Enrollment No: _____ Exam Seat No:_____

C.U.SHAH UNIVERSITY
Summer Examination-2018

Subject Name: Drug Regulatory Aspects & IPR

Subject Code: 4PS08DRA1 **Branch:** B.Pharm

Semester: 8 **Date : 08/05/2018** **Time : 02:30 To 05:30** **Marks : 70**

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 **Define the following terms** **(14)**

a) e-CTD
b) Supplemental NDA
c) RLD
d) Orange book
e) Green book
f) Geographical Indication
g) Intellectual Property rights
h) Orphan drugs
i) Patent
j) Sponsor
k) Trade-Related Aspects of Intellectual Property Rights (TRIPS)
l) World Trade Organization (WTO)
m) The Intellectual Property Appellate Board (IPAB)
n) Center for Drug Evaluation and Research (CDER)

Attempt any four questions from Q-2 to Q-8

Q-2 **Attempt all questions** **(14)**

a. Explain various phases of Drug Development and Approval process as per USFDA **(7)**

b. What are the clinical trials? How are they organized as a part of drug discovery? **(7)**

Q-3 **Attempt all questions** **(14)**

a. Give the concept of ANDA & prepare flow chart showing ANDA review process **(7)**

b. Differentiate INDA and ANDA. Describe various type of INDA. **(7)**

Q-4 **Attempt all questions** **(14)**

a. Write a note on review process of NDA **(7)**

b. Explain in detail about Investigator Brochure **(7)**

Q-5 **Attempt all questions** **(14)**

a. Write a note on TGA. **(7)**

b. Write a note on IIG. **(7)**

Q-6		**Attempt all questions**	**(14)**
	a.	Explain the role of quality assurance.	**(7)**
	b.	Write a note on PCT application.	**(7)**
Q-7		**Attempt all questions**	**(14)**
	a.	Discuss patent analysis & patent drafting	**(7)**
	b.	Discuss Hatch-Waxman Amendments and its impact on Pharmaceutical industry.	**(7)**
Q-8		**Attempt all questions**	**(14)**
	a.	Explain non-patentable inventions as per Indian patent Act.	**(7)**
	b.	Define and explain the importance patent search. Discuss the different sources for patent search.	**(7)**