Enrollment No: _____ Exam Seat No:_____

C.U.SHAH UNIVERSITY

Summer Examination-2017

Subject Name: Drug Regulatory Aspects & IPR

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

Semester: 8 **Date : 26/04/2017** **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) Copyright
b) Product Recalls
c) Sponsor
d) Intellectual Property
e) Trade mark
f) Drug-patent linkage
g) Drug Information
h) Invention
i) Patent Drafting
j) Compulsory License
k) Center for Biologics Evaluation and Research
l) Process Analytical Technologies (PAT)
m) OTC Drugs
n) Dossier

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

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

a. Discuss the role of clinical trials and B.E. studies in a drug discovery. **(7)**
b. Discuss the phases of NDA. **(7)**

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

a. Explain the concept of ANDA and prepare the flow chart showing ANDA review process. **(7)**
b. Explain in detail about Investigator Brochure **(7)**

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

a. Write a introductory note on Orange Book? How changes to the orange book can be made? **(7)**
b. Explain the format and type of INDA. **(7)**

Q-5		**Attempt all questions**	**(14)**
	a.	What is CTD? Discuss structure of CTD. How does it differ from eCTD?	**(7)**
	b.	Discuss role of quality assurance.	**(7)**
Q-6		**Attempt all questions**	**(14)**
	a.	Write about TGA Administration.	**(7)**
	b.	Write about GMP audits.	**(7)**
Q-7		**Attempt all questions**	**(14)**
	a.	What is patent search? Explain importance of patent search and enumerate different sources for patent search.	**(7)**
	b.	Explain in detail about different types of claim.	**(7)**
Q-8		**Attempt all questions**	**(14)**
	a.	Write a note on Hatch-Waxman Amendments and its impact on Pharmaceutical industry	**(7)**
	b.	What is the objective of IIG? Explain general description of IIG.	**(7)**