

Question Paper

Exam Date & Time: 27-Nov-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.
sub title: Quality Control & Quality Assurance
Sub code: PQA-MQA 103T

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) MEC is an approved Institutional Animal Ethical Committee. A proposal has been submitted to this committee to conduct safety testing of a new formulation in rats. How will the committee go ahead with this proposal? (10)
- 2) Enlist and explain the Finished Product Quality Control (FPQC) tests that a quality control analyst should perform for Ointments as per USP. (10)
- 3) Explain various phases involved in the Quality audit (6)
 - a)
 - b) Mention the importance of pharmaceutical distribution records (4)
- 4) Describe handling of waste and scrap disposal in the pharmaceutical industry (5)
 - a)
 - b) What checks should be done in the pharmaceutical packaging operations before starting any drug product packaging? (5)
- 5) In Bengaluru, a pharmaceutical company intends to open a new sterile facility (Parenteral Unit). Provide them with design and aseptic layout suggestions for their sterile facility, and instruct them on how to maintain it. (8)
 - a)
 - b) Give 2 examples for improper maintenance of pharmaceutical sterile area (2)

SECTION - B

Answer all the questions.

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

- 6) What information is required to maintain on labels of pharmaceutical raw materials in the storage area? (5)
- 7) M/S Abhish Pharmaceuticals has isolated a new colouring principle from flowers of "Caesalpinia pulcherrima". They want to use it as natural colouring agent for film coated tablets. What document/s they submit to USFDA? Explain the technical details to be submitted. (5)
- 8) Can expiry date be extended? Justify your answer (5)
- 9) How to maintain and retrieve the documents in the Pharmaceutical Industry? (5)
- 10) Explain quality control tests for plastic containers (5)

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