Printed Pages:01 **Sub Code: MPH104T**

Paper Id: 256104 **Roll No.** | | | | | | | | | | |

M PHARM
(SEM I) THEORY EXAMINATION 2018-19
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 'DMF'?

b. State Hatch-Waxman Act.

c. State the regulatory requirements for product approval of MHRA countries.

d. Define 'CTD' and 'ECTD format'.

e. Mention the role of IMPD in non clinical drug development.

f. What do you mean by global submission of ANDA?

g. Mention the functions of the Institutional Review Board.

h. Mention the steps for developing clinical trial protocols.

i. Explain the term 'CFR'.

j. What do you mean by post approval regulatory affairs?

SECTION B

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

a. Describe the regulatory requirement for product approval of API and biologics.

b. State and explain the regulation for combination products and medical devices.

c. Explain the ANDA regulatory approval process.

SECTION C

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

a. Write short notes on 'master formula record' and 'code of federal regulation'.

b. Describe the ways and means of US registration for foreign drugs.

c. Write short notes on 'CTD' and 'ECTD format'.

d. Write a brief note on 'non clinical drug development'.

e. Describe the formulation and working procedure of Independent Ethics Committee.

f. Write a brief note on 'informed consent process and procedures'.

g. Write short note on 'industry and FDA liaison'.