Name. _____	**Printed Pages:01**
Student Admn. No.: _____	

School of Biological and life sciences
Summer Term Examination – July - August 2024
[Programme: B.Sc.] [Semester:IV] [Batch:2022-23]

Course Title: Regulatory affairs in clinical research	**Max Marks: 100**
Course Code: Q1UF420T	**Time: 3 Hrs.**

Instructions:
1. *All questions are compulsory.*
2. *Assume missing data suitably, if any.*

		K Level	COs	Marks
	SECTION-A (15 Marks) 5 Marks each			
1.	Describe adverse event and serious adverse event.	K2	CO1	5
2.	Define quality control and Quality assurance.	K2	CO2	5
3.	Describe Case report forms.	K3	CO3	5
	SECTION-B (40 Marks) 10 Marks each			
4.	Define Bioavailability and Bioequivalence study.	K3	CO3	10
5.	Analyze NDCT 2019 and its importance.	K3	CO4	10
6.	Illustrate the career opportunities in clinical research.	K2	CO5	10
7.	Demonstrate the unethical clinical trials.	K2	CO6	10
	SECTION-C (45 Marks) 15 Marks each			
8.	Evaluate the all phases of clinical research.	K3	CO1	15
9.	Anayze the ICF process while consenting the patients.	K4	CO2	15
10	Illustrate the principal role and responsibilities in clinical research.	K5	CO3	15