Seat No.: _____ **Enrolment No._____**

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm Semester –I Examination Feb. - 2012

Subject code: 910108 **Date: 13/02/2012**

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)	Enlist the factors to be considered while selecting a site for Pharma. Plant.	**06**
	(b)	Draw a simple layout of Pharma. Production plant along with F & D section. Write a note on personal facilities.	**05**
	(c)	What do you mean by utility services? Enlist them and write a note on any one of them in brief.	**05**
Q.2	(a)	What do you mean by qualitative and quantitative layout for dosage form production?	**06**
	(b)	Draw the flow-sheet of semi-solid dosage form manufacturing	**05**
	(c)	Discuss the selection criteria of material for plant construction, equipment design and capacity of it as per schedule M.	**05**
Q.3	(a)	Suggest important criteria to be incorporated in layout, equipment, process and documents to manufacture PVP-I_2 aerosol spray.	**06**
	(b)	What are the standards for powders? Classify them and suggest a list of equipments for manufacture of powder.	**05**
	(c)	Explain BMR,BPR and SOP for effervescent Powder	**05**
Q.4	(a)	Explain the role of HVAC system in phrama.plant.	**06**
	(b)	Discuss in brief the different components and their functions in HVAC system.	**05**
	(c)	Write a note on water contaminants and validation of water system.	**05**
Q.5	(a)	Discuss the layout, equipments, Q.C., BMR., BPR., & SOP for nicotine patch.	**06**
	(b)	What is ISO 14644?	**05**
	(c)	How GMP does differ from cGMP?	**05**
Q. 6	(a)	What is Good Purchase Practice? , in the context of GMP program, Discuss the raw material and finished goods store.	**06**
	(b)	What is quality audit? How does the process of it is carried out?	**05**
	(c)	What are GMP specifications for labeling and packaging control?	**05**
Q.7	(a)	Define 'Control'. Discuss about GLP practices.	**06**
	(b)	Write a note on distribution records.	**05**
	(c)	Write a procedure for complains and recalls.	**05**

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