

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M.PHARM- SEM-I-EXAMINATION – JULY 2012

Subject code: 910202

Date: 07/07/2012

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.

- Q.1** (a) With a neat sketch, explain the qualitative and quantitative layout of liquid oral department. **06**
- (b) Pharmaceutical facility planning is very critical. Discuss the statement giving suitable examples. **05**
- (c) Write a note on water systems in the pharmaceutical industry. **05**
- Q.2** (a) Explain contamination and cross-contamination. Describe the methods used for contamination control. **06**
- (b) Write a note on raw material warehouse design and its functioning. **05**
- (c) Define SOP. Enlist the objectives of SOP. Explain format of SOP. **05**
- Q.3** (a) With a neat sketch explain rapid mixer granulator. **06**
- (b) Give SOP for rotary tablet machine. **05**
- (c) What is pilot plant scale up? Give its importance. **05**
- Q.4** (a) Design a BMR and BPR for tablet manufacturing. **06**
- (b) Describe the validation of tunnel sterilizer. **05**
- (c) Explain documentation for rejected and recalled goods. **05**
- Q.5** (a) Describe the cGMP requirements for laboratory records and reports. **06**
- (b) Describe the specific requirements for manufacture of parenterals as per revised Schedule M. **05**
- (c) Write a note on inventory control. **05**
- Q. 6** (a) Write a note on labeling requirements. **06**
- (b) Draw a layout for parenteral facility for freeze dried injectables. **05**
- (c) Draw a flowchart for manufacture of paracetamol tablets indicating ingredients, equipments and IPQC parameters. **05**
- Q.7** (a) Define process validation. Highlight the steps for validation of fluid bed dryer. **06**
- (b) What is dimensional analysis? How is it applied in scale up for pilot plant? **05**
- (c) Explain the cGMP requirements for lighting, sanitation and hygiene. **05**
