Enrollment No: _____ Exam Seat No:_____

C.U.SHAH UNIVERSITY

SummerExamination-2022

Subject Name: Pharmaceutical Regulatory Science- Theory
Subject Code: BP804ET **Branch: B.Pharm**
Semester: 8 **Date: 05/05/2022** **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	Give FDA's definition of New Drug.	**2**
	B	Give flow chart of time course for development of new drug.	**2**
	C	What are Innovator and Generic drugs?	**2**
	D	What is regulatory approval process?	**2**
	E	Give names of Regulatory agencies of at least four countries.	**2**
	F	Briefly explain Pharmacovigilance.	**2**
	G	What is eCTD?	**2**
	H	Explain CTD triangle.	**2**
	I	Briefly explain about Orange book.	**2**
	J	What is Federal register?	**2**

Attempt the following questions:

Q-2		**Attempt any two of following: (2*10 Marks = 20 Marks)**	**(20)**
	A	Explain New Drug Development process in detail with flow chart.	**10**
	B	Write a note on safety monitoring in clinical trials.	**10**
	C	Explain in detail about DMF, its content, types and review process.	**10**

Q-3		**Attempt any Seven of following: (7*5 Marks = 35 Marks)**	**(35)**
	A	Discuss the types of IND.	**5**
	B	Describe the regulatory approval process of NDA.	**5**
	C	Briefly explain the types of changes to an approved NDA/ANDA.	**5**
	D	Give detail note on CTD.	**5**
	E	Explain various Indian regulations and guidelines.	**5**
	F	Briefly explain clinical trial protocol.	**5**
	G	Write a note on IRB/IEC.	**5**
	H	Explain composition and role of Drug regulatory authorities/agencies of India.	**5**
	I	Discuss the procedure for export of pharmaceutical products in overseas market from India.	**5**