Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm – SEMESTER – I • EXAMINATION – WINTER -2016

Subject Code: 910202 Date: 04/01/2017

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 about equipments required as per Schedule M for manufacturing of semisolid dosage forms.	**06**
	(b)	Discuss importance of personnel facilities in pharmaceutical factory.	**05**
	(c)	Write a note on Batch manufacturing records for tablet dosage form.	**05**
Q.2	**(a)**	Discuss criteria for selection of pharmaceutical manufacturing plant location.	**06**
	(b)	Differentiate qualitative and quantitative departmental layout plan.	**05**
	(c)	Describe significance HVAC facilities in pharmaceutical premises.	**05**
Q.3	**(a)**	Define SOP and its contents. Describe model SOP for dissolution apparatus.	**06**
	(b)	Discuss departmental layout and manufacturing steps for ophthalmic dosage form.	**05**
	(c)	Describe validation protocol for cleaning process.	**05**
Q.4	**(a)**	Describe objectives of scale-up techniques. Write a note on pilot plant operation.	**06**
	(b)	Write a note on batch packaging records.	**05**
	(c)	What is cross contamination? Describe methods to control cross contamination.	**05**
Q.5	**(a)**	What is production planning? Suggest organization chart and functions of Production planning and material control.	**06**
	(b)	Explain importance of good documentation. Enumerate types of documents required as per WHO GMP guidelines.	**05**
	(c)	Explain any one equipment required in manufacture of liquid dosage forms as per schedule-M	**05**
Q. 6	**(a)**	Suggest department layout with equipments required for preparation of capsule dosage form.	**06**
	(b)	Describe importance of self inspection and quality audit as per GMP.	**05**
	(c)	Describe scale up consideration for liquid dosage form.	**05**
Q.7	**(a)**	Write a note on material control in pharmaceutical industry.	**06**
	(b)	Enlist equipments used for granulation process. Explain RMG.	**05**
	(c)	Describe sanitation facility services in pharmaceutical premise.	**05**

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