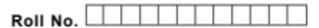


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M.Pharmacy (Pharmacology) (Sem.-2) CLINICAL RESEARCH & PHARMACOVIGILANCE Subject Code : MPL-204T

M.Code: 74946

Time : 3 Hrs.

Max. Marks: 75

INSTRUCTIONS TO CANDIDATES :

- 1. Attempt any FIVE questions out of SIX questions.
- 2. Each question carries FIFTEEN marks.

1.	a)	Outline the requirements for a sterile product manufacturing plant. Indicate areas with the help of an illustration.	various (7.5)
	b)	Describe the constitution of IRB. Mention the functions of IRB.	(7.5)
2.	a)	Write a note on cross sectional observation studies.	(7.5)
	b)	Comment on the responsibilities of study coordinator of a clinical trial.	(7.5)
3.	a)	What is an investigator brochure? Outline the contents of this brochure and men purpose of each entry in the form.	tion the (7.5)
	b)	What is ADR? Give five examples of ADRs. How are ADRs detected and re Outline the format used for this purpose.	ported? (7.5)
4.		atline the importance of safety monitoring in clinical trials. Give a detailed acc fety monitoring in clinical trials,	count of (15)
5.		ve a detailed account of passive and active surveillance in pharmacovigilance. e steps involved in each	Outline (15)
6.	Wı	rite notes on (any three): (5 × 1	3 = 15)
	a)	Pharmacoeconomics	
	b)	Responsibilities of a CRO	
	c)	Pharmacovigilance in hospitals	

d) International classification of diseases

NOTE : Disclosure of Identity by writing Mobile No. or Making of passing request on any page of Answer Sheet will lead to UMC against the Student.

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