

GUJARAT TECHNOLOGICAL UNIVERSITY**M. Pharm. – SEMESTER – I • EXAMINATION – SUMMER • 2015****Subject code: 910202****Date: 25-05-2015****Subject Name: Industrial Pharmacy Practice****Time: 02:30 pm - 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) Describe the factors affecting the location of a pharmaceutical industry. | 06 |
| | (b) Discuss personnel facilities required in pharmaceutical industry. | 05 |
| | (c) Write note on HVAC in pharmaceutical factory. | 05 |
| Q.2 | (a) Describe departmental layout for oral liquid dosage forms. | 06 |
| | (b) Discuss the important factors for material selection in pharmaceutical plant construction. | 05 |
| | (c) Enlist the equipments required for semisolid dosage forms. Describe planetary mixer. | 05 |
| Q.3 | (a) Discuss the equipments required in manufacturing of oral solid dosage forms as per schedule- M. | 06 |
| | (b) Write in brief about equipments used in sterile manufacturing. | 05 |
| | (c) Give a layout of manufacturing area for cosmetics. | 05 |
| Q.4 | (a) Describe the contents of SOP. What is the significance of SOP? | 06 |
| | (b) Describe the preparation of SOP for sterile manufacturing. | 05 |
| | (c) What is documentation? Describe Batch Packaging Record. | 05 |
| Q.5 | (a) What is validation? Discuss the contents of validation protocol. | 06 |
| | (b) What is clean in place? How cleaning validation is carried out? | 05 |
| | (c) Describe the significance of training in pharmaceutical industry. | 05 |
| Q. 6 | (a) What is cGMP? What is its significance in pharmaceutical manufacturing? | 06 |
| | (b) Discuss routing and scheduling with respect to production planning. | 05 |
| | (c) Enumerate methods for inventory control. Describe EOQ method. | 05 |
| Q.7 | (a) Discuss the scale up for tablet coating process. | 06 |
| | (b) Describe the documentation required for batch release. | 05 |
| | (c) What is SUPAC SS? Describe different levels of changes in MR formulations. | 05 |
