Exam Date & Time: 16-Dec-2022 (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. December-2022
Sub title: Quality Control & Quality Assurance
Sub code: PQA-MQA103T

Quality Control and Quality Assurance [PQA-MQA103T]

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

SECTION - A

Answer all the questions.

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

1) While inspecting a microbiological laboratory, a quality auditor noted the presence of a single stereoscopic microscope with a missing ocular lens. Having reviewed the laboratory's SOP for Total Coliform analysis prior to the on-site assessment, the auditor knew the procedure called for the use of a stereoscopic microscope for counting coliform colonies. The auditor asked the analyst, if she used the microscope for standard plate counts, and she responded in the affirmative. The laboratory logbook supported the analyst's statement that she had performed the standard plate counts.
Suspecting that the analyst had fabricated the data, the auditor compiled the objective evidence, and discussed the findings with laboratory management during the exit briefing. Laboratory management was able to produce records showing that they had rented a microscope to complete the plate counts, and returned it the previous day. The analyst, due to either cultural differences or language barriers, was uncomfortable explaining that the laboratory did not have properly functioning equipment, but had used rented equipment. (10)
a. Describe the objective evidence that the auditor should have compiled.
b. What are the lessons for auditor in this case?

2) a) Write a short note on the disposal of expired medicine (5 Marks)
b) What is the importance of the Annual Product Quality Review (APQR) and mention details that should be included in APQR? (5 Marks) (10)

3) Enlist and explain the In-process Quality Control (IPQC) tests that a quality control analyst should perform for Sustained-release Tablets with their significance. (10)

4) a) What are the parameters to be checked during the Deviation Assessment in the Pharmaceutical Industry? (4 Marks)
b) Differentiate trash waste from scrap disposal (3 Marks)
c) What are the precautions to be taken to avoid mix-ups in the Quality Control laboratory? (3 Marks) (10)

5) a) Write the importance of the Master formula record in the ointment manufacturing company (5 Marks)
b) Enlist the contents of the Master formula record in the Pharmaceutical manufacturing (5 Marks) (10)

SECTION - B

Answer all the questions.

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

6) What training is required for a newly recruited fresh graduate as Research Associate in Pharmaceutical Formulation Research & Development department to start his job in his department? Suggest 2 major trainings as per cGMP guidelines. (5)

7) M/S Disid Pharmaceuticals Pvt. Ltd. has constructed a new drug product manufacturing facility and they want the facility to be approved by USFDA. What document will they have to submit to the USFDA and what are its contents? (5)

8) Write a note on the importance of Distribution records in the Pharmaceutical industry (5)

9) What are the criteria for raw material purchase specifications? (5)

10) Mention the requirements to be evaluated for drug industry location to start a pharmaceutical solid oral dosage form unit in India (5)

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