

Exam Date & Time: 13-Sep-2021 (02:00 PM - 05:00 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

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

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) What are the factors to be considered for selection of location of a Pharmaceutical Industry. (10)
- 2) 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? i. USFDA ii. EMEA (10)
- 3) If given a task of making the material handling within the manufacturing facility more efficient, which principles you will follow to achieve it? (10)
- 4) How to distinguish between different types of pharmaceutical grade glasses? Discuss in detail with special emphasize given to the chemical tests. (10)
- 5) Discuss in detail the concept of design space. (10)

SECTION - B

Answer all the questions.

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

- 6) Calculate the ceiling price for the scheduled formulation i.e. Amphotericin B injection by using the following data for the Indian market.

Sl. Number	Manufacturer	Price/Injection (INR)	Market Share based on MAT (CY 2019-20)
1	Dr. Reddy's	4500/-	22%
2	Hetero	3900/-	35%
3	Aurabindo	3500/-	32%
4	Cipla	3800/-	5%
5	Sun	5600/-	4%
6	Lupin	8000/-	0.2%
7	Mylan	7500/-	1.8%

- 7) A highly potent, low therapeutic window drug was developed for treating COVID-19. It was found to be incompatible with commonly used preservatives. Suggest a suitable drug delivery system for this with justification. (5)
- 8) Can the dissolution test be considered In Process Quality Control (IPQC) test? Why (5)

or why not?

- 9) Write a note on LDPE. (5)
- 10) Write any five objectives of production planning. (5)

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