Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: 910108 Date: 07-01-2015

Subject Name: Industrial Pharmacy - I

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 various factors affecting the selection of a pharmaceutical factory location.	**06**
	(b)	Describe the components of vacuum systems. Give the applications of vacuum conveying systems.	**05**
	(c)	Enumerate methods for manufacturing WFI. Draw a water system plant used in a pharmaceutical industry.	**05**
Q.2	(a)	Give the significance of HVAC systems in a pharmaceutical industry. Describe the functions of plenum and blower in a HVAC system.	**06**
	(b)	Highlight the difference between qualitative and quantitative layout. Prepare a quantitative layout of tablet department.	**05**
	(c)	Discuss the selection criteria for a mixer used for mixing powders before granulation in a tablet department.	**05**
Q.3	(a)	Describe in brief the equipments used in a parenteral department.	**06**
	(b)	Enlist the equipments and area requirement for Oral Liquid department as per Schedule M. Explain bottle filling machine.	**05**
	(c)	Enlist the equipments and area requirement for tablet department as per Schedule M. Explain tablet de-duster.	**05**
Q.4	(a)	Define BMR. Design a BMR for liquid syrup product with suitable example.	**06**
	(b)	Write a note on Batch Packing Record.	**05**
	(c)	Describe the validation protocol for steam sterilizer.	**05**
Q.5	(a)	What is the importance of SOP? What information is contained in an SOP? Design an SOP for Fluid Bed Dryer.	**06**
	(b)	Design an SOP for cleaning a mixing tank.	**05**
	(c)	Write a note on disposal of waste in pharmaceutical industry.	**05**
Q. 6	(a)	Explain the terms: PAT, CIP, and SIP.	**06**
	(b)	Write a note on Quality Audit.	**05**
	(c)	Discuss warehouse design and material management.	**05**
Q.7	(a)	Describe In Process Quality Control for parenteral products.	**06**
	(b)	Explain “Line clearance”. Describe reconciliation of labels.	**05**
	(c)	Discuss cGMP guidelines for Quality Control.	**05**

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