

Seat No.: \_\_\_\_\_

Enrolment No. \_\_\_\_\_

# GUJARAT TECHNOLOGICAL UNIVERSITY

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

**Subject code: 2920208**

**Date: 09/07/2012**

**Subject Name: Industrial Pharmacy - IV**

**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.

- Q.1** (a) What do you understand by Quality Assurance? Write about quality audits in detail. **08**  
(b) Write about ISO 9000 series. **08**
- Q.2** (a) What do you mean by Precision, Accuracy and Bias? Write a note on statistical hypothesis testing. **08**  
(b) Write a detailed note on New Drug Application approval process. **08**
- Q.3** (a) Write a note on general requirements of USFDA. **08**  
(b) Write about regulatory aspects of pharmaceutical excipients. **08**
- Q.4** (a) Write about the role of Medicinal Control Council (MCC) in regulating the health of public. **08**  
(b) Write a detailed note on various methods of sampling. **08**
- Q.5** (a) Write about regulatory issues in Indian Pharmaceutical Industry. **08**  
(b) How a monograph for a bulk drug substance is developed in Indian Pharmacopoeia (IP)? **08**
- Q. 6** (a) Write about the followings: **08**  
1) Process validation  
2) Retrospective validation  
3) Revalidation  
4) Concurrent validation  
(b) How a tablet coater is evaluated for coating process? **04**  
(c) Write a note on Electronic Records (21CFR11). **04**
- Q. 7** Write short notes on followings: **16**  
1) Drug Master File(DMF)  
2) CDER  
3) OHSAS  
4) ICH guidelines

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