

GUJARAT TECHNOLOGICAL UNIVERSITY
M.PHARM - SEMESTER-2 EXAMINATION – SUMMER-2019

Subject Code: MQA202T**Date: 29/05/2019****Subject Name: Pharmaceutical Validation****Time: 10:30 AM TO 01:30 PM****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) Write a short note on Validation Master Plan.	06
	(b) Give a brief note on Advantages and Scope of Validation.	05
	(c) Differentiate calibration and Validation with Suitable examples.	05
Q.2	(a) Write a brief note on Validation HVAC Validation.	06
	(b) Write a note on process validation of liquid dosage form.	05
	(c) Explain in brief different types of process validation.	05
Q.3	(a) Explain various parameters for qualification of Autoclave.	06
	(b) Discuss in brief Calibration of UV-Visible Spectrophotometer.	05
	(c) Write a note on Analytical Method Validation	05
Q.4	(a) Discuss in detail Qualification of FTIR.	06
	(b) Write a note on Qualification of dissolution test apparatus.	05
	(c) Write a detail note on cleaning validation.	05
Q.5	(a) Discuss in detail validation of Pharmaceutical Water system.	06
	(b) Write a short note on Computer system validation.	05
	(c) Write a short note on FAT/SAT.	05
Q. 6	(a) Write a short note on Qualification of HPLC.	06
	(b) Write a note on Technology Transfer.	05
	(c) Write a note on mechanism for protection of IPR.	05
Q.7	(a) Write a short note on Patent filing procedure in India.	06
	(b) Write a note on rights and responsibilities of patentee.	05
	(c) Write a note on copyright and trademark.	05

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