Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. PHARM. - SEMESTER – I • EXAMINATION – WINTER 2012

Subject code: 910202 **Date: 11/01/2013**

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 factors to be considered in selection of location for pharmaceutical factory.	**06**
	(b)	Discuss personnel facilities required in pharmaceutical industry.	**05**
	(c)	Describe HVAC as utility service in pharmaceutical manufacturing.	**05**
Q.2	(a)	Describe departmental layout for semi solid dosage forms.	**06**
	(b)	Discuss the important factors for material selection in pharmaceutical plant construction.	**05**
	(c)	Enlist the equipments required for solid dosage forms. Describe fluidized bed drier	**05**
Q.3	(a)	Discuss the equipments required in manufacturing of oral liquid dosage forms as per schedule- M.	**06**
	(b)	Draw the layout of material flow in parenteral manufacturing department.	**05**
	(c)	Give a layout of manufacturing area for cosmetics.	**05**
Q.4	(a)	What is the significance of SOP? Describe the contents of SOP.	**06**
	(b)	What is clean in place? Write SOP for cleaning and disinfection of class 100 clean area.	**05**
	(c)	Write SOP for validation of moist heat sterilizer.	**05**
Q.5	(a)	Explain validation. Discuss the contents of validation protocol.	**06**
	(b)	What is documentation? Describe Batch Manufacturing Record.	**05**
	(c)	Discuss Batch Packing Record.	**05**
Q. 6	(a)	What is cGMP? Discuss its significance in pharmaceuticals in brief.	**06**
	(b)	What are the objectives of production planning and material control?	**05**
	(c)	Write about inventory control of raw materials.	**05**
Q.7	(a)	Discuss the parameters to be considered in tablet coating process scale up.	**06**
	(b)	Write in brief about SUPAC-IR.	**05**
	(c)	Discuss process scale up with different types of batches.	**05**

****