Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – II • EXAMINATION – SUMMER • 2014

Subject Code: 2920208 Date: 31-05-2014

Subject Name: Industrial Pharmacy Paper - IV

Time: 02:30 pm - 05:30 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 compendia? How are they evoluated and have contributed in regularizing Pharma. Industry of different countries?	**06**
	(b)	What are general policies, notices, monographs and appendix contents of different pharmacopoeias? Give comparative picture on this in IP, BP, USP.	**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)	What is quality audit? Give the different aspects of ISO series, cGMP and WHO certification schemes with its comparative aspects.	**05**
	(c)	Write a note on basic terms of precision, accuracy robustness of any assay method.	**05**
Q.3	**(a)**	Define orange book. Describe different equivalency codes.	**06**
	(b)	Describe various phases of drug development.	**05**
	(c)	What is the difference between DMF and SMF?	**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)**	Define CTD and e-CTD. Describe various modules of CTD.	**06**
	(b)	What USFDA does not regulate? How will you prepare docket for USFDA inspection of biotechnology derived products?	**05**
	(c)	What is SUPAC? Describe about SUPAC guideline for MR dosage products.	**05**
Q. 6	**(a)**	What is MCC? How SMF is prepared as per guidelines of MCC?	**06**
	(b)	Why the computer system needs to be validated? How entrepreneur resource planning make use of computers?	**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**

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