Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject code: 910108 **Date: 09/01/2013**

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)	Describe the qualitative and quantitative departmental layout for tablet dosage form.	06
	(b)	Preparation of SOP for sterile packaging.	05
	(c)	How is documentation for raw material specification done?	05
Q.2	(a)	Give a brief account of selection of Pharmaceutical factory location.	06
	(b)	What do you understand by SOP? Write in brief its significance under GMP.	05
	(c)	What are essential utility services in a pharmaceutical factory?	05
Q.3	(a)	Write a note on schedule M for GMP.	06
	(b)	Write SOP for operation of fluid bed dryer.	05
	(c)	Describe various blenders used in pharmaceutical industry.	05
Q.4	(a)	Explain GMP, cGMP and FDA in pharmaceutical industry.	06
	(b)	Write SOP for validation of an autoclave.	05
	(c)	Write a short note on: GMP & its implementation for Active Pharmaceutical Ingredients.	05
Q.5	(a)	What are the objectives of SOP? Explain format, writing style and content of SOP.	06
	(b)	Describe HVAC and its pharmaceutical importance.	05
	(c)	Write a note on ABC concept.	05
Q. 6	(a)	Describe the parameters to be considered during the scale up of Tablet Coating.	06
	(b)	Explain inventory control with example.	05
	(c)	What do you understand by validation? Give types of validation.	05
Q.7	(a)	Describe objectives, similarity consideration and development cycle in pilot-plan and scale-up technique.	06
	(b)	Explain qualitative and quantitative departmental layout for semisolid dosage forms.	05
	(c)	What is validation protocol? Describe contents of validation protocol.	05

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