

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY
M. Pharm. – SEMESTER – I • EXAMINATION – WINTER • 2014

Subject Code: 910208

Date: 09-01-2015

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) | What is pilot plant? Give its significance and general requirements.
Discuss Scale-up technique for Large Volume Parenterals | 06 |
| | (b) | Write a short note on technology transfer for coated tablets. | 05 |
| | (c) | Discuss the stability aspects of Hard capsules on pilot scale to regular manufacturing batches. | 05 |
| Q.2 | (a) | How PPMC department functions in Pharma Mfg. Plant. | 06 |
| | (b) | What do you mean by matrixing and bracketing technique? | 05 |
| | (c) | Write a note on sales forecasting and production scheduling. | 05 |
| Q.3 | (a) | Describe basic classification of GMP norms. | 06 |
| | (b) | Write a note on importance of documents and how does it help in reducing cost of Pharma Product. | 05 |
| | (c) | Which parameters are important while scaling up NDDS product compared to conventional dosages? How will you make them cost effective? | 05 |
| Q.4 | (a) | Define EOQ for inventory and discuss it graphically. | 06 |
| | (b) | What do you mean by selection inventory control? Write a note on modern inventory management systems. | 05 |
| | (c) | How the value analysis of material is carried out? | 05 |
| Q.5 | (a) | Classify maintenance systems of material handling equipments and describe any one of them. | 06 |
| | (b) | How will you rely on documents of HVAC system maintenance? | 05 |
| | (c) | How will you dispose expiry/surplus inventory? | 05 |
| Q. 6 | (a) | Classify industrial hazards and discuss the handling technique of one of them. | 06 |
| | (b) | Define BOD and COD. Discuss to monitor and control it in pharma. plant | 05 |
| | (c) | What do you mean by accident? How will you prevent it? | 05 |
| Q.7 | (a) | Write a SOP for any one dosage form with aspects to safety during life period of product. | 06 |
| | (b) | Write about maintenance program of some dosage form involving various systems in order to follow up cGMP. | 05 |
| | (c) | How will you determine the physico-chemical properties of effluent in pharma plant? | 05 |
