

Seat No.: \_\_\_\_\_

Enrolment No. \_\_\_\_\_

**GUJARAT TECHNOLOGICAL UNIVERSITY**

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

**Subject Code: 1921502**

**Date: 09-12-2015**

**Subject Name: GMP, GLP and Validation**

**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.

<b>Q.1</b>	(a) Define Process Validation. Explain Different types of Process validation and scope of Process validation.	<b>06</b>
	(b) Give a brief account on operational and performance qualification of facilities in pharmaceutical industries.	<b>05</b>
	(c) Write a short note on Validation of UV-Visible Spectrophotometer.	<b>05</b>
<b>Q.2</b>	(a) Explain in detail procedures for quality audit of manufacturing facilities.	<b>06</b>
	(b) Give a brief note on validation master plan.	<b>05</b>
	(c) Explain in detail Good Packaging Practice.	<b>05</b>
<b>Q.3</b>	(a) Give brief note on Complaint and recall procedure for pharmaceutical Product.	<b>06</b>
	(b) Explain Scope of GMP and QA in pharmaceutical industries.	<b>05</b>
	(c) Write a note on responsibilities of personnel in pharmaceutical organization.	<b>05</b>
<b>Q.4</b>	(a) Explain in detail SOP for Cleaning and Coating operations in pharmaceutical industries.	<b>06</b>
	(b) Discuss in detail about Equipment Qualification.	<b>05</b>
	(c) Give factors to be consider for Vendor selection of raw materials.	<b>05</b>
<b>Q.5</b>	(a) Explain in detail different aspects of analytical method validation.	<b>06</b>
	(b) Write short note on validation of Dissolution Apparatus.	<b>05</b>
	(c) Give brief account on Master Formula Record.	<b>05</b>
<b>Q.6</b>	(a) Write a short note on cleaning validation.	<b>06</b>
	(b) Write a short note on Computer System Validation.	<b>05</b>
	(C) Give a brief note on process validation of Coated Tablets	<b>05</b>
<b>Q.7</b>	Write short notes ( <b>any two</b> )	<b>16</b>
	1. Validation of HPLC.	
	2. Good Laboratory Practice.	
	3. Good Distribution Practice	

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