Printed Pages: 01 **Sub Code: MPH 202T**

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M. PHARM.
(SEM II) THEORY EXAMINATION 2017-18
ADVANCE BIOPHARMACEUTICS AND PHARMACOKINETICS

Time: 3 Hours ***Total 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. Define the term In vitro in vivo correlation.

b. What is Noyes-Whitney equation?

c. Define bioequivalence study protocol.

d. What is an orange book?

e. Why is drug biotransformation necessary?

f. What is the rate –limiting step in bioavailability ?

g. Define "pharmaceutically bioequivalent drug product.

h. What is therapeutic equivalence?

i. What is the role of drug transporters?

j. What is difference between protein and peptide?

SECTION B

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

a. Write in detail about alternative methods of dissolution testing.

b. Discuss the pharmacokinetics of one compartment open model for intravenous infusion drug administration?

c. Write a note on nonlinear pharmacokinetics. Explain the kinetics of such a process by Michaelis-Menten equation.

SECTION C

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

a. Define the term 'in vitro-in vivo correlation (IVIVC)' as per United States pharmacopoeia (USP). Explain the levels of IVIVC as specified by USP, applicable to modified release dosafe forms.

b. Discuss the method of absorption rate constant determination by Wagner –Nelson Method and also mention about the merits and demerits of this method.

c. Discuss the effect of protein binding on bioavailability and volume of distribution.

d. Differentiate between first and zero drug elimination kinetics.

e. Define apparent volume of distribution. How it can be related to loading dose

f. Classify various pharmacokinetic compartment open models. Explain them with concepts, schematic representation and relevant mathematical equations

g. Write a detailed note on Generic submission and review.