Subject Code: MPH104T

PAPER ID-421498

Roll No: | | | | | | | | | | | | | |

MPHARM
(SEM I) THEORY EXAMINATION 2021-22
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.	State the structural components of a Drug Master File.
b.	What do you mean by CFR?
c.	Mention the significance of regulation for medical devices.
d.	State the basics of CTD and ECTD formats.
e.	State Hatch-Waxman Act.
f.	State the regulatory requirements for product approval of MHRA countries.
g.	Identify the role of IMPD in non-clinical drug development.
h.	What do you mean by global submission of IND?
i.	Define the role of HIPAA in clinical trials.
j.	State the role of pharmacovigilance in clinical trials.

SECTION B

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

a.	State and explain the regulatory requirement for the approval of biologics.
b.	Highlight and explain the major features of 'informed consent process and procedures'.
c.	Describe the stages of the developing clinical trial protocols.

SECTION C

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

a.	Explain the steps involved in ANDA regulatory approval process.
b.	Describe the ways and means of US registration for foreign drugs.
c.	Describe the various aspects of 'industry and FDA liaison'.
d.	Describe in brief the various stages of 'non clinical drug development'.
e.	Describe the stages of post approval regulatory affairs.
f.	Explain the formulation and working procedures of the Institutional Review Board.
g.	Write in brief the consent process and procedures of the Independent Ethics Committee.