Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – I • EXAMINATION – SUMMER 2013

Subject Code: 910208 **Date: 22-05-2013**

Subject Name: Industrial Pharmacy II

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 significance and general requirements for Pilot plant and scale-up of Tablet Dosage form.	**06**
	(b)	Explain formulation scale-up of Oral liquid from F&D to Ind. Mfg.	**05**
	(c)	Discuss stability aspects of soft gel capsules during mfg. scale-up.	**05**
Q.2	**(a)**	Explain with example production scheduling and forecasting.	**06**
	(b)	Discuss the documents for manufacturing of injectables.	**05**
	(c)	Discuss the vendor development capacity assessment for raw materials to be used in semi-solid dosage forms.	**05**
Q.3	**(a)**	Define Inventory. Discuss modern inventory management and its evaluation.	**06**
	(b)	Define EOQ. Discuss advantages and limitations of this system. How will you dispose expiry dated inventory?	**05**
	(c)	Compare various methods and models for selective inventory	**05**
Q.4	**(a)**	Formulation based scaling-up of liquid oral may not result in required out put at industrial mfg- Comment on this.	**06**
	(b)	Pilot plant and industrial scale equipments does not create any problem with the equipment design. How will you justify this with respect to Semi-solid dosage form?	**05**
	(c)	NDDS products reports problems in product uniformity and stability compared to conventional dosage forms while scaling up: why?	**05**
Q.5	**(a)**	Sales forecasting and production planning is important management tools. Discuss its effect on costing of the product.	**06**
	(b)	Documents help in assessing the capacity of vendors, discuss this on various fronts in production planning giving suitable example.	**05**
	(c)	Expansion in a running production facility is really challenged in Pharma industry. Initial investment vs profit diversion compare pros & cons of this aspect.	**05**
Q. 6	**(a)**	What do you mean by material handling systems? Describe any one of them for Pharma industry.	**06**
	(b)	Classify Maintenance systems. How will it be useful in Pharma industry in order to follow cGMP?	**05**
	(c)	Environmental maintenance is a backbone of a quality. Comment on HVAC system on this aspect.	**05**
Q.7	**(a)**	Classify Industrial hazards and preventive measure for any one of them.	**06**
	(b)	How will you analyze the effluents in general and treat them before disposal as per government requirement ?	**05**
	(c)	Health hazard prevention and GMP development for manufacturing: Discuss giving suitable example.	**05**

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