HU-M2011267 Seat No. _____

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

June / July - 2017

International Regulatory Requirements (Core IV)

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

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

SECTION - I

1 Write any seven out of ten each carry 2 marks. **7×2=14**

1. What is IVIVC?
2. Describe different types of labelling used in pharmaceuticals.
3. Differentiate IND, NDA and ANDA.
4. Describe investigator brochure (IB).
5. Briefly describe over the counter products.
6. Enlist different drug regulatory agencies of various countries.
7. What is the importance of herbal drugs in under developed countries?
8. Define marketing authorization.
9. What is bioequivalence? Where it is needed to perform bioequivalence studies?
10. What is the importance of post marketing surveillance?

2 1. Write a detailed note on Chemistry, Manufacturing and Controls (CMC) of generic drug. **7**

2. Write a note on post approval changes of new drug application. **6**

3	1.	Describe in detail Laboratory Information Management System (LIMS).	**7**
	2.	What are combination products? Describe all class in detail.	**6**
4	1.	Write a note on medical devices.	**7**
	2.	Describe in detail Hatch-Waxman Act.	**6**

SECTION - II

5 Write any two out of three each carry 7 marks. **2×7=14**

1. Describe the differences of CTD and eCTD in detail.
2. Write a note on Contract Research Organization (CRO).
3. Describe in detail Institutional Review Board/Independent Ethics committee-formation and working procedures.

6	1.	Describe the role of Quality Assurance (QA) department in clinical trials.	**7**
	2.	Define the term investigators, sponsors and monitors.	**6**
7	1.	Describe how Indian agency regulates the clinical trials.	**7**
	2.	Write a note on Health Insurance Portability and Ac countability Act of 1996.	**6**
8	1.	Write a note on supplemental abbreviated new drug application.	**7**
	2.	Describe in detail investigation medicinal product dossier.	**6**