

Question Paper

Exam Date & Time: 08-May-2019 (02:00 PM - 05:00 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

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

MPharm - Pharmaceutical Quality Assurance

MPharm Semester 2 - End-Semester Examination May 2019

Date : 08/05/2019

Pharmaceutical Manufacturing Technology [PQA-MQA204T]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

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

- 1) Discuss the levels and steps of production planning? (10)
- 2) Explain the quality challenges of prefilled syringe, needle free injection and large volume parenteral. (10)
- 3) What steps should be taken to improve the efficiency of material handling in pharmaceutical industry? (10)
- 4) Enlist and explain different types of glasses intended for pharmaceutical manufacturing. (10)
- 5) Which PAT tools should be implemented to enable the development of robust manufacturing processes? (10)

SECTION - B

Answer all the questions.

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

- 6) List various forms required to obtain the wholesale and distribution license of drugs in India. (5)
- 7) Write a note on form, fill, seal technology. (5)
- 8) How pan variables affect the quality of tablet coating? (5)
- 9) Discuss the tests for plastic containers intended to use in the packaging of non-injectable preparations. (5)
- 10) Write a note on control strategy used in the QbD approach. (5)

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