Seat No.: _____ *Enrolment No._____*

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. IST Semester Examination – June- 2011
Subject code: 910202
Subject Name: Industrial Pharmacy Practice

Date:24/06/2011 **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)**	Give a layout of batch manufacturing records in general.	**06**
	(b)	How is documentation for raw material specification done?	**05**
	(c)	Give batch packing record of parenterals.	**05**
Q.2	**(a)**	Compare Indian GMP and cGMP of USA	**06**
	(b)	Write in brief on personnel employed under GMP.	**05**
	(c)	What do you understand by SOP? Write in brief its significance under GMP.	**05**
Q.3	**(a)**	Give a brief account of selection of Pharmaceutical factory location.	**06**
	(b)	Write on Medical Services, Protective clothing, and Food Facilities provided to workers in pharmaceutical factory.	**05**
	(c)	What are essential utility services in a pharmaceutical factory?	**05**
Q.4	**(a)**	Write on distribution in details under cGMP.	**06**
	(b)	Give ICH guidelines on specifications for impurities in laboratory control under cGMP.	**05**
	(c)	How is stability testing performed under cGMP?	**05**
Q.5	**(a)**	Write on specific requirements for manufacturing of oral solid dosage forms keeping in view Schedule M.	**06**
	(b)	What are the provisions for plant and equipments for semi-solid preparations under schedule M.	**05**
	(c)	What do you understand by validation? Give types of validation.	**05**
Q. 6	**(a)**	Write in details on Material Control.	**06**
	(b)	Give techniques of inventory control.	**05**
	(c)	Give a layout of cosmetic manufacturing area.	**05**
Q.7	**(a)**	Write Short Note on Validation of Aerosols OR Water for Pharmaceutical use.	**06**
	(b)	Write Short Note on Equipments used in Sterile Manufacturing. OR Sanitation in manufacturing premises	**05**
	(c)	Write Short Note on Different Equipments for coating of Tablets. OR Labelling requirements for biological products	**05**

****