NC-02010304 Seat No. _____

M. Pharm. (Sem. I) (CBCS) Examination

January – 2017

Pharmaceutical Formulation Development & Biopharmaceutics

Time : **3** Hours] [Total Marks : **80**

Instructions : (1) Answer and tie both the sections separately.
(2) Figure to the right indicate marks.
(3) Answer any 3 questions from each section including Que. 1 & Que. 5 which are compulsory.

SECTION - I

1 Answer any seven out of given ten questions : **7×2=14**

(a) Comment: "Preformulation studies are limited to new drug molecules only".

(b) Define sink condition. How it can be achieved?

(c) Enlist the objectives of stability testing.

(d) How will you compare dissolution profiles? Explain the strategies regarding challenges to dissolution for poorly soluble drugs

(e) Comment : Distribution of a drug is not uniform throughout the body.

(f) Give difference between Amorphous and Crystalline forms.

(g) Enlist importance of volume of distribution and plasma protein binding.

(h) Give the examples of BCS Class - II Drugs.

(i) How intrinsic solubility differs from dissolution rate?

(j) Give the significance of BCS and BDDCS Classification.

2 Answer the following :

(a) Define preformulation. Discuss physical parameters influencing formulation of drugs. **7**

(b) Explain Bio-relevant media and Dissolution mimicking. **6**

3 Answer the following :

(a) Enlist various solubilisation techniques with their mechanisms. Discuss in detail about solid dispersion. **7**

(b) Explain in detail various theories of Dissolution. **6**

4 Answer the following :

(a) Discuss the requirement related to stability testing with emphasizing matrixing and bracketing technique. **7**

(b) Explain clearance, apparent Vd, biological half-life. How are they related? How the Vd of the new drug is determined? **6**

SECTION - II

5 Answer any **two** out of given **three** questions : **2×7=14**

(a) Write a brief account on accelerated stability studies.

(b) Discuss different factors affecting drug absorption.

(c) What is polymorphism? Discuss its significance in dissolution. Enumerate the methods to identify polymorphs.

6 Answer the following :

(a) Discuss Factors affecting IVIVC along with methods of establishing IVIVC and Application of IVIVC for biowaivers of immediate release dosage forms. **7**

(b) Discuss the requirement related to stability testing with emphasizing photostability testing. **6**

7 Answer the following :

(a) Write a brief account on Non linear Pharmacokinetic. **7**

(b) Discuss permeability and active drug transport across CACO-2 monolayers. **6**

8 Answer the following :

(a) What is multicompartment model? Enumerate such multicompartment models and write a note on two compartment model. **7**

(b) Write a note on selection of dissolution media and conditions for dissolution study. **6**