



Roll No: _____

MPHARM
(SEM I) THEORY EXAMINATION 2025-26
REGULATORY AFFAIRS

TIME: 3 HRS

M.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.	Define Master Formula Record (MFR).
b.	What is a Drug Master File (DMF)?
c.	Write two key features of the Hatch-Waxman Act.
d.	Define ANDA.
e.	What is CTD format?
f.	Mention two major guidelines under ICH-Q.
g.	Define Investigator's Brochure (IB).
h.	What is the role of an Institutional Review Board (IRB)?
i.	Define informed consent in clinical trials.
j.	What is post-marketing surveillance?

SECTION B

2. Attempt any two parts of the following:

2 x 10 = 20

a.	Explain the NDA and ANDA approval process. Discuss BE studies and drug product performance evaluation.
b.	Describe CTD and e-CTD formats. Explain the regulatory requirements of EU, MHRA, TGA and other ROW countries.
c.	Discuss the process of developing clinical trial protocols. Explain IRB/IEC functions and the informed consent procedure.

SECTION C

3. Attempt any five parts of the following:

7 x 5 = 35

a.	Explain the components and significance of a Drug Master File (DMF).
b.	Discuss CMC and post-approval regulatory requirements.
c.	Explain regulation of combination products and medical devices.
d.	Describe global submission procedures for IND, NDA and ANDA.
e.	Write a detailed note on IMPD and its requirements.
f.	Explain HIPAA requirements in relation to clinical study processes.
g.	Discuss pharmacovigilance and safety monitoring in clinical trials.