Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. - SEMESTER– I • EXAMINATION – WINTER - 2016

Subject Code: 1911601 Date: 02/01/2017

Subject Name: cGMP and Documentation

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)**	How Quality Assurance of finished product is an impossible without cGMP and cGLP? Explain it.	**06**
	(b)	Why Pharmaceuticals need Trained and Qualified employee? Explain it.	**05**
	(c)	Draw the plant layout of Tablet manufacturing unit and explain it.	**05**
Q.2	**(a)**	Write a note on DQ, IQ, OQ and PQ of any type of pharmaceutical machine.	**06**
	(b)	Write a note on maintenance of Raw material store.	**05**
	(c)	Describe different criteria for the vender validation with example.	**05**
Q.3	**(a)**	Write a note on BMR.	**06**
	(b)	Enlist lists of SOPs for Pharmaceutical Quality Assurance recommended by WHO.	**05**
	(c)	Explain how the internal audit is helpful in pharmaceutical regulatory compliance?	**05**
Q.4	**(a)**	Describe the different IPQC tests for the liquid dosage forms.	**06**
	(b)	Write a note on the SOP's for Steam Sterilizer.	**05**
	(c)	Explain significance of packaging and labeling control. Give importance of Line clearance during product change over.	**05**
Q.5	**(a)**	Describe in detail the role and responsibilities of quality control manager.	**06**
	(b)	Give a brief note on sampling plan to control quality of sterile products.	**05**
	(c)	Why companies preserve documentation for handling of returned goods, recovered and reprocessing materials?	**05**
Q. 6	**(a)**	Discuss the important tests carried out for glass ampoules and vials for the use in Parenteral packaging.	**06**
	(b)	Company needs which types of documents for the evaluation of complaints and recall procedures for the legal protection?	**05**
	(c)	Write a short note on Good Warehousing Practice.	**05**
Q.7	**(a)**	Define GLP. Explain in details why company needs GLP?	**06**
	(b)	Define BMS and PICS. Give importance about the specifications for intermediates materials and finished product.	**05**
	(c)	Explain the Annual product quality review with respect to finished product documents.	**05**

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