DM-M-2011123 Seat No. _____

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

April / May – 2015

Global Regulatory Requirements

(Pharmaceutics)

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

Instructions : (1) Answer and tie up both the sections separately.
(2) Figure to the right indicates marks.
(3) Answer any three (03) questions from each section.
(4) Question one (1) and questions five (5) are compulsory.
(5) Draw neat and clean diagrams as required.

SECTION – I

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

(a) Give full form of: CDER and CDRH
(b) Enumerate various components of FDA.
(c) What is SUPAC?
(d) What do you mean by Reference listed drugs?
(e) Define: Therapeutic Equivalent
(f) What are the main functions of WHO?
(g) Give difference between DMF and Applications.
(h) Define: Orange book, Green book.
(i) Enlist the benefits of Process Validation
(j) What do you mean by ERP?

2 Answer the following.

(a) Define validation? Give its types and discuss its scope in pharmaceutical industry. **7**
(b) Discuss the WHO certification scheme for pharmaceutical products. **6**

3 Answer the following.

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

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

4 Answer the following.

(a) Write in brief account on freedom of information. **5**

(b) Give functions of CDSCO **5**

(c) What are the statistical criteria for Bio-equivalence as per Orange book? **3**

SECTION – II

5 Answer **Any TWO** out of given THREE questions. **2×7=14**

(a) Write a brief note on IIG.

(b) Define Drug Development Process and write a note on New Chemical Entity development.

(c) Discuss the coding system for Therapeutic Equivalence Evaluation and how it can be changed giving suitable illustration?

6 Answer the following.

(a) Differentiate IND and ANDA. Describe various type of IND. **7**

(b) What are DMFs? Enumerates the various types of DMFs and explain in detail type II DMFs. **6**

7 Answer the following.

(a) Write a short note on ANDA para IV filing. **7**

(b) What USFDA does and does not regulate? How will you prepare for USFDA inspection. **6**

8 Answer the following.

(a) Write a note on TGA. **7**

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