

**MANIPAL UNIVERSITY**

**FIRST YEAR M. PHARM. DEGREE EXAMINATION - JULY 2017**  
**SUBJECT: MODERN PHARMACEUTICAL ANALYSIS (PQA 601T)**  
**(SPECIALIZATION: PHARMACEUTICS/INDUSTRIAL PHARMACY/PHARM. QUALITY**  
**ASSURANCE/PHARM. BIOTECHNOLOGY)**  
**(2014 REGULATIONS)**  
**Monday, July 17, 2017 (10.00 - 13.00 Hrs.)**

**Marks: 100****Duration: 180 mins.****Answer ALL the questions:**

- 1A) Explain the effect of solvent and crossed conjugation on absorption spectra with example. (5)
- 1B) Explain the Woodward-Fieser rules for Dienes. (5)
- 2A) Explain the instrumentation of Raman spectroscopy. (5)
- 2B) Why the vibrational frequency of C=O shifts from its normal value in IR spectrum? Explain. (5)
- 3A) What is the scope of 'decoupling methods' in  $^{13}\text{C}$  NMR spectroscopy? Explain. (5)
- 3B) Explain the causes for deshielding of aldehyde protons in  $^1\text{H}$  NMR spectroscopy. (5)
- 4A) Explain the gas phase ionization techniques in mass spectroscopy and their applications. (7)
- 4B) What are M+1 ion peak, M+2 ion peak and metastable ion? (3)
- 5A) Explain any four mechanisms responsible for separation in chromatography. (5)
- 5B) Explain the variables that affects the column efficiency in a chromatographic separation. (5)
- 6A) Explain the columns and stationary phases in GC. (5)
- 6B) Explain the working of Electron capture detector. (5)
- 7A) Explain the theory and instrumentation of HPLC. (5)
- 7B) Explain the theory, process and applications of Ion-exchange HPLC. (5)
- 8) Explain the principle and applications of micellar electrokinetic chromatography in brief. (10)

**Write short notes:**

- 9A) Detection techniques in HPTLC. (5)
- 9B) Applications of Hyphenated techniques. (5)

**Write briefly on the following:**

- 10A) Merits and demerits of phosphorimetry over fluorimetry. (5)

10B)

Principle and experimental requirements for ELISA.

(5)

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## MANIPAL UNIVERSITY

FIRST YEAR M. PHARM. DEGREE EXAMINATION - JULY 2017  
SUBJECT: ADVANCED INDUSTRIAL PHARMACY (PIP 601T)  
(SPECIALIZATION: INDUSTRIAL PHARMACY)  
(2014 REGULATION)

Wednesday, July 19, 2017 (10.00 - 13.00 Hrs.)

Marks: 100

Duration: 180 mins.

**Answer ALL the questions:**

- 1) Mention and discuss on different types of site for pharmaceutical industry. (10)
- 2) Discuss Installation Qualification and Operational qualification of an HVAC system. (10)
- 3) Explain process validation with respect to tablet dosage form. (10)
- 4) Explain any two methods of inventory control. (10)
- 5) What is a deviation? Explain the procedure for handling planned deviations. (10)
- 6) Define stability study? What is a significant change? Explain the stability study at various conditions. (10)
- 7) Discuss on 'Preventive maintenance' in pharmaceutical industry. (10)
- 8) Explain importance of training and development as per schedule M. Give the procedure in brief. (10)

**9. Write short notes:**

- 9A) User Requirement Specification (URS). (5)
- 9B) Critical Process parameters in dry granulation. (5)

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

- 10A) Preparation of Master manufacturing procedures in scale up stage. (5)
- 10B) Different types of store houses in pharmaceutical industry. (5)



## MANIPAL UNIVERSITY

FIRST YEAR M. PHARM. DEGREE EXAMINATION - JULY 2017  
SUBJECT: BIOPHARMACEUTICS AND PHARMACOKINETICS (PCE 602T)  
(SPECIALIZATION: PHARMACEUTICS / INDUSTRIAL PHARMACY / PHARM. QUALITY  
ASSURANCE)

(2014 REGULATION)

Friday, July 21, 2017 (10.00 - 13.00 Hrs.)

Marks: 100

Duration: 180 mins.

