HV-M2011123 Seat No. _____

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

June/July – 2017

Global Regulatory Requirements

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

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

SECTION – I

1 Answer any **SEVEN** out of given TEN questions : **7×2=14**

(a) Give full form of :
  (i) CDRH
  (ii) ERP
  (iii) QbD
  (iv) MCA

(b) What do you mean by reference listed drug?

(c) What do you mean by Generic drug?

(d) Give difference between DMF and Applications.

(e) Define : Therapeutic Equivalent and Pharmaceutical Equivalent.

(f) What do you mean by Hatchwaxman ammendments?

(g) Discuss different plans of USFDA.

(h) What USFDA does and does not regulate?

(i) Enlist the different sections of NDA.

(j) What is the role of ICH in improving pharmaceutical product quality?

2 Answer the following :

(a) Define Pharmaceutical validation? Give its types and discuss its scope in Pharmaceutical industry. **7**

(b) Define IND. Enlist the category of IND application. **6**

3 Answer the following :

(a) What are Orange Book, Green Book and Blue Book? Discuss the coding system for Therapeutic Equivalence Evaluation and how it can be changed giving suitable illustration? **7**

(b) Define CTD and e-CTD. What are technical requirements for e-CTD ? **6**

4 Answer the following :

(a) Discuss SUPAC guidelines for modified release dosage forms. **7**

(b) Write a note on validation of Dissolution Apparatus. **6**

SECTION – II

5 Answer any **TWO** out of given THREE questions : **2×7=14**

(a) What are clinical trials? How are they organized as the part of drug discovery process?

(b) Explain the concept of ANDA and prepare the flow chart showing ANDA review process.

(c) Write a brief account on IIG.

6 Answer the following :

(a) What are DMFs? 'Enumerate the various types of DMFs and explain in detail type II DMFs. **7**

(b) Discuss Structure and functions of USFDA. **6**

7 Answer the following :

(a) Write a note on ANVISA OR TGA **7**

(b) What is MHRA? Write down the function of MHRA. **6**

8 Answer the following :

(a) Discuss the WHO certification scheme for pharmaceutical products. OR Give details about Equipment Qualification for Rapid Mixer Granulator. **7**

(b) Write a note on computer system validation. **6**