HDY-1603120602030200 Seat No. _____

M. Sc. (Biochemistry) (Sem. III) (CBCS) Examination

November / December – 2017

EBC-2 : Pharmaceutical Biochemistry & Regulatory Affairs

Time : $2\frac{1}{2}$ Hours] [Total Marks : **70**

1 Answer briefly any seven of the following questions : **14**

(a) What is the need to study dose-effect relationship?

(b) Why do we need to study pharmacokinetics?

(c) Data mining and it's benefits.

(d) What is pharmacology? Enlist its various branches.

(e) Enlist the members of review team for CRF development process.

(f) What is drug excretion? Enlist its types.

(g) What is patent drafting?

(h) Explain the prodrug technology.

(i) What is the function of FDA? What it regulate?

(j) LD_{50} and ED_{50}

2 Answer any **two** of the following questions : **14**

(a) What do you mean by drug distribution? What are the factors that affect drug distribution?

(b) Write note on cGMP

(c) Explain linear, non-linear and steady-state pharmacokinetics with appropriate example and figure wherever required

3 (a) What is drug absorption? Explain the various mechanisms by which the drug absorption occurs in the body. **7**

(b) Case report form development, purpose and importance in clinical documentation. **7**

OR

(c) Explain the factors modifying drug action. **7**

(d) Explain: Monograph development according to intellectual property. **7**

4 Answer the following questions : **14**

(a) Write a note on plasma drug concentration time profile.

(b) Explain the prodrugs and its classification with suitable figures and examples.

5 Answer the following questions : (any **two**) **14**

(a) Explain the factors affecting renal drug metabolism.

(b) Give the structure of ICH. What are the five steps of ICH?

(c) Write a detailed note on drug receptor interaction theories.

(d) Enlist various governing Laws of IPR in India. Give detailed procedure for grant of patent.