

# UKA TARSADIA UNIVERSITY

M. Pharm (Pharmacology) (3rd Semester)

Subject : 040050302-Clinical Pharmacology and Pharmacy Practice

Time : 10:00 am to 01:00 pm

Date : 08/01/2014

Duration : 3Hours

Max. Marks : 70.

Section -I			
Q.1	A	i) Write composition & responsibilities of IRB. ii) Write about informed consent process	[05]
		<b>OR</b>	
	A	i) What is Clinical hold? ii) Describe grounds for imposition of clinical hold under an IND	[05]
	B	i) Describe the predicted effects of perturbations on free and total steady state concentration using the venous equilibrium model for hepatic clearance. ii) Write about dose adjustment in renal failure. Give measures to enhance clearance	[06]
		<b>OR</b>	
Q.2	A	How will you interpret a TDM result, explain using giving a suitable example.	[06]
		<b>OR</b>	
	A	Write general principles for management of poisoning	[06]
	B	i) Describe various clinical aspect of NDA Submission . ii) Discuss role & responsibility of Investigator as per ICH GCP guideline.	[06]
		<b>OR</b>	
Q.3		Write short notes on <b>any two</b> of the following:	[12]
	A	Investigator brochure.	
	B	Kinetics of drugs & its clinical implications in GI diseases	
	C	Pharmacogenetics	
Section -II			
Q.4	A	i) Describe the criteria involved in designing the bioavailability studies ii) Enlist and explain the importance of the parameters involved in interpretation of a bioavailability and or bioequivalence studies.	[05]
		<b>OR</b>	
	A	i) What is the scope of pharmacoepidemiology? Justify its need. ii) Describe the DNR ethical issues associated with Critical Care Therapy.	[05]
	B	Compare and contrast – cost benefit analysis and cost effectiveness analysis.	[06]
		<b>OR</b>	
Q.5	A	Explain the essential drug concept. Describe various steps necessary to be taken for the success in preparing of EDL.	[12]

		<b><u>OR</u></b>	
	<b>A</b>	Explain and outline the National Pharmacovigilance policy of India along with its objectives and framework.	<b>[12]</b>
<b>Q.6</b>		Write short notes on <b>any two</b> of the following:	<b>[12]</b>
	<b>A</b>	Hematological and biochemical estimations as markers of diseases/organ damage.	
	<b>B</b>	Prescription monitoring	
	<b>C</b>	Transplantations	