_____ C. U. SHAH UNIVERSITY Winter Examination-2022

Subject Name : Quality by Design and Process Analytical Technology

Subjec	t Code	e : 4PS07QBD1	Branch: B.Pharm	
Semest	er: 7	Date: 28/11/2022	Time: 11:00 To 02:00	Marks: 70
(2) (3)	Use o Instru Draw	of Programmable calculator & any other actions written on main answer book a r neat diagrams and figures (if necessar me suitable data if needed.	re strictly to be obeyed.	hibited.
Q-1		Attempt the following questions:		(14)
	d) e) f) g) h) i) j) k) l) m)	Give the full name of QTPP. Give the full name of CMA. Give the full name of CQA. Give the full name of CPP. What is design of experiment? Define QbR What is Quality? Define PAT. Give the full name of FMEA Define Factor with example. Define Level with example. What is Reference Listed Drug Produ Define Design Space Define Number of Experiments	ct?	
Q-2	A B	Attempt all questions Define QbD. Discuss the elements of Q Discuss its advantages and limitations of	•	(14) 07 07
	A B	Attempt all questions Enlist the different parts of CTD. Exp Classify the optimization techniques an	-	(14) 07 07
	A B	Attempt all questions Write about scope and principles of Qu Explain the Failure Mode Effects Analy	•	(14) 07 07
Q-5	4	Attempt all questions Discuss in brief about continual improv	vement of the Pharmaceutical Q	(14) Juality 07



	В	System. Give brief review on ICH Q9.	07
Q-6		Attempt all questions	(14)
	Α	Discuss in detail case study of QbD for any one Modified release dosage forms.	07
	В	Write the detailed case study of QbD for any one Immediate release dosage forms.	07
Q-7		Attempt all questions	(14)
-	Α	Discuss scope and principle of PAT.	07
	B	Explain in brief Risk Base Approach and Integrated System Approach	07
Q-8		Attempt all questions	(14)
-	Α	Write on PAT Framework and Tools	07
	B	Write about need of QbD for Pharma sector.	07

