Seat No.: _____ *Enrolment No._____*

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. Semester – IIND Examination –June/July- 2011

Subject code: 920207

Subject Name: Quality Control & Quality Assurance

Date:04/07/2011 **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)**	Discuss the steps involved in ANDA submission. How does ANDA differ from NDA?	**06**
	(b)	Discuss the following terms in association with ICH : (i) EWG (ii) Concept Paper (iii) Final Business Plans	**05**
	(c)	Write an explanatory note on NDA submission.	**05**
Q.2	**(a)**	Discuss in detail 'Steps of ICH Process'.	**06**
	(b)	Describe the structure of ICH.	**05**
	(c)	Write Short Notes: (i) Types of IND (ii) Exploratory IND studies.	**05**
Q.3	**(a)**	Enlist different modes of drug degradation. Discuss chemical pathway of degradation.	**06**
	(b)	Describe ICH guidelines for stability testing of new drug substance.	**05**
	(c)	Write a note on protocol & documentation of stability study.	**05**
Q.4	**(a)**	How does bracketing and matrixing is useful in stability study? Give guidelines for the same.	**06**
	(b)	Give an account of guidelines for photostability testing of new drug substance.	**05**
	(c)	What is shelf life? How does shelf life determination is carried out for a drug?	**05**
Q.5	**(a)**	What is GLP? Give its scope. Explain the following terms: SOPs, Study Director, Regulatory study, Raw data.	**06**
	(b)	Discuss Management's responsibilities in the light of GLP principles.	**05**
	(c)	Write an explanatory note on handling and care of animals as per GLP guidelines.	**05**
Q. 6	**(a)**	Give content of study plan and discuss in brief conduct of study as per GLP regulations.	**06**
	(b)	Discuss building and manufacturing facilities for pharmaceuticals.	**05**
	(c)	Write a note on : (i) Vendor qualification (ii) Master batch packing formula.	**05**
Q.7	**(a)**	Discuss in detail process validation as per CGMP	**06**
	(b)	Describe Master production and control records in detail	**05**
	(c)	Write an explanatory note on responsibilites of Quality control unit	**05**

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