Question Paper

Exam Date & Time: 01-Dec-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 : 01-12-2017
TIME : 2:00PM - 5:00PM

Quality Control and Quality Assurance [PQA-MQA103T]

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

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

1)	Discuss the responsibilities of study director and quality assurance unit in non-clinical testing facility as per Good Laboratory Practices (GLP).	(5)
2)	Discuss the building design and construction features of pharmaceutical plant as per cGMP guidelines.	(5)
3)	Classify impurities in new drug substance. Discuss the approach to develop the specification for the same as per the thresholds.	(5)
4)	Enlist and explain the IPQC test for tablets and capsules.	(5)
5)	Explain types of disposal methods for waste and scrap in pharmaceuticals.	(5)
6)	What is copyright? explain its types.	(5)
7)	Explain the content and structure of Standard operating procedure	(5)
8)	Explain in detail about Batch manufacturing record	(5)

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

9)	Differentiate between Quality Assurance (QA) and Quality Control (QC).	(2)
A)		
B)	Enlist the types of trainings in pharmaceutical industry.	(2)
C)	Enlist the IPQC tests for parenterals.	(2)

D) What are the objectives of IPQC test? (2)

E) Give two examples for level 2 and level 4 documents (2)

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