Paper ID : 250355

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

BPHARM
(SEM VIII) THEORY EXAMINATION 2024-25
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.	What is the purpose of IND filing?
b.	How will you define generic product?
c.	What is ASEAN common technical document?
d.	What do you mean by post marketing surveillance?
e.	Enumerate the GCP obligations of the investigators.
f.	What is Investigator brochure?
g.	Summarize different phases of clinical trials.
h.	Write down the importance of regulatory affairs.
i.	Describe the term 'Pharmacovigilance'.
j.	Give the importance of purple book.

SECTION B

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

a.	Discuss the various stages of new drug development.
b.	Explain the organization structure and functions of CDSCO.
c.	Discuss the clinical trial protocol development in detail.

SECTION C

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

a.	Explain the regulatory approval process of ANDA.
b.	What do you mean by CFR? Discuss Federal Register.
c.	Write a note on 'CTD' and 'eCTD'.
d.	How pharmacovigilance safety monitoring done in clinical trials?
e.	Write a detailed note on drug master file.
f.	What is Institutional review board? Discuss formation and working procedure.
g.	Write a note on Orange book.