Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY M. Pharm. – SEMESTER – II • EXAMINATION – SUMMER • 2014

Sub	ject	Code: 2920208Date: 31-05-2014Name: Industrial Pharmacy Paper - IVTotal Marks: 80	
Instr	uctio 1. 2.		
Q.1	(a)	What is compendia? How are they evoluated and have contributed in regularizing Pharma. Industry of different countries?	06
	(b)		05
	(c)	What are the commercial impact of pharmacopoeias specifications on patent and proprietary brands? Explain giving suitable example.	05
Q.2	(a)	What is validation? Explain it with respect to process validation and analytical method validation. Describe program to develop validation of Dissolution Apparatus.	06
	(b)		05
	(c)	Write a note on basic terms of precision, accuracy robustness of any assay method.	05
Q.3	(a) (b) (c)	Define orange book. Describe different equivalency codes. Describe various phases of drug development. What is the difference between DMF and SMF?	06 05 05
Q.4	(a)	Prepare flow chart of NDA and enlist different sections of it. Compare it with ANDA and cocept of Para I to IV filing.	06
	(b)	Categorize ICH activities. Enlist quality guideline with reference to stability data evaluation.	05
	(c)	What are basic functions of WHO? How are the herbal medicinal products regulated as per WHO?	05
Q.5	(a) (b)	Define CTD and e-CTD. Describe various modules of CTD. What USFDA does not regulate? How will you prepare docket for USFDA inspection of biotechnology derived products?	06 05
	(c)	What is SUPAC? Describe about SUPAC guideline for MR dosage products.	05
Q. 6	(a) (b)	What is MCC? How SMF is prepared as per guidelines of MCC? Why the computer system needs to be validated? How entrepreneur resource planning make use of computers?	06 05
	(c)	Describe structure and mission of EMEA?	05
Q.7	(a)	Explain the scope of TGA regulations in Indian companies for export. Discuss the guideline for OTC products to be exported as per TGA.	06
	(b)	Write a note on export certificates as per MHRA. Discuss the legal status and reclassification of medicinal products.	05
	(c)	Which medicines are not accepted as generics as per ANVISA?	05