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 in developed in Indian Pharmacopoeia (IP)?	**08**
Q. 6	(a)	Write about the followings: 1) Process validation 2) Retrospective validation 3) Revalidation 4) Concurrent validation	**08**
	(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: 1) Drug Master File(DMF) 2) CDER 3) OHSAS 4) ICH guidelines	**16**

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