. List the applications of LASER and Raman spectroscopy.

(5+5 = 10 marks)

3A. Explain the application of signal splitting in interpretation of PMR spectrum with suitable example.

3B. How the electronegativity influences the chemical shift value of CH_3 Protons? Explain.

(5+5 = 10 marks)

4. Discuss the soft ionization techniques in mass spectroscopy.

(10 marks)

5A. Explain the importance of separation techniques in pharmaceutical sciences and medicine. List the important separation techniques.

5B. Write and explain the terms in van-Deemter equation and discuss how band broadening is explained.

(5+5 = 10 marks)

6A. Discuss on the sample injection systems used in GC.

6B. Explain the construction and working of thermal conductivity detector and list any two advantages and disadvantages.

(5+5 = 10 marks)

7A. Differentiate between analytical column and preparative column and classify the stationary phases used in HPLC.

7B. Explain the principle, process and applications of supercritical fluid chromatography.

(5+5 = 10 marks)

8. Explain the principle, instrumentation and applications of capillary zone electrophoresis.

(10 marks)

9. **Write short notes on:**

9A. Detection techniques in HPTLC

9B. Structural features essential for a molecule to exhibit the fluorescence

(5 marks × 2 = 10 marks)

10. **Write briefly on the following:**

10A. Principle and applications of ELISA

10B. Advantages and disadvantages of GC- MS

(5 marks × 2 = 10 marks)

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MANIPAL UNIVERSITY

FIRST YEAR M. PHARM. DEGREE EXAMINATION – JULY 2015

SUBJECT: BIOPHARMACEUTICS AND PHARMACOKINETICS (PCE 602T)

(SPECIALIZATION: PHARMACEUTICS/ INDUSTRIAL PHARMACY/ PHARM. QUALITY ASSURANCE)
(2014 REGULATION)

Friday, July 24, 2015

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

✍ **Answer ALL the questions.**

1. Explain the kinetics of protein binding. (10 marks)

2. Discuss the various types of volumes of distribution in two compartment open model. (10 marks)

3. Explain the various clearance models. (10 marks)

4. Describe rotating basket and paddle methods for dissolution. (10 marks)

5. Discuss the various functions of therapeutic drug monitoring services. (10 marks)

6. Describe the Wagner-Nelson method to calculate fraction of drug absorbed. (10 marks)

7. What is the Michaelis-Menten equation? How are V_{max} and K_m obtained? (any two methods). What are the potential reasons for unsuspected nonlinearity? (10 marks)

8. Write about the elements of a Bioavailability Study protocol. (10 marks)

9. **Write short notes on:**

9A. Time dependent pharmacokinetics
9B. Phase II acetylation and sulfation biotransformation reactions (5 marks × 2 = 10 marks)

10. **Write briefly on the following:**

10A. The term pharmacokinetic – pharmacodynamic model and explain E_{max} Model
10B. Criteria for obtaining a waiver for in vivo BE studies (5 marks × 2 = 10 marks)