

Exam Date &amp; Time: 11-Sep-2021 (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]**

**Marks: 75**

**Duration: 180 mins.**

### SECTION - A

**Answer all the questions.**

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

- 1) Explain the principle and procedure involved in the preparation and maintenance of master formula record, batch formula record and three tier documentation. (10)
- 2) Discuss aseptic process control and sanitation of manufacturing premises. (10)
- 3) Write about In process quality control and finished product quality control tests for tablets and capsules. (10)
- 4) Give the scope of guidelines and mention Q1 and Q9 specifications. Discuss the principles and objectives of GMP and mention the various aspects of GMP. (3+7) (10)
- 5) How is documentation done in cGMP? Explain, how self-audit and inspections happens in cGMP? (5 +5) (10)

### SECTION - B

**Answer all the questions.**

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

- 6) Mention the various factors to be considered under CPCSEA guidelines. (5)
- 7) Explain WHO guidelines for the manufacturing of sterile pharmaceutical products. (5)
- 8) Give the scope of guidelines and mention ICH Q3 and Q6 specifications. (5)
- 9) Define GLP. Discuss the main consideration under GLP as per OECD guidelines. (5)
- 10) Explain cGMP regulations. What are the various components of cGMP? (5)

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