Exam Seat No: ______ C.U. SHAH UNIVERSITY **Summer Examination-2019**

	•	Name: Pharmaceutical Manufacturing TechnologyCode: MQA204TBranch: M.Pharm (QA)r: 2Date: 25/04/2019Time: 02:30 To 05:30Marks: 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. 		
Q-1	Attempt the following questions:		(20)
Atten	a) b) c) d) e) f) g) h) i) j) npt the f	Explain CMA. Define API. How to identify Critical process parameter. Define Quality by Design. Discuss Critical Quality Attribute. Explain CIP. Give a note on Risk Managment. Define RLD. Explain Sterilization in Place. Explain Risk Assesment. Ollowing questions:	
Q-2	A	Attempt any two of following : Describe the IPQC test of following: a) Tablet b) Capsule	(20) 10
	B C	Explain process automation in Small and Large volume parentral. Write a note on sterile manufacturing technology.	10 10
Q-3	A B C D E F G H	 Attempt any Seven of following : Explain the role of QbD in product development. Write a note on Lyophilization technology. Describe the types of container and closure. Explain in short automation in pharmaceutical technology with reference to Batch mixing of tablet. Give evaluation of stability of packaging material. Write IPQC test for suspension and Emulsion Define plant layout and explain the factors affecting plant layout. Write a note on coating technology. 	(35) 5 5 5 5 5 5 5 5 5
	Ι	Explain PAT in detail.	5

