

Your Roll Number.....

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Centre for Translational & Clinical Research
M.Sc. in Clinical Research Semester I
Semester Examination – December 2023

Paper Code – MCR DCC 102; Paper Title: Regulatory Affairs in Clinical Research

Time : 2 hour 30 mins

Total Marks: 60

Write the roll number at the top immediately on receipt of this question paper. Attempt all questions. All parts of a question must be attempted in continuation. Start answer of a fresh question on a new page. Cite examples whenever necessary

Section-A	
All questions are compulsory	
Marks)	
1	BCS III
2	ICH
3	Bioequivalence
4	GRASE
5	DSUR
6	Parameters of Bioavailability
7	eCTD
8	GCP
9	ANDA
10	GLP
Section-B	
Write Short Note on ANY FOUR of the following	
Marks)	
11	CTD
12	MAH
13	PMS
14	Regulation of nonprescription drugs.
15	Patent term restoration act
16	Discuss OECD guidelines
Section-C	
Attempt TWO of the following	
Marks)	
17	Discuss salient features of GCP & GLP?
18	Discuss the objectives & evolution of ICH and describe ICH guidelines in detail?
19	Discuss the regulatory system of Brazil?
20	Write down a comparison of NDA & IND

*****END OF QUESTION PAPER*****