Enrollment No: _____ Exam Seat No:_____

C.U.SHAH UNIVERSITY

Winter Examination-2022

Subject Name: Pharmaceutical Regulatory Science-Theory

Subject Code: BP804ET **Branch: B.Pharm**

Semester: 8 **Date: 21/09/2022** **Time: 02:30 To 05:30** **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 **Elaborate the terms:** **(20)**

a) New drug
b) CDSCO
c) Purple Book
d) Regulatory authorities of Canada
e) WHO
f) Regulatory authorities of Australia
g) Functions of Ethics committee.
h) Pharmacovigilance
i) Safety monitoring in clinical trials
j) Master formula record.

Q-2 **Attempt any two of following :** **(20)**

A	Explain the approval process of timeline involved in Investigational New Drug.	**10**
B	Discuss about various stages of drug discovery	**10**
C	Explain the design in developing clinical trial protocols.	**10**

Q-3 **Attempt any Seven of following :** **(35)**

A	Describe the procedure for Generic drug approval from CDSCO in India.	**5**
B	Write a note on Preclinical studies	**5**
C	Explain the purpose and procedure for IND application to USFDA.	**5**
D	What is DMF? Write a note on type of DMF	**5**
E	Write a note on International Good Clinical Practices.	**5**
F	Write a note on investigator's brochure.	**5**
G	What is Common Technical Document? Describe various CTD modules	**5**
H	Explain the concept of generics & generic drug product development.	**5**
I	Explain the Orange Book features.	**5**