

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

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

**GUJARAT TECHNOLOGICAL UNIVERSITY**  
**B.Ph. SEMESTER-VII • EXAMINATION – WINTER- 2022**

**Subject Code: BP702TT**

**Date: 03/01/2023**

**Subject Name: INDUSTRIAL PHARMACY-II**

**Time: 10:30am to 01:30pm**

**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) Write about the uses of Platform Technology.	<b>06</b>
	(b) Write on Quality Risk Management.	<b>05</b>
	(c) Discuss responsibilities of regulatory affairs professionals.	<b>05</b>
<b>Q.2</b>	(a) Discuss historical overview of regulatory affairs.	<b>06</b>
	(b) Write a note on TIFAC.	<b>05</b>
	(c) Write in brief about APCTD and NRDC.	<b>05</b>
<b>Q.3</b>	(a) Write a note on SUPAC guidelines.	<b>06</b>
	(b) Write the protocol to conduct non clinical testing.	<b>05</b>
	(c) Discuss Investigational New Drug (IND) Application	<b>05</b>
<b>Q.4</b>	(a) Describe pilot plant scale up considerations for semi-solid dosage forms.	<b>06</b>
	(b) What are the objectives and significance of pilot plants?	<b>05</b>
	(c) Write a note on Total Quality Management.	<b>05</b>
<b>Q.5</b>	(a) Write in brief about qualification and validation in technology transfer.	<b>06</b>
	(b) Discuss about technology transfer protocol.	<b>05</b>
	(c) Write a note on Certificate of Pharmaceutical Product (COPP).	<b>05</b>
<b>Q.6</b>	(a) Write about significance of documentation in technology development and transfer.	<b>06</b>
	(b) Write a note on Six sigma as a tool for quality management.	<b>05</b>
	(c) How Bioequivalence are documented?	<b>05</b>
<b>Q.7</b>	(a) Describe Pilot plant scale up considerations for solid dosage forms.	<b>06</b>
	(b) Write about the role of regulatory affairs department in industry.	<b>05</b>
	(c) Discuss selection of pharmaceutical packaging materials.	<b>05</b>

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