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MPHARM
(SEM I) THEORY EXAMINATION 2024-25
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 the term "CMC"	CO2	K1
b.	State Hatch-Waxman act.	CO1	K1
c.	Discuss in brief about regulatory requirement for product approval.	CO2	K2
d.	Classify Different types of documents required in pharmaceutical industry.	CO1	K2
e.	Differentiate between IND and NDA.	CO3	K4
f.	Explain the role of ANDA in non-clinical development.	CO4	K2
g.	Compare CTD and ECTD format and its significance.	CO2	K4
h.	List the function of Institutional review board in clinical trials.	CO5	K1
i.	Describe the term pharmacovigilance.	CO5	K2
j.	Relate the role of outsourcing BA and BE to CRO.	CO	K4

SECTION B

2. Attempt any two parts of the following:

2 x 10 = 20

a.	Describe the various component of master formula record (MFR) and its significance in pharmaceutical industry	CO1	K2
b.	Explain HIPAA and its requirement to clinical study process.	CO5	K2
c.	Compare the global submission of NDA and ANDA in non-clinical drug development.	CO3	K4

SECTION C

3. Attempt any five parts of the following:

7 x 5 = 35

a.	Describe the generic product development and its significance.	CO1	K2
b.	Explain US registration for foreign drugs in regulatory product approval process.	CO2	K2
c.	Relate the role of CMC and post approval regulatory affairs.	CO3	K4
d.	Discuss the different phases of clinical trial.	O5	K3
e.	Compare the regulatory requirement of EU, MHRA and ROW countries.	CO4	K4
f.	Describe the regulation of combination products and medical devices.	CO4	K2
g.	Discuss the drug master file and distribution records role in documentation in pharmaceutical industry.	CO,	K2