

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.

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| 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 |
