Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – I • EXAMINATION – WINTER • 2015

Subject Code: 910108 **Date: 31-12-2015**

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)	Discuss the factors affecting the location of a pharmaceutical industry.	**06**
	(b)	Describe HVAC in details.	**05**
	(c)	Enlist the service facilities for a pharmaceutical industry and discuss about water facilities in brief.	**05**
Q.2	(a)	Describe qualitative and quantitative pharma departmental layout for tablet dosage form.	**06**
	(b)	Explain departmental layout for pharma liquid orals.	**05**
	(c)	What points are to be considered while preparing layout for semisolids.	**05**
Q.3	(a)	Describe rapid mixer granulator in details.	**06**
	(b)	Classify the dryers used for a tablet department.	**05**
	(c)	Write a not on: Chilsonator.	**05**
Q.4	(a)	Explain BMR with suitable examples.	**06**
	(b)	Write a not on BPR for tablet dosage forms.	**05**
	(c)	Describe various parameters to be validated for sterilization of parenteral dosage forms.	**05**
Q.5	(a)	Describe the SOP for cleaning and disinfection of sterile area class 100.	**06**
	(b)	Write a note on: SOP for operation of fluid bed dryer.	**05**
	(c)	i. Enumerate the objectives of SOP giving suitable examples. ii. Comment: Effluent treatment plant should be outside the pharma unit.	**05**
Q. 6	(a)	Describe the requirements for pharma building and premises as per GMP.	**06**
	(b)	Discuss the quality audits for manufacturing processes and facilities.	**05**
	(c)	Write a note on: Product Recalls as per GMP.	**05**
Q.7	(a)	Describe the specific requirements for manufacture of sterile products, parenteral preparations and sterile ophthalmic preparations.	**06**
	(b)	Write a note on: Reprocessing and Recoveries as per GMP.	**05**
	(c)	i. Enumerate the factors affecting the pharma equipment design. ii. Enlist the minimum equipments required in manufacturing of any one dosage form.	**05**

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