

Exam Date & Time: 25-Mar-2021 (01:30 PM - 04:30 PM)



## MANIPAL ACADEMY OF HIGHER EDUCATION

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

### Good Regulatory Practices [PQA-MRA101T]

**Marks: 75**

**Duration: 180 mins.**

#### SECTION - A

**Answer all the questions.**

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

- 1) Write a note on Code of Federal Regulations (10)
- 2) Compare ISO/IEC 17025 and OECD GLP guidelines. (10)
- 3) A new software is developed by your company to prepare ANDA. Prepare a checklist for validating the same. (10)
- 4) List the topics for training the following persons in a Pharmaceutical wholesale firm as per WHO GDP guideline. (10)  
Quality Assurance chemist  
Office Assistant  
Vehicle Driver
- 5) What is cleaning validation? Discuss how cleaning validation is performed (10)

#### SECTION - B

**Answer all the questions.**

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

- 6) List and briefly explain FIVE key concepts of GAMP 5 guidelines (5)
- 7) Write an information flow chart for a LIMS software for analysis of dissolution test samples (5)
- 8) Explain major differences between WHO and EU GDP guidelines (5)
- 9) Design a change control form for a pharmaceutical facility as per the regulatory requirement (5)
- 10) Discuss out of specification with the help of any case studies (5)

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