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

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm Semester –I Examination Feb. - 2012

Subject code: 910202 **Date: 15/02/2012**

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)	Discuss the factors affecting the location of a pharmaceutical industry.	**06**
	(b)	Describe the service facilities for a pharmaceutical industry.	**05**
	(c)	Write a note on: HVAC.	**05**
Q.2	(a)	Describe the qualitative and quantitative departmental layout for tablet dosage form.	**06**
	(b)	Draw the layout of material flow in parenteral production department**.**	**05**
	(c)	Write a not on: BMR and BPR for manufacturing of parenteral dosage forms.	**05**
Q.3	(a)	Classify dryers for a tablet department and describe fluid bed dryer in detail.	**06**
	(b)	Describe various parameters to be validated for sterilization of parenteral dosage forms.	**05**
	(c)	Write a note on: Plate-Frame filter press.	**05**
Q.4	(a)	Write SOP for operation of fluid bed dryer.	**06**
	(b)	Write SOP for cleaning & disinfection of the sterile area class 10,000 and class 100.	**05**
	(c)	Write SOP for validation of an autoclave.	**05**
Q.5	(a)	Discuss the specific requirements for manufacture of Metered Dose Inhalers (MDI) as per GMPs regulations.	**06**
	(b)	What is production planning and control? Describe the types and advantages of planning.	**05**
	(c)	Write a note on: Comparison of GMPs of different countries.	**05**
Q. 6	(a)	Discuss the objectives of production planning and materials control.	**06**
	(b)	What is importance of documentation and records in GMP?	**05**
	(c)	Write a short note on: GMP & its implementation for Active Pharmaceutical Ingredients.	**05**
Q.7	(a)	Describe the parameters to be considered during the scale up of Tablet Coating.	**06**
	(b)	Discuss various types of batches in scale up process development.	**05**
	(c)	How scalability can be improved in pharma processes?	**05**

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