

# Question Paper

Exam Date & Time: 03-May-2018 (02:00 PM - 05:00 PM)



## MANIPAL ACADEMY OF HIGHER EDUCATION

### MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES END SEMESTER THEORY EXAMINATIONS - MAY 2018 PROGRAM: MPHARM SEMESTER 2 (INDUSTRIAL PHARMACY)

DATE: 03/05/2018

TIME: 02:00 PM - 5:00 PM

#### Scale-up and Technology Transfer [PCE-MIP202T]

Marks: 50

Duration: 180 mins.

**a**

#### Answer all the questions.

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

- 1) Discuss on processing equipment selection in pilot plant scale up. (5)
- 2) Explain the critical parameters to be considered in scale up of capsule filling and quality control tests to evaluate the same. (5)
- 3) Explain the method to determine Biological oxygen demand in effluent. (5)
- 4) Discuss on preventive measures for electrical hazards in pharmaceutical industry. (5)
- 5) List out the documents required while qualifying a new API vendor. Briefly give the importance of facility audit of vendor. (5)
- 6) Write a short note on cleaning validation and state the acceptance criteria as per FDA standards. (5)
- 7) What is Performance Qualification? List out the important acceptance criteria in PQ. (5)
- 8) Define material safety data sheets (MSDS). Give the procedure for using MSDS. (5)

**b**

#### Answer all the questions.

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

- 9) Mention the types of process validation. (2)

- A)
- B) Mention the evaluation tests to be carried during validation of tablet coating phase. (2)
- C) Explain sealing evaluation test for parenterals. (2)
- D) State the differences between protocol and report with a specimen format. (2)
- E) Write a brief note on Hearing protection in pharmaceuticals. (2)

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