

GUJARAT TECHNOLOGICAL UNIVERSITY**M. Pharm. – SEMESTER – I • EXAMINATION – SUMMER • 2015****Subject Code: 910108****Date: 21-05-2015****Subject Name: Industrial Pharmacy-I****Time: 02:30 pm to 05:30 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 the factors to be considered while selecting a location for pharmaceutical factory. | 06 |
| | (b) | Explain HVAC giving its importance. | 05 |
| | (c) | Write a note on water systems in pharmaceutical industry. | 05 |
| Q.2 | (a) | Explain the layout of material flow in parenteral production department. | 06 |
| | (b) | Write a note on schedule M for tablet manufacturing unit. | 05 |
| | (c) | Define production planning and explain various procedures used for production planning. | 05 |
| Q.3 | (a) | Explain BMR with suitable examples. | 06 |
| | (b) | Explain documentation of rejected and recalled goods. | 05 |
| | (c) | Describe the validation of tunnel sterilizer. | 05 |
| Q.4 | (a) | Describe the cGMP requirements for laboratory records and reports. | 06 |
| | (b) | Write SOP for cleaning and disinfection of the sterile area for class 10,000 and class 100. | 05 |
| | (c) | Give ICH guidelines on specifications for impurities in laboratory control under cGMP. | 05 |
| Q.5 | (a) | Describe objectives of scale up techniques. Explain scale up consideration for semisolid dosage forms. | 06 |
| | (b) | Explain GMP guidelines for packaging and labeling controls. | 05 |
| | (c) | Explain validation protocol and its contents. | 05 |
| Q. 6 | (a) | Explain inventory management and economic order quantity. | 06 |
| | (b) | Write about inventory control of raw materials. | 05 |
| | (c) | Write a note on ABC concept. | 05 |
| Q.7 | (a) | Explain in processes quality control tests for sterile dosage forms. | 06 |
| | (b) | Give a layout of manufacturing area for cosmetics. | 05 |
| | (c) | How scalability can be improved in pharma processes? | 05 |
