GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. Semester – IIND Examination –June/July- 2011
Subject code: 920202
Subject Name: Global Regulatory Requirements

Date:04/07/2011   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)**	Explain CIP and SIP systems. What are the benefits of these systems? Briefly explain cleaning validation parameters.	**06**
	(b)	Write a note on validation of dry heat sterilizer.	**05**
	(c)	Differentiate prospective and retrospective validation.	**05**
Q.2	**(a)**	Explain the terms IQ, OQ and PQ. Discuss IQ and OQ parameters for a rotary tablet machine.	**06**
	(b)	Write a note on strategy for Analytical Method Development for a new formulation.	**05**
	(c)	What is Orange Book? Give a brief discussion on therapeutic codes in Orange Book.	**05**
Q.3	**(a)**	What are clinical trials? How are they organized as a part of drug discovery process?	**06**
	(b)	Write a note on IIG.	**05**
	(c)	Describe the policy on disclosure of FDA records. Explain partial disclosure of records.	**05**
Q.4	**(a)**	Differentiate NDA and ANDA. Explain the concept of PARA I to IV filing.	**06**
	(b)	Write a short note on CDER.	**05**
	(c)	What is SUPAC? Discuss SUPAC guidelines for modified release dosage forms with special reference to site changes.	**05**
Q.5	**(a)**	Discuss the WHO certification scheme for pharmaceutical products.	**06**
	(b)	Write a short note on ANVISA.	**05**
	(c)	Give the organization of ICH. What is the role of ICH in improving pharmaceutical product quality.	**05**
Q. 6	**(a)**	Explain the scope of USFDA regulations. Discuss the preparations required for facing USFDA audit.	**06**
	(b)	Write a short note on TGA.	**05**
	(c)	Write a short note on MHRA.	**05**
Q.7	**(a)**	What are ERP systems? Explain the advantages of implementation of ERP systems.	**06**
	(b)	Describe the salient features of SAP with reference to pharmaceutical industry.	**05**
	(c)	Write a note on computer system validation.	**05**

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