



PAPER ID-411459

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MPHARM
(SEM II) THEORY EXAMINATION 2023-24

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS

TIME: 3 HRS**M.MARKS: 75**

Note: 1. Attempt all Sections. If require any missing data; then choose suitably.

SECTION A

1. Attempt all questions in brief.**10 x 2 = 20**

a.	Give the structure of octanol.
b.	Explain tight-junction complex.
c.	Define <i>in vitro-in vivo</i> correlation as per USFDA.
d.	State Fick's law of diffusion equation.
e.	List the causes of non-linearity.
f.	Explain the purpose of Latin square cross over design.
g.	Explain the regulatory relevance of BCS.
h.	Give the purpose of bioequivalence studies.
i.	Describe biosimilar drug products.
j.	Give the clinical importance of oligonucleotides.

SECTION B

2. Attempt any two parts of the following:**2 x 10 = 20**

a.	Compare and contrast active and facilitated drug transport.
b.	Outline the pharmacokinetics of modified release drug products.
c.	Derive mathematical expression to calculate the plasma concentration at any time for a drug following one compartment open PK model: IV infusion

SECTION C

3. Attempt any five parts of the following:**5 x 7 = 35**

a.	Discuss pH partition hypothesis and its implications and role in drug absorption.
b.	Illustrate the problems of variable control that can affect the drug dissolution data.
c.	Outline the steps to develop Level A <i>in-vitro and in-vivo</i> correlation.
d.	Explain the pharmacokinetic parameters of the two-compartment pharmacokinetics model from plasma concentration obtained after a single IV administration.
e.	Examine the key considerations in the study protocol for conducting a bioequivalence study.
f.	Discuss various approaches of targeted drug delivery system.
g.	Demonstrate the role of hybridoma technology in the manufacturing of the Monoclonal antibodies.