

# Question Paper

Exam Date & Time: 17-May-2024 (02:00 PM - 05:00 PM)



## MANIPAL ACADEMY OF HIGHER EDUCATION

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

**Quality Control and Quality Assurance [PCH-MPA203T -S2]**

**Marks: 75**

**Duration: 180 mins.**

### SECTION - A

**Answer all the questions.**

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

- 1) Explain in detail various aspects related to the analysis of raw materials used in Pharmaceuticals (10)
- 2) A). Discuss the various steps involved in the report preparation and documentation of nonclinical study results. (10)  
B). Explain the objectives of the following ICH-Q series guidelines: Q1, Q2(R1), Q5C, Q7A, Q9, Q12 and Q14
- 3) Discuss the principle, personnel, key personal and personal hygiene for the manufacture of pharmaceutical products according to good manufacturing practices (10)
- 4) Write the objective, and functions of the Committee for the Purpose of Control and Supervision on Experiments on Animals Guidelines and explain anaesthesia and euthanasia as per this guideline. (10)
- 5) What is standard operating procedure? Why SOPs are important in pharmaceutical industries? Explain. (5)  
A)  
B) What is an audit? Enlist its types. Explain the Quality System Inspection Technique Audit QSIT (5)

### SECTION - B

**Answer all the questions.**

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

- 6) Which are the different types of water used in pharma industry? What are the different contaminants of water? How can you get purified and sterile water for pharma products? (5)
- 7) Enumerate the ideal requirements of good package. (5)
- 8) What are the sources of Mix-up and contamination? How can you control them. (5)
- 9) What is a Batch Formula Record? Write the information that is typically included in it. (5)
- 10) Explain the finished product quality control tests for parenterals. (5)

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