Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – I • EXAMINATION – SUMMER 2016

Subject Code: 910202 **Date:30/05/2016**

Subject Name: Industrial Pharmacy Practice

Time: 10:30 AM to 1:30 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 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.2	**(a)**	Define validation. Discuss various types of validation.	**06**
	(b)	Discuss importance of HVAC facilities for pharmaceutical industry.	**05**
	(c)	Enlist and discuss essential utility services in a pharmaceutical factory?	**05**
Q.3	**(a)**	Define the term contamination and cross-contamination. Describe the methods used for contamination control.	**06**
	(b)	Define production planning. Explain various procedures used for production planning.	**05**
	(c)	Discuss departmental layout for semi solid dosages forms.	**05**
Q.4	**(a)**	Discuss specific requirements for manufacturing of oral solid dosage forms keeping in view Schedule M.	**06**
	(b)	Discuss criterion to be considered for scale up of tablet dosage forms.	**05**
	(c)	Discuss importance of water systems in the pharmaceutical industry.	**05**
Q.5	**(a)**	Enlist the objectives of SOP. Explain format, writing style and content of SOP.	**06**
	(b)	Discuss documentation for rejected and recalled goods.	**05**
	(c)	Write a note on GMP requirements of labeling.	**05**
Q. 6	**(a)**	Enlists merits and demerits of cGMP guideline of India.	**06**
	(b)	Discuss on Medical Services and Food Facilities provided to workers in Pharmaceutical factory.	**05**
	(c)	Discuss ICH guidelines on specifications for impurities in laboratory control under cGMP.	**05**
Q.7	**(a)**	Enlist different equipments used in tablet coating and explain in brief about FBD.	**06**
	(b)	Discuss role of GMP in employment of personnel.	**05**
	(c)	Define the term pilot plant. Describe pilot plant operation.	**05**

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