

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

# C.U.SHAH UNIVERSITY

## Winter Examination-2022

**Subject Name: Regulatory Affairs**

**Subject Code: MPH104T**

**Branch: M.Pharm (Pharmaceutics)**

**Semester: 1**

**Date: 16/03/2023**

**Time: 10:30 To 01:30**

**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>Elaborate the following:</b>	<b>(20)</b>
<b>A</b>	Generic Drug user free amendments (GDUFA)	<b>2</b>
<b>B</b>	Medical Product Dossier	<b>2</b>
<b>C</b>	HIPAA	<b>2</b>
<b>D</b>	ICH Q9	<b>2</b>
<b>E</b>	ANDA	<b>2</b>
<b>F</b>	Distribution records	<b>2</b>
<b>G</b>	Pharmacovigilance	<b>2</b>
<b>H</b>	Centre for Drug Evaluation and Research	<b>2</b>
<b>I</b>	Hatch-Waxman act	<b>2</b>
<b>J</b>	Orphan Drug.	<b>2</b>
<b>Q-2</b>	<b>Attempt any two of following :</b>	<b>(20)</b>
<b>A</b>	Scale up process and its significance	<b>10</b>
<b>B</b>	Investigator's Brochure	<b>10</b>
<b>C</b>	Format and type of IND	<b>10</b>
<b>Q-3</b>	<b>Attempt any Seven of following :</b>	<b>(35)</b>
<b>A</b>	Write a short note on TGA.	<b>5</b>
<b>B</b>	What is CTD? Discuss structure of CTD. How it's differ from eCTD?	<b>5</b>
<b>C</b>	Explain Drug Master File	<b>5</b>
<b>D</b>	Discuss ICH-M Guidelines	<b>5</b>
<b>E</b>	Discuss the phases of NDA	<b>5</b>
<b>F</b>	Discuss Clinical Trials and B.E. studies in a drug discovery.	<b>5</b>
<b>G</b>	Write a note on institutional review board for clinical trials.	<b>5</b>
<b>H</b>	Describe the procedure for New drug approval from CDSCO in India.	<b>5</b>
<b>I</b>	Describe the organization chart, structure and activity of MHRA.	<b>5</b>

