Enrollment No: _____ Exam Seat No:_____

C.U.SHAH UNIVERSITY

Winter Examination-2020

Subject Name: Product Development and Technology Transfer

Subject Code: MQA104T **Branch: M.Pharm (Quality Assurance)**

Semester: 1 **Date: 12/03/2021** **Time: 11:00 To 02:00** **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.

Q-1		**Attempt the following questions:**	**(20)**
	a)	What is aseptic packaging?	**2**
	b)	Comment on : issues facing by modern drug packing	**2**
	c)	Enumerate packing requirements	**2**
	d)	Explain QC test for containers	**2**
	e)	List out QC tests for secondary packing materials	**2**
	f)	Comment on: SUPAC	**2**
	g)	Enumerate techniques to study crystal properties	**2**
	h)	Comment on: ANDA	**2**
	i)	What is stability studies?	**2**
	j)	List out QC tests for parenteral dosage forms	**2**

Attempt the following questions:

Q-2		**Attempt any two of following :**	**(20)**
	A	What is technology transfer? Discuss steps involved in technology transfer process	**10**
	B	Explain concept, significance, design of pilot plant scale up study	**10**
	C	Describe packaging material and common testing methods used for Enteral device packaging	**10**
Q-3		**Attempt any seven of following :**	**(35)**
	A	Write a note on Medical device packaging	**5**
	B	Discuss on any two methods to improve solubility of drugs	**5**
	C	Discuss Qualitative and Quantitative models of Technology transfer	**5**
	D	Discuss manufacturing aspects of oral liquids	**5**
	E	Explain pilot plant scale up for tablets	**5**
	F	Discuss Quality control of Solids and Liquids	**5**
	G	Give format and content of IND and NDA	**5**
	H	Discuss on BACPAC guidelines	**5**
	I	Discuss on Pre-formulation studies	**5**