Enrollment No: _____ Exam Seat No: _____

C.U.SHAH UNIVERSITY

Summer Examination-2017

Subject Name: Drug Regulatory Aspects & IPR
Subject Code: 5PS02DRI2 Branch: M.Pharm (Pharmaceutics, QA)

Semester: 2 Date: 02/05/2017 Time: 02:00 To 05:00 Marks: 70

Instructions:

(1) Use of Programmable calculator and 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.

SECTION – I

Q-1 **Define the following terms:** **(07)**

a. Pharmaceutical Equivalents **1**
b. Drug Master File **1**
c. Orange book **1**
d. Bio-equiavalence **1**
e. Orphan drug **1**
f. Stability **1**
g. Validation **1**

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

(a) What are the clinical trials? How are they organized as a part of drug discovery? **7**
(b) Explain in brief freedom of information (FOIA). **7**

OR

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

(a) Write a note on Post Marketing Surveillance. **7**
(b) Discuss Supplemental New Drug Application with recent examples. **7**

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

(a) Differentiate NDA and ANDA. Explain the concept of PARA I to IV filing. **7**
(b) Define CTD & eCTD. Explain modules of CTD. **7**

OR

Q-3 **Attempt all questions**

(a) Discuss role of CBER in USFDA. **7**
(b) What is TGA ? Discuss TGA's risk management approach. **7**

SECTION – II

Q-4 **Write the full form of following terms:** **(07)**

a. EMEA **1**
b. WIPO **1**
c. CDER **1**

	d.	TRIPS	**1**
	e.	IPR	**1**
	f.	IND	**1**
	g.	NDA	**1**
Q-5		**Attempt all questions**	**(14)**
	(a)	Describe the activity regulated by MHRA.	**7**
	(b)	Write a note on Hatch-Waxman Amendments and its impact on Pharmaceutical industry.	**7**
		OR	
Q-5		**Attempt all questions**	**(14)**
	(a)	Write a short note on patent drafting.	**7**
	(b)	Describe briefly the FDA Medicare Modernization Act, 2003 .	**7**
Q-6		**Attempt all questions**	**(14)**
	(a)	Write the general rules for PCT.	**7**
	(b)	Write a short note on patent licensing.	**7**
		OR	
Q-6		**Attempt all Questions**	**(14)**
	(a)	Give brief introduction of ANVISA and enlist various regulations covered by the said agency.	**7**
	(b)	Describe the benefits of IPRs to improve the quality of research work.	**7**