DK-M-2011267 Seat No. _____

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

April / May – 2015

International Regulatory Requirement
(Pharma. Drug Regulatory Affairs)
(Specialization Paper - IV) (Core Subject - IV)

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 the three (03) questions from each section.
(4) Question one (1) and question Five (05) are compulsory.
(5) Draw neat and clean diagrams as required.

SECTION - I

1 How will you differentiate quality control and quality assurance? Discuss the role of QA and QC in pharmaceutical industry with suitable example. **14**

2 (a) What is the difference between innovator product and generic product? Discuss the role Hatch-Waxman law in generic drug development. **8**

(b) What do you mean by bioavailability and bioequivalence? Why innovator product is comparatively more costlier than generic product? **5**

3 (a) Differentiate NDA and ANDA. **8**

(b) Discuss the content of NDA as per US-FDA guideline. **5**

4 (a) Explain the term : **8**
(1) Investigator
(2) Sponsor
(3) Monitor
(4) Subject

(b) Role of Pharmacovigilance in clinical trial. **5**

SECTION - II

5 What is CTD? Differentiate CTD and eCTD. Discuss the need and content of CTD in detail. **14**

6 (a) What is marketing authorization? Discuss in detail. **8**

(b) Write an informative note on SUPAC. **5**

7 (a) Explain the term non clinical drug development. **8**

Discuss submission of investigational new drug as per US- FDA guideline.

(b) Discuss the basic structure of clinical trial protocol. **5**

8 (a) Discuss the role of : **8**

(1) 21 CFR

(2) ICH

(3) GLP

(4) GLP

(b) Write a short note on CRO. **5**