

Exam Date & Time: 18-Jul-2022 (10:00 AM - 01:00 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) What is cross contamination? How will you maintain sanitation of manufacturing premises? Explain. (10)
- 2) With a diagram explain in detail three tier documentation. What is Master Formula Record? How will you maintain it? (10)
- 3) Discuss the objectives and the protocol for the conduct of non- clinical laboratory studies in GLP (10)
- 4) Explain how record and reports and self-audit is executed in cGMP? 5 marks
Explain how documentation and quality review is undertaken in GMP? 5 marks (10)
- 5) Explain in process and finished product quality control tests for tablets and capsules. (10)

SECTION - B

Answer all the questions.

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

- 6) What are the various contents considered in GMP? (5)
- 7) Explain the various steps involved in packaging of sterile products (5)
- 8) Write the important aspects of ICH Q3 and Q6 guidelines (5)
- 9) Explain the quality control tests for containers, closures and secondary packing materials (5)
- 10) Write about CPCSEA guidelines with respect to transportation and quarantine. (5)

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