C.U.SHAH UNIVERSITY Winter Examination-2019

		Name : Product Development and Technology TransferCode : MQA104TBranch: M.Pharm (QA)	
	Semeste		
	Instruction		
	 Use of Programmable calculator & any other electronic instrument is prohibited. Instructions written on main answer book are strictly to be obeyed. 		
		Draw neat diagrams and figures (if necessary) at right places.	
	(4)	Assume suitable data if needed.	
Q-1		Attempt the following questions:	(20)
	a)	Give the concept of Pilot plant scale up.	
	b)	List out QC tests for closures.	
	c)	What is SUPAC ?	
	d)	Surfactants used to improve solubility of drugs, why?	
	e)	Define co-solvency.	
	f)	List out techniques to study crystal properties.	
	g)	Enumerate methods to increase solubility of drugs.	
	h)	Write a note on Pharmaceutical packaging material.	
	i)	Explain QC test for containers	
A 44 -	j)	Explain aseptic packaging system.	
Atte	empt the I	following questions:	
Q-2		Attempt any two of following :	(20)
	Α	Define technology transfer? Discuss in brief the steps involved in technology transfer process.	10
	В	Discuss different steps involved in clinical research process for drug discovery	10
	2	and development.	10
	С	Give a brief on Preformulation studies? What are objectives and principles of Preformulation?	10
Q-3	1	Attempt any Seven of following :	(35)
Q -5	A	Enlist in brief the evaluation parameters of pharmaceutical packaging materials.	5
	B	Give format and content of IND.	5
	Č	Write a brief note on BACPAC.	5
	D	Give a brief on product registration guidelines.	5
	Ε	Discuss manufacturing aspects of oral liquids.	5
	F	Explain in brief the Pilot plant scale up for tablets.	5
	G	Development of technology by R & D, explain.	5
	Η	Differentiate NDA and ANDA in brief.	5
	Ι	Discuss Qualitative and Quantitative models of Technology transfer.	5