**Answer ALL the questions:**

- 1) Explain the pharmacokinetics of a drug following two compartment open model when administered as an IV bolus. (10)
- 2) Explain the application of the sigma - minus method to determine the pharmacokinetics of drugs in urine administered by IV bolus assuming that it follows one compartment open model. (10)
- 3) Explain the determination of absorption rate constant of drug in blood by the method of residuals when administered by extravascular route assuming that it follows one compartment open model. (10)
- 4) Explain with examples the applications of pharmacokinetics on therapeutic drug monitoring. (10)
- 5) Discuss the evaluation of in vivo bioavailability data for modified release drug products. (10)
- 6) Describe the phase-1 oxidative reactions in biotransformation of drugs with examples. (10)
- 7) How pharmacokinetics and pharmacodynamics can be related? Explain (10)
- 8) How  $V_{max}$  and  $K_m$  are determined? Discuss at least two methods. (10)

**9. Write short notes:**

- 9A) Time-dependent pharmacokinetics. (5)
- 9B) Drug accumulation index 'R'. (5)

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

- 10A) Solubility and permeability criteria as per the BCS. (5)
- 10B) Importance of  $K_a$  and  $T_{max}$  and AUC in Bioavailability. (5)



## MANIPAL UNIVERSITY

**FIRST YEAR M. PHARM. DEGREE EXAMINATION - JULY 2017**  
**SUBJECT: ADVANCES IN DRUG DELIVERY SYSTEMS (PCE 603T)**  
**(SPECIALIZATION: PHARMACEUTICS / INDUSTRIAL PHARMACY)**  
**(2014 REGULATION)**  
**(Monday, July 24, 2017 (10.00 - 13.00 Hrs.))**

**Marks: 100**

**Duration: 180 mins.**

**Answer ALL the questions.**

- 1) Briefly discuss different factors influencing the design of sustained release dosage forms. (10)
- 2) Write the principle, composition and general methods of preparation of matrix tablets. (10)
- 3) Mention different systems used in buccal muco-adhesive drug delivery and explain any TWO systems in detail. (10)
- 4) Discuss the evaluation aspects of liposomes in detail. (10)
- 5) Mention different evaluation tests for pulmonary drug delivery systems and explain any TWO important tests. (10)
- 6) Explain the principle, composition and evaluation aspects of effervescence based gastro-retentive systems. (10)
- 7) Give a detailed note on IUDs. (10)
- 8) What are different ADVANCED transdermal drug delivery techniques? Give a brief account on any TWO techniques. (10)

**9. Write short notes:**

- 9A) Approaches (Any TWO) to deliver protein/ peptide based drugs. (5)
- 9B) Applications of polymers in drug delivery. (5)

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

- 10A) Advantages and disadvantages of nanocarriers. (5)
- 10B) Ocuserts. (5)



## MANIPAL UNIVERSITY

FIRST YEAR M. PHARM. DEGREE EXAMINATION - JULY 2017  
SUBJECT: PHARMACEUTICAL PRODUCT DEVELOPMENT (PCE 604T)  
(SPECIALIZATION: PHARMACEUTICS / INDUSTRIAL PHARMACY)  
(2014 REGULATION)

Wednesday, July 26, 2017 (10.00 - 13.00 Hrs.)

Marks: 100

Duration: 180 mins.

**Answer all the questions.**

- 1) Explain any FIVE applications of DSC with suitable examples. (10)
- 2) Write briefly about GRAS and Inactive Ingredient Database. Explain any THREE factors affecting selection of pharmaceutical excipients. (10)  
(4+6 = 10 marks)
- 3) Discuss the effect of prodrug and pharmaceutical salts on the solubility enhancement of drugs. (10)  
(5+5 = 10 marks)
- 4) Explain the role of QbD in generic drug development. Discuss QbD cycle. (10)  
(3+7 = 10 marks)
- 5) Enlist the official dissolution apparatus as per USP. Explain any two apparatus in detail. (10)  
(2+8 = 10 marks)
- 6) Discuss in brief the ICH Q1A guidelines. (10)
- 7) Explain the concept of hypothesis testing and types of errors with suitable examples. (10)  
(5+5 = 10 marks)
- 8) Describe the objectives of Response Surface Methodology (RSM) and experimental designs in RSM. (10)  
(3+7 = 10 marks)

**9. Write short notes:**

- 9A) Particle morphology study of drug substance in preformulation. (5)
- 9B) Process Validation. (5)

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

- 10A) Oxidative degradation of drugs. (5)
- 10B) Simplex method of optimization. (5)