

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharmacy Sem-I Regular / Remedial Examination January/February 2011

Subject code: 910202

Subject Name: Industrial Pharmacy

Date: 03 /02 /2011

Time: 10.30 am – 01.30 pm

Instructions:

Total Marks: 80

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) | Discuss various factors to be considered for selection of pharmaceutical factory location. | 06 |
| | (b) | Describe the equipments required in the manufacture of solid dosage forms as per Schedule-M. | 05 |
| | (c) | Write a note on personnel facilities for pharmaceutical industry. | 05 |
| Q.2 | (a) | What are the objectives of SOP? Explain format, writing style and content of SOP. | 06 |
| | (b) | Explain inventory control with examples. | 05 |
| | (c) | What is pilot plant? Describe pilot plant operation. | 05 |
| Q.3 | (a) | Explain qualitative and quantitative departmental layout for semisolid dosage forms. | 06 |
| | (b) | Define production planning. Explain various procedures used for production planning. | 05 |
| | (c) | Explain fluid bed processor with its application. | 05 |
| Q.4 | (a) | Enlist types of equipments required for semisolid dosage form. Explain planetary mixture. | 06 |
| | (b) | Explain departmental layout with specific requirement of equipments for oral liquid dosage forms. | 05 |
| | (c) | What is validation protocol? Describe contents of validation protocol. | 05 |
| Q.5 | (a) | Enlist the type of utility services required for pharmaceutical factory. Explain any two in detail. | 06 |
| | (b) | Enumerate types of documents. Describe the general guidelines to be followed for design and use of documents. | 05 |
| | (c) | Explain scale-up consideration for sterile dosage forms. | 05 |
| Q. 6 | (a) | Describe objectives of scale up techniques. Explain scale up consideration for semisolid dosage forms. | 06 |
| | (b) | Enlist types of documents with its importance are to be attached to BMR of capsule batch. | 05 |
| | (c) | Enlist ideal characteristics of clean room. Draw a detailed rough layout of the plant for production of sterile dosage forms according to the GMP guidelines. | 05 |
| Q. 7 | (a) | What is cGMP? Discuss briefly its significance. | 06 |
| | (b) | Describe importance of HVAC facilities for pharmaceutical industry. | 05 |
| | (c) | Write a note on batch packaging record. | 05 |
