Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – I • EXAMINATION – WINTER • 2014

Subject Code: 910202 **Date: 09-01-2015**

Subject Name: Industrial Pharmacy Practice

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)**	Describe the equipments required in the manufacture of solid dosage forms as per Schedule-M.	**06**
	(b)	Discuss the objectives of production planning and materials control.	**05**
	(c)	Write SOP for cleaning & disinfection of the sterile area class 10,000 and class 100.	**05**
Q.2	**(a)**	Describe HVAC as utility service in pharmaceutical manufacturing.	**06**
	(b)	Write guidelines of SOP text for manufacturing or processing steps.	**05**
	(c)	What is dimensional analysis? How is it applied in scale up for pilot plant?	**05**
Q.3	**(a)**	Explain qualitative and quantitative departmental layout for Sterile dosage forms.	**06**
	(b)	Write in brief of layout of Pharmaceutical factory location.	**05**
	(c)	Write a note on Master Formula record.	**05**
Q.4	**(a)**	Write a note on inventory control.	**06**
	(b)	Enumerate types of documents. Describe the general guidelines to be followed for design and use of documents.	**05**
	(c)	Write in detail on Batch Manufacturing Record with suitable examples.	**05**
Q.5	**(a)**	Describe specific requirements for manufacturing of oral liquid dosage forms as per Schedule M.	**06**
	(b)	Explain the equipments required at the various stages of manufacturing of semi-solid dosage forms.	**05**
	(c)	Write a note on production planning and scheduling.	**05**
Q. 6	**(a)**	Describe In process quality control evaluation of each solid, semi solid and sterile dosage forms.	**06**
	(b)	Explain fluid bed processor with its application.	**05**
	(c)	Write significance and general requirements of pilot plant and manufacturing scale up techniques.	**05**
Q.7	**(a)**	Give a brief account of selection of Pharmaceutical factory location.	**06**
	(b)	Explain validation protocol and its contents.	**05**
	(c)	Discuss equipment in context to GMP.	**05**

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