Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER I • EXAMINATION – SUMMER -2018

Subject Code: 910202 **Date: 07/05/2018**

Subject Name: Industrial Pharmacy Practice

Time: 02:30PM TO 05:30PM **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)**	Prepare departmental layout with equipment required for liquid orals.	**06**
	(b)	Give a layout of cosmetic manufacturing area.	**05**
	(c)	Describe sanitation facility services in pharmaceutical premise.	**05**
Q.2	**(a)**	Enlist the objectives of SOP. Explain format, writing style and content of SOP.	**06**
	(b)	Give SOP for rotary tablet machine.	**05**
	(c)	Describe the cGMP requirements for laboratory records and reports.	**05**
Q.3	**(a)**	Describe objectives of scale-up techniques. Write a note on pilot plant operation.	**06**
	(b)	Enlist equipments used for granulation process. Explain RMG.	**05**
	(c)	What is cross contamination? Describe methods to control cross contamination.	**05**
Q.4	**(a)**	Enlist and discuss selection criterion for pharmaceutical industry location.	**06**
	(b)	Discuss inventory control giving suitable examples.	**05**
	(c)	Give full form of BMR and BPR. Discuss its significance in manufacturing of parenteral dosage forms.	**05**
Q.5	**(a)**	Enlists merits and demerits of cGMP guideline of India.	**06**
	(b)	Write note on HVAC in pharmaceutical factory.	**05**
	(c)	Describe the parameters to be considered during the scale up of tablet Coating.	**05**
Q. 6	**(a)**	Discuss personnel facilities required in pharmaceutical industry.	**06**
	(b)	Discuss the important factors for material selection in pharmaceutical plant construction.	**05**
	(c)	Describe the documentation required for batch release.	**05**
Q.7	**(a)**	Explain qualitative and quantitative departmental layout for Sterile dosage forms.	**06**
	(b)	Write a note on Master Formula record	**05**
	(c)	Explain validation protocol and its contents.	**05**

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