

GUJARAT TECHNOLOGICAL UNIVERSITY
M.PHARM - SEMESTER II- • EXAMINATION – WINTER-2016

Subject Code: 2920202**Date: 02/12/2016****Subject Name: Global Regulatory Requirements****Time: 10.30 am - 01.30 pm****Total Marks: 80****Instructions:**

1. Attempt any five questions.
2. Make suitable assumptions wherever necessary.
3. Figures to the right indicate full marks.

Q.1	(a)	What is process validation? Discuss the advantages and disadvantages of organizational structures for process validation.	06
	(b)	Write a note on ERP with advantages and disadvantages.	05
	(c)	Write a note on validation of Autoclave.	05
Q.2	(a)	Enumerate key parameters of the analytical method validation and discuss any two.	06
	(b)	Write a note on Enterprise Resource Planning (ERP) system.	05
	(c)	Write a note on computer system validation.	05
Q.3	(a)	What is the objective of IIG? Explain general description of IIG.	06
	(b)	Define 'Orange Book', 'Green Book' and 'Blue Book'. Explain statistical criteria for Bio-equivalence in context to orange book.	05
	(c)	What is DMF? Write a short note on Type-I DMF.	05
Q.4	(a)	Write a note on ANDA. Explain the concept of PARA I to IV filling.	06
	(b)	Mention the goals of NDA. Discuss the general requirements for filing NDA.	05
	(c)	Define and explain IND, stating its objectives.	05
Q.5	(a)	Write a note on Hatch-Waxman Amendments and its impact on pharmaceutical industry.	06
	(b)	Write a note on ANVISA.	05
	(c)	Write a note on Post Marketing Surveillance.	05
Q. 6	(a)	Define CTD & eCTD. Explain modules of CTD.	06
	(b)	Describe in brief about SUPAC guidelines for immediate release dosage forms.	05
	(c)	What is TGA? Discuss TGA's risk management approach.	05
Q.7	(a)	Write a note on MHRA.	06
	(b)	Explain various phases of Drug Development and Approval process as per USFDA.	05
	(c)	Describe evaluation of the stability data as per ICH guidelines.	05
