Question Paper

Exam Date & Time: 07-May-2018 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

MANIPAL COLLEGE OF PHARMACEUTICAL SCIENCES
END SEMESTER THEORY EXAMINATIONS- MAY 2018
PROGRAM: MPHARM SEMESTER 2
(PHARMACEUTICAL QUALITY ASSURANCE)
DATE: 07/05/2018
TIME: 2:00 PM - 5:00 PM

Audits and Regulatory Compliance [PQA-MQA203T]

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

a

Answer all the questions.

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

1)	Discuss in detail about management of audit in terms of planning process and responsibilities	(5)
2)	Explain the role of quality systems and audits in pharmaceutical manufacturing facility.	(5)
3)	Prepare a detailed audit checklist for GMP certified liquid oral dosage formulation manufacturing facility.	(5)
4)	Prepare detailed audit checklist for packing material supply vendor	(5)
5)	Explain the importance of pharmaceutical warehousing facility and write a summarised checklist for auditing a warehouse.	(5)
6)	Write a detailed checklist for auditing microbiology laboratory.	(5)
7)	Classify and explain in detail about GMP deficiencies with examples	(5)
8)	Write the audit checklist for Effluent Treatment Plant	(5)

b

Answer all the questions.

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

9)	Write a note on administration of an audit	(2)

A)

B)	Write a note on management responsibilities toward audit	(2)
C)	Write the requirements for water distribution system pipework in Pharmaceutical industry.	(2)
D)	Give a comparative chart for HVAC parameters in sterile and non-sterile area	(2)
E)	Write the parameters to be checked in Effluent and its standards before discharge into the environment as per EPA	(2)

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