Exam Date & Time: 20-Jul-2022 (10:00 AM - 01:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education
Manipal Collge of Pharmaceutical Sciences, Manipal M. Pharm Theory End-Semester Examinations.
July-2022.
Department of Pharmaceutical Quality Assurance
Specialization: Pharmaceutical Quality Assurance
Subject title: Pharmaceutical Manufacturing Technology
Sub code: PQA-MQA204T

PHARMACEUTICAL MANUFACTURING TECHNOLOGY [PQA-MQA204T-S1]

Marks: 75 **Duration: 180 mins.**

SECTION - A

Answer all the questions.

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

1) Following observations are made by an FDA inspector in a sterile dosage manufacturing unit. List which sections of the GMP is/are violated in each of above observations. Suggest Corrective action and Preventive action for the same.
i. Operators placed their head and upper torso inside the filling cabinet during interventions and performed interventions over open vials without clearing them.
ii. Operators excessively handled sterile stopper bags before introduction into the stopper chute in the ISO 5 filling cabinet.
iii. Operators shook stopper bags inside the ISO 5 area and the bag also contacted the interior of the stopper chute. (10)
iv. Interventions require a large door to be opened. When opened, the door is exposed to the ISO 7 area, and when being closed, there is a significant risk of the lower quality room air sweeping into the ISO 5 filling cabinet. Empty sterile vials are located extremely close to the door.
v. Certain interventions performed on the ISO 5 filling line were not documented in intervention log records.

2) a. Enlist the problems encountered in tablet compression, mention the cause and write the remedies to avoid such problems (7 Marks) (10)
b. Differentiate batch mixing from continuous mixing (3 Marks)

3) Explain how derived factors and fundamental factors are influencing pharmaceutical plant location (10)

4) a. Enlist the risks involved and their respective control mechanism in the Tramadol tablet Unit operation. (7 Marks) (10)
b. Write the benefits of the Implementation of PAT. (3 Marks)

5) a. Enlist and explain various Quality Control Tests for Non-Parenteral preparations (7 Marks)
b. Explain about interaction between packaged materials and their enclosed drug product (3 Marks) (10)

SECTION - B

Answer all the questions.

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

6) Kasturba Hospital, Manipal wants to start a sterile manufacturing unit for its captive usage. Should they go for BFS/FFS technology or conventional method? Justify your answer. (5)

7) Mention the importance of loading in pharmaceutical production planning (5)

8) Explain the procedure for sampling and testing of incoming production materials in the pharmaceutical industry (5)

9) Explain about different types of closures (5)

10) Enlist and explain the Finished Product Quality Control Tests that a quality control analyst should analyse for Metformin sustained release tablets (5)

-----End-----