PAPER ID-311945

Subject Code: BP804ET

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

BPHARM

(SEM VIII) THEORY EXAMINATION 2025-26

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.	Elaborate CTD and ACTD.
b.	Differentiate between NDA and ANDA.
c.	Define innovator and generic drug product.
d.	Enlist the various regulatory authorities and agencies.
e.	List various stages of drug discovery.
f.	What do you mean by pre-clinical studies?
g.	State the significance of orange book.
h.	Define pharmacovigilance mentioning its importance.
i.	What is the significance of informed consent?
j.	Define clinical trial. Mention various phases.

SECTION B

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

a.	Discuss the technical documentation required for registration of Indian pharmaceutical products in overseas markets with reference to CTD and eCTD.
b.	Explain the regulatory concepts including guidelines, regulations, laws and acts related to pharmaceutical regulatory science.
c.	Describe in detail the entire process of new drug discovery and development.

SECTION C

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

a.	Outline the concept and development of generic drug products.
b.	Summarize the IND approval process and timelines.
c.	Describe the formation and functions of Institutional Review Board.
d.	Illustrate the development of clinical trial protocol.
e.	Give a brief account of the procedure for exporting pharmaceutical products.
f.	Explain GCP obligations of investigators and sponsors.
g.	Discuss the significance of the Federal Register and Code of Federal Regulations (CFR).

QP26DP1_241 | 24-Jan-2026 1:55:16 PM | 103.146.232.25