Question Paper

Exam Date & Time: 21-May-2024 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal College of Pharmaceutical Sciences, MAHE, Manipal
M. Pharm Theory End-Semester Examinations, May-2024
Department of Pharmaceutical Quality Assurance
Specialization- Pharmaceutical Quality Assurance
Sub title: PHARMACEUTICAL MANUFACTURING TECHNOLOGY
Sub code: PQA -MQA 204T

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)	You are working in a large scale sterile manufacturing unit as a quality assurance executive. As a part of investigation, you need to collect swab samples from the filling machine. List the steps you will follow to enter the manufacturing area to accomplish this task.	(10)
2)	How can quality control analysts ensure the quality of modified-release tablets through In-process Quality Control (IPQC) tests, and what are the significance of these tests?	(10)
3)	What primary and secondary factors should a pharmaceutical company meticulously evaluate when deliberating on the location for constructing a new facility dedicated to non-sterile formulations in Hyderabad, Telangana State? Provide a comprehensive explanation detailing significance of each factor and its potential impact on the overall success of the facility.	(10)
4)	Utilizing an Ishikawa fishbone diagram, delineate the Critical Quality Attributes (CQAs), Critical Material Attributes (CMAs), and Critical Process Parameters (CPPs) involved in the development of Paracetamol Tablets 650 mg.	(10)
5)	Provide a comprehensive overview of the stability testing methods employed to assess pharmaceutical packaging materials.	(10)

SECTION - B

Answer all the questions.

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

6)	2.5 m^3 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	(5)
7)	Design a machine loading chart to accommodate the production of two soft gelatin capsule formulations over six months	(5)
8)	How do various factors influence the scheduling of different formulations in the pharmaceutical industry?	(5)
9)	Explain the various types of closure liners used in the Pharmaceutical industry	(5)
10)	Write the principle involved in the operation of spermonizers	(5)

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