

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

Subject code: 910108**Date: 09/01/2013****Subject Name: Industrial Pharmacy - I****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 qualitative and quantitative departmental layout for tablet dosage form. | 06 |
| | (b) | Preparation of SOP for sterile packaging. | 05 |
| | (c) | How is documentation for raw material specification done? | 05 |
| Q.2 | (a) | Give a brief account of selection of Pharmaceutical factory location. | 06 |
| | (b) | What do you understand by SOP? Write in brief its significance under GMP. | 05 |
| | (c) | What are essential utility services in a pharmaceutical factory? | 05 |
| Q.3 | (a) | Write a note on schedule M for GMP. | 06 |
| | (b) | Write SOP for operation of fluid bed dryer. | 05 |
| | (c) | Describe various blenders used in pharmaceutical industry. | 05 |
| Q.4 | (a) | Explain GMP, cGMP and FDA in pharmaceutical industry. | 06 |
| | (b) | Write SOP for validation of an autoclave. | 05 |
| | (c) | Write a short note on: GMP & its implementation for Active Pharmaceutical Ingredients. | 05 |
| Q.5 | (a) | What are the objectives of SOP? Explain format, writing style and content of SOP. | 06 |
| | (b) | Describe HVAC and its pharmaceutical importance. | 05 |
| | (c) | Write a note on ABC concept. | 05 |
| Q. 6 | (a) | Describe the parameters to be considered during the scale up of Tablet Coating. | 06 |
| | (b) | Explain inventory control with example. | 05 |
| | (c) | What do you understand by validation? Give types of validation. | 05 |
| Q.7 | (a) | Describe objectives, similarity consideration and development cycle in pilot-plan and scale-up technique. | 06 |
| | (b) | Explain qualitative and quantitative departmental layout for semisolid dosage forms. | 05 |
| | (c) | What is validation protocol? Describe contents of validation protocol. | 05 |
