

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – I • EXAMINATION – WINTER 2013

Subject Code: 910202

Date: 26-12-2013

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) | What are the objectives of a pilot plant? Explain scale up for tablet dosage form. | 06 |
| | (b) | Explain cGMP requirements for records and reports. | 05 |
| | (c) | Write a note on label reconciliation. | 05 |
| Q.2 | (a) | Define SOP. What are the objectives of SOP? Give ideal requirements for SOP preparation. | 06 |
| | (b) | Prepare a SOP for operation of digital weighing balance. | 05 |
| | (c) | Prepare an SOP for operation of Disintegration test machine. | 05 |
| Q.3 | (a) | Draw a neat sketch of RMG. Enlist the Installation qualifications (IQ) and Operation qualifications (OQ) for RMG. | 06 |
| | (b) | Write a note on validation of dry heat sterilizer. | 05 |
| | (c) | What is the importance of production planning? Give methods for inventory control. Using suitable example, explain the production planning for a product. | 05 |
| Q.4 | (a) | Discuss factors affecting selection of site for a pharmaceutical industry. | 06 |
| | (b) | Enlist utility services in required in pharmaceutical industry. Explain the production and distribution of steam. | 05 |
| | (c) | “Personnel are a key factor in preventing contamination.” Explain the statement giving examples. | 05 |
| Q.5 | (a) | Highlight the importance of HVAC in the pharmaceutical industry. Describe the function and use of blower and ducts in HVAC system. | 06 |
| | (b) | Give a list of equipments required to set up a liquid oral manufacturing department giving functions of each. | 05 |
| | (c) | Define Schedule M. Explain DeMineralized (DM) water plant. | 05 |
| Q. 6 | (a) | Draw a process flow sheet for ointment manufacturing. Describe ointment filling machine. | 06 |
| | (b) | Enlist documents required for parenteral manufacturing. | 05 |
| | (c) | Write a note on Batch Processing Record (BPR). | 05 |
| Q.7 | (a) | Draw a qualitative and quantitative layout for tablet department. | 06 |
| | (b) | Write a note on AutoCoater. | 05 |
| | (c) | A market sample of tablet product of a company has been found of substandard quality. Carry out an audit to find out the reasons of failure. | 05 |
