Enrollment No: _____ Exam Seat No:_____

C.U.SHAH UNIVERSITY

Winter Examination-2020

Subject Name : Regulatory Affairs

Subject Code : MPH104T **Branch: M.Pharm (Pharmaceutics)**

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)	Process validation	**2**
	b)	Generic drug	**2**
	c)	Clinical trials	**2**
	d)	Pharmacovigilance	**2**
	e)	ANDA	**2**
	f)	IND	**2**
	g)	Orange book	**2**
	h)	Clinical trials	**2**
	i)	Hatch- Waxman act	**2**
	j)	Components of FDA	**2**

Attempt the following questions:

Q-2		**Attempt any two of following :**	**(20)**
	A	What is DMF? Write a note on type of DMF.	**10**
	B	Explain in details Master Formula Record. (MFR).	**10**
	C	Explain the guideline of TGA for generic products.	**10**
Q-3		**Attempt any seven of following :**	**(35)**
	A	Describe general guidelines for dossier preparation for ROW market.	**5**
	B	Write a note on NDA.	**5**
	C	Give details note on MHRA.	**5**
	D	Write in detail about the developing of clinical trials protocols.	**5**
	E	Describe CFR 21 (code of federal regulation) in details.	**5**
	F	Write a note on HIPAA.	**5**
	G	What is ICH? Explain ICH M in brief.	**5**
	H	Explain regulation for medical devices.	**5**
	I	Give important of CRO. What about out sourcing of BA & BE studies to CRO?	**5**