| Seat 1 | No.: _            | Enrolment No   |                |
|--------|-------------------|--|----------------|
|        |                   | GUJARAT TECHNOLOGICAL UNIVERSITY   |                |
|        |                   | M. Pharm. – SEMESTER – I • EXAMINATION – WINTER 2013   |                |
| Subj   | ject (            | Code: 910202 Date: 26-12-2013  |                |
| Subj   | ject I            | Name: Industrial Pharmacy Practice   |                |
|        |                   | .30 am - 01.30 pm Total Marks: 80  |                |
| Instr  |                   |  |                |
|        | 2.                | Attempt any five questions.  Make suitable assumptions wherever necessary.  Figures to the right indicate full marks.  |                |
| Q.1    | (a)               | What are the objectives of a pilot plant? Explain scale up for tablet dosage form.   | 06             |
|        | (b)<br>(c)        | Explain cGMP requirements for records and reports. Write a note on label reconciliation.   | 05<br>05       |
| Q.2    | (a)               | Define SOP. What are the objectives of SOP? Give ideal requirements for SOP preparation.   | 06             |
|        | (b)<br>(c)        | Prepare a SOP for operation of digital weighing balance. Prepare an SOP for operation of Disintegration test machine.  | 05<br>05       |
| Q.3    | (a)               | Draw a neat sketch of RMG. Enlist the Installation qualifications (IQ) and Operation qualifications (OQ) for RMG.  | 06             |
|        | (b)<br>(c)        | Write a note on validation of dry heat sterilizer. What is the importance of production planning? Give methods for inventory control. Using suitable example, explain the production planning for a product.                               | 05<br>05       |
| Q.4    | (a)<br>(b)        | Discuss factors affecting selection of site for a pharmaceutical industry.<br>Enlist utility services in required in pharmaceutical industry. Explain the production and distribution of steam.  | 06<br>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>(b)</b>        | Give a list of equipments required to set up a liquid oral manufacturing department giving functions of each.  | 05             |
|        | <b>(c)</b>        | 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)<br>(c)        | Enlist documents required for parenteral manufacturing. Write a note on Batch Processing Record (BPR).   | 05<br>05       |
| Q.7    | (a)<br>(b)<br>(c) | Draw a qualitative and quantitative layout for tablet department. Write a note on AutoCoater. 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. | 06<br>05<br>05 |

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