



MANIPAL UNIVERSITY

FIRST YEAR M. PHARM. DEGREE EXAMINATION - MAY 2017
SUBJECT: ADVANCED PHARMACEUTICS (PCE 601T)
(SPECIALIZATION: PHARMACEUTICS)
(2014 REGULATION)
Saturday, May 20, 2017 (10.00 - 13.00 Hrs.)

Marks: 100

Duration: 180 mins.

Answer ALL the questions.

- 1) Explain the decision tree (with flow chart) for selection of most appropriate manufacturing platform according to dose for formulation of low dose drugs. (10)
- 2) Define Intellectual Property Rights. Explain in detail about the criteria for patentability. (10)
- 3) What is Product Recall? Explain with a case study. Discuss the various types of Recall and reasons for the same. (10)
- 4) Discuss methods of manufacturing ointments on a small scale as well as large scale. (10)
- 5) Explain the various types of water treatment processes. (10)
- 6) Explain four quality control tests for parenterals. (10)
- 7) Explain the various methods used for the preparation of microcapsules. (10)
- 8) Mention the packaging accessories and explain any three. (10)

Write short notes:

- 9A) Bar coding. (5)
- 9B) Co-Processed excipients. (5)

Write briefly on the following:

- 10A) Factors affecting material flow. (5)
- 10B) Characteristics of ideal Warehouses. (5)



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FIRST YEAR M. PHARM. DEGREE EXAMINATION - MAY 2017
SUBJECT: BIOPHARMACEUTICS AND PHARMACOKINETICS (PCE 602T)
(SPECIALIZATION: PHARMACEUTICS/INDUSTRIAL PHARMACY/PHARM. QUALITY ASSURANCE)
(2014 REGULATION)
Tuesday, May 23, 2017 (10.00 - 13.00 Hrs.)

Marks: 100

Duration: 180 mins.

Answer ALL the questions.

- 1) Using the method of residuals, determine the absorption rate constant of drug in blood when administered by extravascular route assuming that it follows one compartment open model. (10)
- 2) Explain the determination of biological half-life and clearance for a drug in blood when administered as IV bolus assuming that it follows one compartment open model. (10)
- 3) Using Michaelis-Menton equation, explain the non-linear pharmacokinetics of drug when administered as IV bolus assuming that it follows one compartment open model. (10)
- 4) Discuss the applications of Pharmacokinetics in Therapeutic Drug Monitoring and Dosage form design. (10)
- 5) Discuss on protein binding of drugs and its clinical significance. Give examples. (10)
- 6) What are the objectives of Bioavailability studies? How the BA BE studies are established? (10)
- 7) Discuss on Hepatic clearance of drugs? (10)
- 8) What is apparent volume of distribution? What is its significance? How it can be determined? Support your answers with suitable equations and graphs. (10)

Write short notes:

- 9A) Compartmental modelling of drugs. (5)
- 9B) Renal clearance determination. (5)

Write briefly on the following:

- 10A) Effect of Food on drug absorption. (5)
- 10B) Determination of AUC. (5)



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FIRST YEAR M. PHARM. DEGREE EXAMINATION - MAY 2017
SUBJECT: ADVANCES IN DRUG DELIVERY SYSTEMS (PCE 603T)
(SPECIALIZATION: PHARMACEUTICS / INDUSTRIAL PHARMACY)
(2014 REGULATION)

Thursday, May 25, 2017 (10.00 - 13.00 Hrs.)

Marks: 100

Duration: 180 mins.

Answer ALL the questions.

- 1) Explain different approaches to improve oral bioavailability of drugs in brief. (10)
- 2) What are different microencapsulation methods? Explain any ONE important method in detail. (10)
- 3) Classify injectable controlled release formulations and explain any THREE formulations. (10)
- 4) What are different types of pulmonary drug delivery systems? Explain any TWO important systems. (10)
- 5) Discuss the evaluation aspects of transdermal drug delivery systems. (10)
- 6) Discuss the theories of muco-adhesion in detail. (10)
- 7) Define microspheres. Mention different methods of preparation of microspheres and explain any TWO methods. (10)
- 8) Discuss the composition and principle of (i) expansive and (ii) effervescence based gastro-retentive dosage forms. (10)

Write short notes:

- 9A) Ocular drug delivery device. (Any one type) (5)
- 9B) Define and classify polymers with examples. (5)

Write briefly on the following:

- 10A) Any TWO approaches to deliver vaccine based formulations. (5)
- 10B) Definition and classification of liposomes. (5)



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FIRST YEAR M. PHARM. DEGREE EXAMINATION - MAY 2017
SUBJECT: PHARMACEUTICAL PRODUCT DEVELOPMENT (PCE 604T)
(SPECIALIZATION: PHARMACEUTICS / INDUSTRIAL PHARMACY)
(2014 REGULATION)
Saturday, May 27, 2017 (10.00 - 13.00 Hrs.)

Marks: 100

Duration: 180 mins.

Answer ALL the questions.

- 1) Explain the preliminary preformulation and molecular optimization with respect to stability of drug substance. (10)
- 2) Explain the importance of developing new pharmaceutical excipient and write a note on direct compression excipients. (6+4 = 10 marks) (10)
- 3) Discuss in detail the factors affecting solubility of drugs. (10)
- 4) Explain generic drug review process with the help of flowchart and write briefly about Hatch-Waxman Act. (6+4 = 10 marks) (10)
- 5) Explain in detail the dissolution apparatus as per IP. (10)
- 6) Enlist the chemical degradation pathways. Describe any two pathways with examples. (10)
- 7) Explain graphical representation of data and measures of central tendencies. (5+5 = 10 marks) (10)
- 8) Explain various stages in optimization methodology. (10)

Write short notes:

- 9A) Principle and applications of Thermo Gravimetric Analysis (TGA). (5)
- 9B) Quality by Design (QbD). (5)

Write briefly on the following:

- 10A) Effect of compression force on dissolution of drugs. (5)
- 10B) Types of Variables. (5)