Enrollment No:-_____ Exam Seat No:-_____

C.U.SHAH UNIVERSITY

Summer-2015

Subject Code: 5PS02DRI2 **Subject Name: Drug Regulatory Aspects & IPR**

Course Name: M.Pharm (Pharmaceutics, QA) Date: 18/5/2015

Semester:II Marks:70

Time:10:30 TO 01:30

Instructions:

1) Attempt all Questions in same answer book/Supplementary.
2) Use of Programmable calculator & any other electronic instrument prohibited.
3) Instructions written on main answer book are strictly to be obeyed.
4) Draw neat diagrams & figures (if necessary) at right places.
5) Assume suitable & perfect data if needed.

SECTION – I

Q.1		Define the following terms: a) Copyright b) Green book c) Exclusive licence d) Patentee	 **2** **2** **2** **1**
Q.2	**(a)**	What is the need for Orange book? Suggest equivalence related terms and statistical criteria for bio-equivalence. How to use cumulative supplement?	**05**
	(b)	Differentiate IND, NDA and ANDA. Which are the four pillers for timely approval of NDAs/ ANDAs?	**05**
	(c)	Describe the policy on disclosure of FDA records. Explain partial disclosure of records.	**04**
		OR	
Q.2	**(a)**	What are clinical trials? How are they organized as a part of drug discovery process?	**05**
	(b)	Write in brief about IIG.	**05**
	(c)	Write a note on orphan drugs.	**04**
Q.3	**(a)**	Define patent. Explain in detail the different types of patent.	**05**
	(b)	Define the term invention. Write a note on non-patentable invention.	**05**
	(c)	Give a brief overview of websites that provide free information on patent.	**04**
		OR	
Q.3	**(a)**	How is SMF prepared for MCC guideline?	**05**
	(b)	Write a note on EMEA implementation of New EU Pharma. legislation.	**05**
	(c)	Write a note on export certificates as per MHRA. Discuss legal status and reclassification of medicinal products.	**04**

SECTION – II

Q.4		Define the following terms: a) Sponsor b) Investigator c) Appellate Board d) Budapest Treaty	**2** **2** **2** **1**
Q.5	**(a)**	Write a note on Drug Master File(DMF) in detail.	**05**
	(b)	Define CTD & eCTD. Explain modules of CTD.	**05**
	(c)	Discuss role of CBER in USFDA.	**04**
		OR	
Q.5	**(a)**	Discuss in detail TRIPS council.	**05**
	(b)	Explain the role of quality assurance.	**05**
	(c)	Write a note on child resistant container.	**04**
Q.6	**(a)**	Describe basic functions and steps for new drug registration at ANVISA.	**05**
	(b)	Describe Hatch Waxman Act and amendments.	**05**
	(c)	Describe various activity regulated by TGA.	**04**
		OR	
Q.6	**(a)**	Discuss FDA Medicare Modernization Act 2003.	**05**
	(b)	Describe package integrity tests for Parenterals. Write a note on packages for pediatrics and geriatrics.	**05**
	(c)	Write a note on Objections to overbroad intellectual property laws.	**04**