PAPER ID-410764

Subject Code: BP804ET

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

BPHARM

(SEM VIII) THEORY EXAMINATION 2023-24

PHARMACEUTICAL REGULATORY SCIENCE

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 generic drugs.
b.	Why preclinical studies are not required for ANDA?
c.	Describe the Nonclinical drug development process.
d.	Define post marketing surveillance.
e.	Describe typical difference between CTD and eCTD.
f.	Enlist different clinical trial phases.
g.	Discuss investigator brochure.
h.	Explain the need of independent ethics committee.
i.	Discuss the GCP obligations of Investigators.
j.	Discuss Orange book.

SECTION B

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

a.	Discuss the organization structure of European Union and types of applications.
b.	Discuss in detail about Investigational New Drug (IND).
c.	Discuss in detail about New Drug Application (NDA).

SECTION C

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

a.	Illustrate the different Stages of drug discovery.
b.	Write an overview of regulatory authorities of India.
c.	Explain the Drug Master Files (DMF).
d.	Illustrate the procedure for export of pharmaceutical products.
e.	Elaborate the clinical trial protocol development.
f.	Discuss the Federal Register and CFR.
g.	Describe the formation and working procedure of Institutional Review Board.