

Question Paper

Exam Date & Time: 04-Dec-2017 (02:00 PM - 05:00 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES END SEMESTER THEORY EXAMINATIONS - NOVEMBER 2017

PROGRAM : MPHARM SEMESTER I

DATE : 04-12-2017

TIME : 2:00PM - 5:00PM

Product Development and Technology Transfer [PQA-MQA104T]

Marks: 50

Duration: 180 mins.

Answer all the questions.

Answer the following (5 marks x 8 = 40 marks)

- 1) What is pre-formulation? Why it is essential for drug development. (5)
- 2) What is solubility? Explain co-solvency and hydrotrophy with an example. (5)
- 3) Briefly discuss on Phase III clinical trials. (5)
- 4) What are the types of certifications under ANDA application? Write the procedure for ANDA application under paragraph IV certification. (5)
- 5) Briefly explain the BACPAC guidelines of USFDA. (5)
- 6) Discuss intra-cutaneous test for plastic containers for injectable preparation. (5)
- 7) Explain the responsibilities of receiving unit in technology transfer. (5)
- 8) Explain the documentation required in technology transfer in brief. (5)

Answer the following with specific answers (2 marks x 5 = 10 marks)

- 9) Why stability testing is essential? (2)
 - A)
 - B) What are the quality control tests for plastic containers for non-parenteral preparations. (2)
 - C) What is "sterilization test" and "fragmentation test" for the (2)

evaluation of rubber closures.

- D) What is a "phase IV clinical trial" as per USFDA? (2)
- E) List the stages of formulation development in technology transfer. (2)

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