

Enrollment No: \_\_\_\_\_ Exam Seat No: \_\_\_\_\_

**C.U.SHAH UNIVERSITY**  
**Winter Examination-2021**

**Subject Name: Industrial Pharmacy II - Theory**

**Subject Code: BP702T**

**Branch: B.Pharm**

**Semester: 7**

**Date: 14/12/2021**

**Time: 11:00 To 02:00**

**Marks: 75**

Instructions:

- (1) Use of Programmable calculator & any other electronic instrument is prohibited.
- (2) Instructions written on main answer book are strictly to be obeyed.
- (3) Draw neat diagrams and figures (if necessary) at right places.
- (4) Assume suitable data if needed.

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<b>Q-1</b>	<b>Attempt the following questions:</b>	<b>(20)</b>
	a) Different level of changes according to SUPAC	2
	b) Define: Regulatory Affairs	2
	c) NDA	2
	d) Orange Book	2
	e) Quality Risk Management (QRM)	2
	f) Six Sigma	2
	g) Enumerate the types of INDs	2
	h) Process Analytical Technology (PAT)	2
	i) Quality by Design (QbD)	2
	j) Certificate of Pharmaceutical Product (COPP).	2

**Attempt the following questions:**

<b>Q-2</b>	<b>Attempt any two of following :</b>	<b>(20)</b>
<b>A</b>	What are the different Regulatory Authority? Discuss the role of regulatory affairs department and responsibility of regulatory affairs professionals.	<b>10</b>
<b>B</b>	What do you mean by technology transfer from R&D to Production? Explain along with steps involved in it.	<b>10</b>
<b>C</b>	Explain in brief pilot plant operation	<b>10</b>
<b>Q-3</b>	<b>Attempt any Seven of following :</b>	<b>(35)</b>
<b>A</b>	Write a note on Investigator's Brochure.	<b>5</b>
<b>B</b>	What is NABL Accreditation? Why it is important? What are its scope in pharmacy?	<b>5</b>
<b>C</b>	What is TQM? Write its key elements along with its philosophies and importance in pharma industry.	<b>5</b>
<b>D</b>	Enumerate the Stages of Drug Approval Process in India in brief.	<b>5</b>
<b>E</b>	Give the Administrative Structure and Functions of Drug Regulatory Authorities In India.	<b>5</b>
<b>F</b>	Write importance of technology transfer in pharmacy	<b>5</b>
<b>G</b>	Give a note on SUPAC guideline.	<b>5</b>
<b>H</b>	Explain the procedure for pilot plant scale up for liquid oral	<b>5</b>
<b>I</b>	Write a note on ISO 14000 and PDCA cycle.	<b>5</b>

