Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: 1911601 **Date: 31-12-2015**

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)**	Write a note on Quality audit and self inspection in pharmaceutical industry.	**06**
	(b)	Explain the scope of MHRA regulations. Discuss the planning necessary for facing MHRA inspection.	**05**
	(c)	Discuss the tests carried for parenteral packaging material like glass bottles and vials.	**05**
Q.2	**(a)**	Define Quality Assurance, GMP, GLP and explain their interrelationship.	**06**
	(b)	Explain the waste and scrap disposal procedure in Pharmaceutical industry.	**05**
	(c)	Write a note on objectives and provision for WHO certification.	**05**
Q.3	**(a)**	Explain the importance and role of Quality Assurance in Pharma industry.	**06**
	(b)	What is packing line clearance and reconciliation of label?	**05**
	(c)	Write a note on distribution records	**05**
Q.4	**(a)**	Give a standard format of batch formula records.	**06**
	(b)	What do you understand by SOP? Discuss guideline for preparing SOP and give blank format for SOP.	**05**
	(c)	Write about quality audits of manufacturing processes and facilities.	**05**
Q.5	**(a)**	Write down general guidelines given for personnel selection and training.	**06**
	(b)	Explain the purchase specification and vendor selection of raw materials.	**05**
	(c)	Enlist the objectives of SOP. Write down the SOP of sterilization operation.	**05**
Q. 6	**(a)**	Define GLP. Discuss sub part C- Facilities as described in GLP guideline.	**06**
	(b)	What are the objectives of GLP guideline?	**05**
	(c)	Explain the guidelines regarding organizational and personnel in Pharmaceutical industry.	**05**
Q.7	**(a)**	What is IPQC? Explain IPQC test for tablet manufacture.	**06**
	(b)	Short note on Good Warehousing Practice.	**05**
	(c)	Importance of Packaging and labelling control in Pharma. Industry.	**05**

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