### MANIKGAD – V: SUMMER- 2017 SUBJECT : CLINICAL RESEARCH

		SUBJECT: CENTRAL	
Day : 1	Thursd: 06/04/2	2017	_
N. B. : 1) 2 3 4	) )	Q. No. 1 and Q. No. 5 are COMPULSORY. Out of the remaining attempt ANY TWO questions from each section.  Figures to the right indicate FULL marks.  Answers to both the sections should be written in the SEPARATE answer boo Draw neat and labeled diagram WHEREVER necessary.	ks. 
		SECTION - I	08)
Q. 1 A	i) iii ii	Institutional Ethics Committee	
	<b>B</b> )	Toxicity studies in preclinical research.	(03)
Q. 2		Explain in detail the different stages of drug discovery and development process.	(12)
Q. 3	n) b)	Discuss the various drug characteristics techniques during drug development process.  Write the ethical principles of ICH-GCP in Clinical Research.	(07) (05)
Q. 4	n) b) c) d)	Write short notes on ANY THREE of the following: IND Application Investigational product Design of clinical research Challenges in implementing ethical guidelines in Clinical Research	(12)

P. T. O.

#### **SECTION - II**

Q. 5	A)	Answer ANY FOUR of the following:	(08)
ų. <i>3</i>	,	i) Assent in Clinical Research	
		ii) Essential documents in Clinical Research	
		iii) Selection and withdrawal of subjects in clinical trials	
		iv) Regulatory authority responsibility in safety	
		v) Who are sponsors in clinical trial?	
		vi) PMS Studies	
	B)	Differentiate between NDA and ANDA.	(03)
Q. 6		Discuss in detail clinical research and the various phases of clinical trials.	(12)
Q. 7	a)	Explain the role of clinical investigator in clinical trials as per ICH-GCP.	(07)
	b)	Discuss safety monitoring in clinical trials.	(05)
Q. 8		Write short notes on ANY THREE of the following:	(12)
	a)	Data Management Process	
	b)	Design and development of Protocol	
	c)	Differentiate eCRF v/s paper CRF	
	d)	CDSCO Guidelines	

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## MANIKGAD-V: SUMMER- 2017 SUBJECT: PHARMACOEPIDEMIOLOGY AND PHARMACOEOCONOMICS

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		R)	What are the two ways of collecting costs?	(03
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Q.6	Expla advar	ain Cost Effectiveness Analysis (CEA) with suitable example. State its stages in economic analysis.	(12)
Q.7	a)	Explain Standard Gamble Method for utility valuation.	(07)
	b)	Differentiate between Direct and Indirect costs.	(05)
Q.8	Write	e short notes on any THREE of the following:	(12)
	a)	Quality Adjusted Life Year	
	b)	Cost of Illness	
	c)	Time-Trade-off (TTO)	
	ď)	Willingness to pay	
	e)	Various clinical problems in risk management research.	

Phalm - D

# MANIKGAD - V: SUMMER- 2017 SUBJECT: CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING

Time : 10.00 A.M. TO 01.00 PM Day : Tuesday Max. Marks: 70 : 11/04/2017 Date N. B.: Q. No. 1 and Q. No. 5 are COMPULSORY. Out of remaining Any TWO 1) questions from Section - I and Any TWO questions from Section - II. Both the sections should be written in the SEPARATE answer book. 2) Figures to the right indicate FULL marks. 3) SECTION - I (08)Answer Any FOUR of the following: Q.1 a) i)) Name two inhibitors of drug metabolism. What are the main kinds of drug dosage? ii) iii) Define loading dose. iv) Define therapeutic index. Enlist factors affecting drug absorption. Enlist the advantages of compartmental model. (03)Describe drug dosing in obese patients. Discuss the applications of pharmacokinetic/ pharmacodynamic correlation in (12) Q.2 drug therapy. (07)Describe the intravenous to oral dosing conversion. Q.3a) Describe Nomograms and tabulation in designing dosage regimen. (05)Write short notes on Any THREE of the following: (12)**Q.4** Aminoglycosides a) TDM of digitalis b) First pass metabolism c) Inhibition of biliary excretion and its effect on pharmacokinetics

P.T.O.

### SECTION - II

Q.5	a)	Answer Any FOUR of the following:	(08)
	i))	Enumerate four causes of renal dysfunction.	
	ii)	What is meant by dosing with feedback?	
	iii)	Enumerate the methods used to determine GFR.	
	iv)	Explain the various liver function tests and their significance.	
	v)	Write the significance of pharmacokinetic-pharmacodynamic correlation.	
	vi)	Calculate the creatinine clearance for a child (8 years, body length 122 cm) whose serum creatinine value is 0.9 mg/dl.	
	b)	The maintenance dose of Gentamicin is 80 mg every 6 hours in a patient with normal renal function (normal creatinine clearance of 100 ml/min). calculate the dose for a uremic patient with creatinine clearance of 20ml/min (given ku/KN=0.2)	(03)
Q.6		Explain Bayesian theory with a suitable example and briefly the concept of dosing with feedback.	(12)
		To the state of th	(07)
Q.7	a)	Explain in detail Hemodialysis.	(05)
	b)	Explain pharmacokinetic considerations during renal impairment.	(05)
Q.8		Write short notes on Any THREE of the following:	(12)
Ų.o	۵)	Approaches for dose adjustment during renal disease.	
	a)	Role of liver enzymes in drug interaction with suitable examples.	
	b)	Determination of creatinine clearance?	
	c)	Pharmacokinetic-pharmacodynamic correlations in drug therapy.	
	d)	Pnarmacokinetic-pharmacoa, manne	