

Question Paper

Exam Date & Time: 19-Jun-2023 (10:00 AM - 01:00 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal College of Pharmaceutical Sciences, Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations. May-2023

Department of Pharmaceutical Quality Assurance

Sub code: PQA -MQA 204T

Sub title: Pharmaceutical Manufacturing Technology

Pharmaceutical Manufacturing Technology [PQA-MQA204T -S3]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

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

- 1) Air from 2.5 m³ area of a sterile manufacturing unit was sampled. This sample had 5,000 particles of size greater than 0.5µm. For which sterile manufacturing activity this area can be used as per the following regulatory agencies and why? (10)
 - i. USFDA
 - ii. EMEA
- 2) Discuss the defects found during the tablet coating process and mention the causes and remedies for the same using a tabular column (10)
- 3) Draw a flowchart for production planning and explain the procedure involved in production scheduling and what are the factors affecting scheduling (10)
- 4) Explain the various Process Analytical Technology tools. (10)
- 5) Describe the potential interactions between the packaging and the medication product. (10)

SECTION - B

Answer all the questions.

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

- 6) Why some intravenous solutions are marketed in glass containers in spite of availability of advanced technology like form (blow) fill seal? (5)
- 7) What are the legal requirements required to start an API manufacturing industry? (5)
- 8) Discuss the loading importance in pharmaceutical production units (5)
- 9) Why packaging is necessary for Pharmaceutical products? (5)
- 10) Differentiate between batch and continuous granule mixing. (5)

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