Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M.PHARM- SEM-I–EXAMINATION – JULY 2012

Subject code: 910204 Date: 07/07/2012

Subject Name: Good Manufacturing Practices and Good Laboratory Practices

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)	Write a note on vendor selection and certification.	**06**
	(b)	Discuss the general guideline for personnel selection, training and hygiene.	**05**
	(c)	Describe the maintenance of sterile area.	**05**
Q.2	(a)	Define SOPs. What are objectives of writing SOPs	**06**
	(b)	Write an SOP for any one equipment used in sterile area.	**05**
	(c)	Describe the factors affecting location and construction of pharmaceutical industry.	**05**
Q.3	(a)	Enlist the types of documents made in quality assurance department of pharmaceutical industry. What is specification and what information's it contains?	**06**
	(b)	Give the importance of documentation control in industry	**05**
	(c)	Give a standard format of master formula record.	**05**
Q.4	(a)	Write a note on Quality audit and self inspection in pharmaceutical industry.	**06**
	(b)	What are service facility available in pharmaceutical industry.	**05**
	(c)	Write a note on WHO certification scheme.	**05**
Q.5	(a)	Define GLP and OECD. Explain the key points in GLP.	**06**
	(b)	What is packing line clearance and reconciliation of label.	**05**
	(c)	What is quality control? Explain importance of quality control in pharma industry.	**05**
Q. 6	(a)	Write a note on sampling plan.	**06**
	(b)	How disposal of waste is carried out in pharmaceutical industry.	**05**
	(c)	Give a format of Batch Manufacturing Record for manufacture of Hard Gelatin Capsule.	**05**
Q. 7	(a)	What is IPQC? Explain IPQC test for tablet manufacture.	**06**
	(b)	Enlist the commonly used equipments in quality control dept. Explain any one equipment.	**05**
	(c)	Describe the control of contamination.	**05**

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