Seat No.:	Enrolment No.	

GUJARAT TECHNOLOGICAL UNIVERSITY M. Pharm - SEMESTER-I • EXAMINATION - SUMMER-2017

Subject Code: 910204 Date: 01/05/2017 Subject Name: Good Manufacturing and Good Laboratory Practice

Time: 10:30 AM to 01:30 PM Total Marks: 80

Instructions:

1.	Attempt	anv	five	questions.
	LICULIA	ully	1110	questions.

- 2. Make suitable assumptions wherever necessary.
- 3. Figures to the right indicate full marks.

Q.1	(a) (b) (c)	Explain the concept of quality assurance in pharma manufacturing. What factors are considered in selection of premises for production? What are the responsibilities of personnel as per GMP?	06 05 05
Q.2	(a) (b)	How should raw materials be received, stored and issued? Discuss the good practices for use, cleaning and maintenance of equipments.	06 05
	(c)	What are IPQC tests? Describe IPQC tests for liquid orals.	05
Q.3	(a) (b) (c)	Explain (i)Retention samples (ii)Recalls (iii)Purchase specifications Who are vendors? Discuss procedure for vendor certification. Describe the content of a master formula record.	06 05 05
Q.4	(a)	What good practices are followed during labelling of finished products? What is the significance of line clearance?	06
	(c) (p)	Discuss the main principles of Good Laboratory Practices. Explain importance of proper sampling. Describe sampling plans.	05 05
Q.5	(a)	Discuss the requirements of a good warehouse. What records are maintained in the finished goods warehouse?	06
	(c) (p)	Define SOP. Discuss points to be considered in making a SOP. Explain the methods for pharmaceutical waste disposal.	05 05
Q. 6	(a) (b) (c)	What are the duties of the quality control unit? Write the importance of quality audits. Write steps of internal audit. What are complaints? How should complaints be handled?	06 05 05
Q.7	(a) (b) (c)	Write a note on WHO certification scheme. How are glass materials evaluated before being used in packaging? What are specifications? Describe their different types.	06 05 05
