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.	What are controlled documents?
b.	Relate the role of SOP in pharmaceutical industry.
c.	Classify different type of documents.
d.	Summarize the role of institutional review board.
e.	Explain the importance of code of federal regulation.
f.	Summarize different phases of clinical trials.
g.	Explain combination products.
h.	Compare typical difference between IND and NDA.
i.	What is ANDA?
j.	Explain the role of ICH in quality of finished product.

SECTION B

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

a.	Discuss the major component of Master formula record.
b.	Explain the ANDA for generic drugs approval in US.
c.	Describe the submission of DMF (Drug Master File).

SECTION C

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

a.	How would you apply the significance of Hatch- Waxman act and amendments?
b.	Outline Investigator brochure.
c.	Illustrate the regulation for medical device.
d.	Analyze Global submission of IND.
e.	Illustrate the role of HIPAA
f.	Illustrate the Industry and FDA liaison
g.	Assess the Pharmacovigilance safety monitoring in clinical trials.

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