Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject code: 2920207 Date: 09/07/2012

Subject Name: Quality Control and Quality Assurance

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)	Explain the difference between QA and QC activities.	**06**
	(b)	Describe the objectives and constitution of ICH.	**05**
	(c)	Describe the different climatic zones as per ICH guideline. What is meant by 'significant change'?	**05**
Q.2	(a)	Describe the content of CMC section in NDA submission.	**06**
	(b)	What is ANDA? How is it different from a NDA?	**05**
	(c)	Discuss the principles of ICH Good Clinical Practices.	**05**
Q.3	(a)	Discuss the role of QA unit in a non-clinical testing laboratory.	**06**
	(b)	Write briefly the content of a master manufacturing record.	**05**
	(c)	Describe the responsibilities of personnel working in a pharma manufacturing unit.	**05**
Q.4	(a)	What is an investigator brochure? Write briefly its content.	**06**
	(b)	Write the good practices followed during sampling of raw materials.	**05**
	(c)	Describe the process and benefits of WHO certification.	**05**
Q.5	(a)	What are the different records maintained in a pharmaceutical company? Describe the content of batch packaging record.	**08**
	(b)	Describe the GMP guidelines for design, construction and location of equipments.	**08**
Q. 6	(a)	Describe the responsibilities of QC in pharma manufacturing.	**06**
	(b)	Explain the objectives and scope of GLP guidelines.	**05**
	(c)	Discuss the role of study director of a non-clinical study.	**05**
Q.7	(a)	Explain the terms: (i) SOP (ii) Line clearance (iii) Bioequivalence.	**06**
	(b)	Describe the testing frequency and storage conditions for long term and accelerated stability studies of a new drug as per ICH.	**05**
	(c)	Describe the animal care facilities required as per GLP.	**05**

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