

# C.U.SHAH UNIVERSITY

## Summer Examination-2019

Subject Name : Pharmaceutical Validation

Subject Code : MQA202T

Semester : 2

Date : 20/04/2019

Branch: M.Pharm (QA)

Time : 02:30 To 05:30

Marks : 75

**Instructions:**

- (1) Use of Programmable calculator & any other electronic instrument is prohibited.
  - (2) Instructions written on main answer book are strictly to be obeyed.
  - (3) Draw neat diagrams and figures (if necessary) at right places.
  - (4) Assume suitable data if needed.
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<b>Q-1</b>	<b>Attempt the following questions:</b>	<b>(20)</b>
	a) Define the term Validation with types.	2
	b) Describe Factory acceptance test.	2
	c) Explain the significance of transfer technology.	2
	d) Define qualification.	2
	e) Explain site acceptance test.	2
	f) Write down the types of Patent Application.	2
	g) Explain briefly Claim.	2
	h) Describe briefly Statistical Process control.	2
	i) What is validation master plan	2
	j) Define and explain IPP.	2

**Attempt the following questions:**

<b>Q-2</b>	<b>Attempt any two of following :</b>	<b>(20)</b>
	A Give concept, process and documentation of process validation; Explain in brief process validation of tablets.	10
	B Enumerate the concept of Intellectual property; give the role of IP in Pharmaceutical industry.	10
	C Explain the validation and qualification of HVAC system.	10
<b>Q-3</b>	<b>Attempt any Seven of following :</b>	<b>(35)</b>
	A Differentiate Calibration and Validation in brief.	5
	B Explain USFDA guidelines for process Validation.	5
	C Give general principles for validation of analytical method as per ICH.	5
	D Explain in brief the international patenting requirement procedure and cost.	5
	E Describe in brief the validation of pharmaceutical water system.	5
	F Write down the brief procedure for the qualification of UV-Visible spectrophotometer.	5
	G Explain cleaning method development.	5
	H Write down the advantage and scope of validation.	5
	I Explain computerized system validation.	5

