Exam Date & Time: 13-Sep-2021 (02:00 PM - 05:00 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.

Biological Evaluation of Drug Therapy [PBT-MPB204T]

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٠	Marks: 75	Duration: 180 mins.		
	SECTION - A			
Answer all the questions.				
Answer the following (10 marks $x = 50$ marks)				
	1)	Outline the microbiological assays of antibiotics and explain turbidimetric assay of antibiotics in detail.	(10)	
	2)	What are the goals of biosafety levels and personal controls? Why is biosafety important? Describe the layout of a biosafety level-3 laboratory. Describe the automation and applications of a class II type A2 biosafety cabinet.	(10)	
	3)	Discuss the methods used for Bioassay of biological drugs.	(10)	
	4)	Describe the physico-chemical and pharmacological factors affecting bioavailability of biologicals.	(10)	
	5)	Outline the features of a new drug application. Discuss the goals, summary requirements and guidance documents of NDA.	(10)	
	SECTION - B			
Answer all the questions.				
Answer the following (5 marks x 5 = 25 marks)				
	6)	Penicillin is an antibiotic. Then how is the sterility test performed?	(5)	
	7)	Briefly outline the source, and the mechanism of action and applications of interferons.	(5)	
	8)	Explain the Kendrick test used for standardization of pertussis vaccine.	(5)	
	9)	Illustrate and explain the mamillary model used to describe pharmacokinetics of drugs.	(5)	
	10)	Explain the composition and function of EMA.	(5)	
	End			