Question Paper

Exam Date & Time: 27-Nov-2017 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES
END SEMESTER THEORY EXAMINATIONS - NOVEMBER 2017
PROGRAM : MPHARM SEMESTER I
DATE : 27-11-2017
TIME : 2:00PM - 5:00PM

Good Regulatory Practices [PQA-MRA101T]

Marks: 50 **Duration: 180 mins.**

a

Answer all the questions.

Answer the following (5 marks x 8 = 40 marks)

1) What are the concepts of GAMP-5? Explain MES life cycle approach. (5)

2) Write the GLP inspection checklist which assist in self-regulatory preparation. (5)

3) Write the general checklist of 21 CFR part 11. (5)

4) Write a note on GDP as per CDSCO guidance. (5)

5) Give the reasons for disqualification of testing facilities. What are the actions taken on disqualification? (5)

6) What are the legal requirements and documentation requirement for GDP. (5)

7) Explain process validation in detail. (5)

8) Explain out of specification in detail with the help of a flowchart. (5)

b

Answer the following with specific answers (2 marks x 5 = 10 marks)

9) List any four importance of quality by design (2)

A)

B) Write the principle of GALP. (2)

C)	Compare 21 CFR part 11 and EU GMP annex 11	(2)
D)	What are the quality system requirements as per IMDRF and 21 CFR part 820 for medical devices?	(2)
E)	Give diagrammatic representation of V model design for GAMP.	(2)

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