Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – II • EXAMINATION – SUMMER • 2015

Subject Code: 2920207 **Date: 16-05-2015**

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)**	What are the responsibilities of quality control unit?	**06**
	(b)	What is documentation? Describe statutory requirements and procedure for documentation.	**05**
	(c)	Explain the following terms: SOPs, Study Director, Regulatory study, Raw data, Line clearance.	**05**
Q.2	**(a)**	Describe the process of WHO certification.	**06**
	(b)	Discuss in detail about the application of computers in quality control laboratory.	**05**
	(c)	Discuss the principles of ICH Good Clinical Practices.	**05**
Q.3	**(a)**	Describe the content of CMC section in NDA submission.	**06**
	(b)	Describe the structure of ICH.	**05**
	(c)	Discuss Management's responsibilities in the light of GLP principles.	**05**
Q.4	**(a)**	How does bracketing and matrixing is useful in stability study? Give guidelines for the same.	**06**
	(b)	Discuss the following terms in association with ICH : (i) EWG (ii) Concept Paper (iii) Final Business Plans	**05**
	(c)	Discuss exploratory IND studies.	**05**
Q.5	**(a)**	Write a note on: (i) Vendor qualification (ii) Master batch packing formula.	**06**
	(b)	Give content of study plan and discuss in brief conduct of study as per GLP regulations.	**05**
	(c)	Give an account of guidelines for photostability testing of new drug substance.	**05**
Q. 6	**(a)**	Explain the terms INDA, NDA and ANDA in brief.	**06**
	(b)	Discuss in detail process validation as per CGMP.	**05**
	(c)	What is shelf life? Explain shelf life determination performed for a drug?	**05**
Q.7	**(a)**	Discuss building and manufacturing facilities for pharmaceuticals.	**06**
	(b)	Describe the different climatic zones as per ICH guideline. What is meant by 'significant change'?	**05**
	(c)	What is Bioequivalence and bioavailability? Describe importance of bioequivalence study.	**05**

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