

Exam Date & Time: 07-Dec-2018 (02:00 PM - 05:00 PM)



## MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.

Specialization: Pharmaceutical Quality assurance

Date: 07-12-2018

Product Development and Technology Transfer [PQA-MQA104T]

Marks: 75

Duration: 180 mins.

### SECTION - A

Answer all the questions.

Answer the following (10 marks x 5 = 50 marks)

- 1) Discuss SUPAC guidelines of USFDA (10)
- 2) What is stability analysis? Explain stability testing methods (10)
- 3) What is a "phase III clinical trial" as per USFDA? Explain. (10)
- 4) Explain the steps involved in technology transfer in analytical R & D (10)
- 5) Discuss the quality control tests for metal containers for eye ointments (10)

### SECTION - B

Answer all the questions.

Answer the following (5 marks x 5 = 25 marks)

- 6) Enlist the techniques for the study of crystal properties in pre-formulation and explain any one. (5)
- 7) What is technology transfer? Why it is done? Explain (5)
- 8) Explain CTD structure as per FDA (5)
- 9) Explain bulk characterization of solid dosage form in pre-formulation studies. (5)
- 10) Discuss the adverse event reporting requirements of PMS of USFDA (5)

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