Exam Date & Time: 29-Mar-2021 (01:30 PM - 04:30 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

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

Quality Control and Quality Assurance [PQA-MQA103T - S2]

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

SECTION - A

Answer all the questions.

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

1) What are the possible contaminants likely to be present in the pharmaceutical manufacturing facility? How to control them? (10)

2) Classify the residual solvents used in the manufacturing of pharmaceutical substances and products with appropriate examples. Further, discuss the various options to describe the limits of residual solvents. (10)

3) Enlist the elements of Batch Manufacturing Records (BMR). Prepare a dummy format of BMR. (10)

4) How IPQC tests are different from QC tests? Enlist and explain the IPQC tests for immediate release tablets. (10)

5) Categorize pharmaceutical waste. Discuss in detail the methods of waste disposal. (10)

SECTION - B

Answer all the questions.

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

6) Discuss the statistical methods to device sampling plan for raw materials (5)

7) How the record of distribution of pharmaceutical products is kept? Write the significance of distribution records. (5)

8) Enlist the criteria to qualify as regulated and non- regulated market. (5)

9) Pfizer is planning to launch and new drug product in two formulations with multiple strength as shown below:
Capsules: 50mg, 150mg, 250mg
Syrup: 50ml, 150ml, 250ml
Mention the studies to be performed and submitted to the regulatory authorities to establish the stability of the drug product. (5)

10) Prepare a protocol for conducting non- clinical testing to be submitted to Institutional Ethical Committee for establishing the bioequivalence of an antipyretic drug. (5)

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