

Exam Date & Time: 14-Dec-2022 (10:00 AM - 01:00 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

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

Quality Management Systems [PQA-MQA102T]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

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

- 1) Define Quality. What is a quality system, what are the benefits of a quality system and how to present a quality system? (10)
- 2) Adira Pharmaceuticals is a drug manufacturing company established in United States of America under section 510 of FD and C act. The company received a notice from USFDA to submit a compiled report of its quality metrics data. Should the company submit the same and if "YES" what should be the contents of the same? (10)
- 3) Design an annual product review document for a tablet formulation available in the market for last 12 years. (10)
- 4) Explain the process of long-term stability studies for zone IVA countries with the help of a stability study protocol for an enteric coated tablets adopting bracketing strategies (10)
- 5) Explain the statistical process control of a parenteral preparation with the help of variable and attribute control charts (10)

SECTION - B

Answer all the questions.

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

- 6) Purvish Laboratories is a Mumbai based testing and calibration laboratory accredited by NABL. They saw an advertisement by a Germany based Pharmaceutical company for outsourcing analytical testing services by an internationally accredited laboratory. Can Purvish lab apply for the same without any other regulatory requirements? If NO, why and if YES, why? (5)
- 7) M/S ArGir Pharmaceuticals is a unit manufacturing tablets. They decide to start a capsule manufacturing operations, hence require to procure empty gelatin capsules. What will be QAU's role in this and how do they execute their role? (5)
- 8) Albendazole Tablets I.P. 400 mg B. No.: AT10-22-245 Mfg dt: 07/2022 Exp dt: 06/2024 Mfd by: M/s. Ornate Labs Pvt. Ltd., Bela Industrial Estate, Muzaffarpur -842 005, Bihar was found not meeting Assay and Dissolution specifications. Write a recall procedure for the same as per CDSCO guidelines. (5)
- 9) Prepare a risk assessment plan for a stability chamber (5)

- 10) Explain the process of benchmarking studies with any two disadvantages of the same (5)

-----End-----