

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
