

GUJARAT TECHNOLOGICAL UNIVERSITY
M. PHARM. - SEMESTER – I • EXAMINATION – WINTER 2012

Subject code: 910202**Date: 11/01/2013****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.

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| Q.1 | (a) Describe the factors to be considered in selection of location for pharmaceutical factory. | 06 |
| | (b) Discuss personnel facilities required in pharmaceutical industry. | 05 |
| | (c) Describe HVAC as utility service in pharmaceutical manufacturing. | 05 |
| Q.2 | (a) Describe departmental layout for semi solid dosage forms. | 06 |
| | (b) Discuss the important factors for material selection in pharmaceutical plant construction. | 05 |
| | (c) Enlist the equipments required for solid dosage forms. Describe fluidized bed drier | 05 |
| Q.3 | (a) Discuss the equipments required in manufacturing of oral liquid dosage forms as per schedule- M. | 06 |
| | (b) Draw the layout of material flow in parenteral manufacturing department. | 05 |
| | (c) Give a layout of manufacturing area for cosmetics. | 05 |
| Q.4 | (a) What is the significance of SOP? Describe the contents of SOP. | 06 |
| | (b) What is clean in place? Write SOP for cleaning and disinfection of class 100 clean area. | 05 |
| | (c) Write SOP for validation of moist heat sterilizer. | 05 |
| Q.5 | (a) Explain validation. Discuss the contents of validation protocol. | 06 |
| | (b) What is documentation? Describe Batch Manufacturing Record. | 05 |
| | (c) Discuss Batch Packing Record. | 05 |
| Q.6 | (a) What is cGMP? Discuss its significance in pharmaceuticals in brief. | 06 |
| | (b) What are the objectives of production planning and material control? | 05 |
| | (c) Write about inventory control of raw materials. | 05 |
| Q.7 | (a) Discuss the parameters to be considered in tablet coating process scale up. | 06 |
| | (b) Write in brief about SUPAC-IR. | 05 |
| | (c) Discuss process scale up with different types of batches. | 05 |
