Seat No.: _____   Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY
M. Ph. - SEMESTER– 2 • EXAMINATION – SUMMER -2018

Subject Code: MPA203T   **Date: 18/05/2018**
Subject Name: QUALITY CONTROL AND QUALITY ASSURANCE
Time: 10:30 AM TO 01:30PM   **Total Marks: 80**

Instructions:
1. Attempt any five questions.
2. Make suitable assumptions wherever necessary.
3. Figures to the right indicate full marks.

Q.1	(a)	Distinguish between GMP and CGMP.	06
	(b)	Describe the responsibilities of the Quality assurance unit of a non-clinical testing laboratory.	05
	(c)	Write note on Good Documentation Practices.	05
Q.2	(a)	Explain briefly about Indian GMP guidelines for the manufacturing of sterile dosage forms as per schedule M.	06
	(b)	Describe In-process tests in manufacture of oral solids	05
	(c)	Describe the key components of a master manufacturing record.	05
Q.3	(a)	What are standard operating procedures? What are the factors that must be considered while writing a SOP?	06
	(b)	Briefly describe finished product release procedure and documentation for release.	05
	(c)	Write note on master batch documents for tablet dosage form.	05
Q.4	(a)	What do you mean by IPQC? Give importance of it.	06
	(b)	Write quality assurance procedure for maintenance of raw materials in stores.	05
	(c)	Write a note on GLP.	05
Q.5	(a)	Write the GMP guidelines for the manufacturing and control of biological products.	06
	(b)	Explain standard operating procedures for operation of Membrane filtration.	05
	(c)	Write a short note on personnel hygiene and training in sterile area.	05
Q. 6	(a)	Describe in detail problems encountered and their rectification in parenteral production.	06
	(b)	Discuss the evolution of IP, BP, USP and compare the policies.	05
	(c)	Describe in detail quality assurance of API.	05
Q.7	(a)	Give a detailed account on location and building requirements for pharma industry.	06
	(b)	Write a note on Warehousing management.	05
	(c)	Outline the packaging material used in pharmaceutical industry and explain the different types of quality assuring test for glass container.	05

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