

Question Paper

Exam Date & Time: 16-May-2023 (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 -S1]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

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

- 1) Explain the components of Three tier documentation in Pharmaceutical industry with diagram (10)
- 2) Discuss aseptic process control. How will you calculate expiry date and yield? (10)
- 3) Explain the quality control tests for containers, closures and secondary packing materials. (10)
- 4) Explain in process and finished product quality control tests for tablets and capsules. (10)
- 5) Mention the objectives of GMP. How is qualification, validation and quality audits and suppliers' audit approval is performed in GMP? (10)

SECTION - B

Answer all the questions.

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

- 6) Give an overview of Q series guidelines (5)
- 7) Define GLP. Mention the objectives of GLP as per OECD guidelines. Explain how documentation and report preparation is done in GLP? (5)
- 8) Explain the various aspects of cGMP. How cGMP is different from GMP? Explain returned and salvaged drug products in cGMP (5)
- 9) How will you prepare and maintain Master Formula Record? (5)
- 10) Write the important aspects of ICH Q3 and Q6 guidelines. (5)

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