

Question Paper

Exam Date & Time: 02-May-2019 (02:00 PM - 05:00 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

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

Specialization: Industrial Pharmacy

MPharm Semester II- End Semester Examination May 2019

Date:02/05/19

Scale-up and Technology Transfer [PCE-MIP202T]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

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

- 1) Discuss on raw material selection, space requirement, personal requirement and review of formula during scale up stage of formulations. (10)
- 2) Discuss on different stages of process validation. (10)
- 3) Explain the vendor development procedure for a new Active Pharmaceutical Ingredient as per GMP system. (10)
- 4) What is User Requirement Specification? Discuss the components of URS. (10)
- 5) Explain Installation Qualification with an example. (10)

SECTION - B

Answer all the questions.

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

- 6) Explain the primary treatment of effluent by coagulation method. (5)
- 7) Discuss on causes of fire hazards in pharma industry. (5)
- 8) Define following terms (i) Pilot plant (ii) Biological oxygen demand (iii) Effluent (iv) Process validation (v) Chemical hazards (5)
- 9) Write a note on Factory acceptance testing (FAT). (5)
- 10) Give any five importance of primary protective equipment (PPE). (5)

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