Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: 2920207 **Date: 09-12-2015**

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)**	Briefly explain responsibilities of quality control unit	**06**
	(b)	Write a note on Good Clinical Practice (GCP) as per ICH guidelines	**05**
	(c)	Describe the process of WHO certification for pharmaceutical products	**05**
Q.2	**(a)**	Differentiate INDA and ANDA. Describe various type of INDA.	**06**
	(b)	Discuss diverse applications of computers in quality control laboratory	**05**
	(c)	Describe Master production and control records in detail	**05**
Q.3	**(a)**	Write a note on stability studies of a new drug product as per ICH guidelines.	**06**
	(b)	Explain objectives and constitution of ICH. Write a note on different climatic zones as per ICH guideline	**05**
	(c)	Write a note on shelf life determination based on stability studies	**05**
Q.4	**(a)**	Write a note on process validation as per cGMP	**06**
	(b)	Give content of study plan and discuss in brief conduct of study as per GLP regulations	**05**
	(c)	Define Biowaiver, Bioequivalence and bioavailability. Describe importance of bioequivalence study	**05**
Q.5	**(a)**	Explain the objectives and scope of GLP guidelines	**06**
	(b)	Write a note on care and handling of animals as per GLP guidelines	**05**
	(c)	Describe protocol for non-clinical laboratory study as per GLP regulation	**05**
Q. 6	**(a)**	What is documentation? Describe statutory requirements and procedure for documentation	**06**
	(b)	Write a note on ANDA. Explain the concept of PARA I to IV filing	**05**
	(c)	Discuss patent regime in India with respect to its issues, challenges and opportunities for pharmaceutical industry.	**05**
Q.7	**(a)**	Describe the GMP guidelines for design, construction and location of equipments	**08**
	(b)	Discuss GMP guidelines for sampling of raw material, packaging and labelling operations	**08**

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