JBL-014-0032003 Seat No. _____

Master of Pharmacy Management (Sem. XI) (CBCS) (W.E.F.-2014-15 & 2015-16) Examination

December – 2019

International Regulatory Environment

Faculty Code : 014
Subject Code : 0032003

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

Instructions :

(1) Attempt three questions from each section.

(2) Questions **1** and **5** are compulsory.

(3) Figure to the right indicates full marks for the respective question.

(4) Draw neat and clean diagram when required.

SECTION - I

1 Answer the following questions : (Any **Seven**) **14**

1. What is the full form of ICH and CMC?
2. Enumerate the tragedies which lead to availability of safety requirements in the trial.
3. Define clinical trial.
4. What are the labeling and packing requirements for schedule x drugs?
5. Give the name of the father of the clinical trials and explain its study in brief.
6. Write down the name of the regulatory authorities of India and Europe.
7. Explain hybrid NDA.
8. What are generic drugs? Which application is filled for generic drug products?
9. Enumerate general labeling requirements of drugs given in Indian regulations.
10. What are biological drugs? Give 4 examples of the same.

2 Answer the following questions :

(1) Write a detail note on CMC. **7**

(2) Define clinical trial and discuss about different phases of clinical trials in detail. **6**

3 Answer the following questions :

(1) Explain ICH and its organizing structure in detail. **7**

(2) Describe in brief about hybrid NDA and its advantages. **6**

4 Answer the following questions :

(1) Write a note on Non-clinical trials. **7**

(2) Enumerate types of DMF and differentiate between API CMC & FPP CMC. **6**

SECTION - II

5 Answer the following questions : (Any **Two**) **14**

(1) Give similarities and differences of regulatory requirements of US and Europe for drug products.

(2) Explain DMF in detail.

(3) Describe in details about NDA.

6 Answer the following questions :

(1) Write a history of development of pharmaceutical industries. **7**

(2) Give the flowchart for NDA and ANDA approval process. **6**

7 Answer the following questions :

(1) Write a note on regulatory requirements of biological products. **7**

(2) Give the history of the development of ICH and enumerate any 10 guidelines given by ICH. **6**

8 Answer the following questions :

(1) Discuss in detail: ANDA. **7**

(2) Write down the documents required for approval of new drugs related to clinical trials. **6**
