Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY M. Pharm. – SEMESTER – II • EXAMINATION – SUMMER • 2015

Subj	ect	Code: 2920208 Date: 16-05-2015	
Subj	ect 1	Name: Industrial Pharmacy - IV	
Time	: 10	0:30 am - 01:30 pm Total Marks: 80	
Instructions:			
	2.	Attempt any five questions. Make suitable assumptions wherever necessary. Figures to the right indicate full marks.	
Q.1	(a)	facing USFDA audit.	06
	(b) (c)		05 05
Q.2	(a)	Write a note on export certificates as per MHRA. Discuss legal status and Re-classification of medicinal products.	06
	(b) (c)		05 05
Q.3	(a) (b)		06 05
	(c)	•	05
Q.4	(a) (b) (c)	Write in brief about regulatory issues in Indian pharmaceutical industry.	06 05 05
Q.5	(a) (b) (c)	Write in detail of requirements of GLP.	06 05 05
Q.6	(a) (b) (c)	Write a note on statistical hypothesis testing.	06 05 05
Q.7	(a)	What is Orange Book? Give a brief discussion on therapeutic codes in Orange Book.	06
	(b) (c)		05 05
