Sub Code:MPH104T

Paper Id: 256104 Roll No:

M PHARM

(SEM I) THEORY EXAMINATION 2019-20

REGULATORY AFFAIRS

TIME: 3 HOURS ***TOTAL MARKS: 75***

Note: 1. Attempt all Sections. If require any missing data; then choose suitably.

SECTION A

1. Attempt *ALL* questions in brief. 10 x 2 = 20

a. What do you mean by CMC?
b. Discuss in brief about Post Marketing Surveillance.
c. Write down the importance of Regulatory Affairs.
d. What do you mean by Distribution records?
e. Describe outsourcing BA and BE to CRO.
f. What are the phases of clinical trials?
g. Write a brief note on Hatch-Waxman Act and amendments.
h. What do you mean by ICH?
i. What is Contract Research Organization?
j. Describe the term Pharmacovigilance.

SECTION B

2. Attempt any *TWO* parts of the following: 2 x 10 = 20

a. Describe HIPPA as a new requirement to clinical study process.
b. Write a detailed note on Global submission of Investigational New Drug.
c. Discuss in detail about Scale up process approval changes.

SECTION C

3. Attempt any *FIVE* parts of the following: 7 x 5 = 35

a. Write short notes on ‘drug master file and ‘master formula record’’.
b. Describe the ICH guidelines of ICH-Q and ICH-S.
c. Discuss the regulatory requirements for the conduction of clinical trials.
d. Write a brief note on ‘Global submission of NDA’.
e. Describe the formulation and working procedure of Institutional review board.
f. Explain the purpose and content of Investigator brochure.
g. Discuss the regulatory requirements of ROW countries for product approval.