PAPER ID-310563

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. | Discuss a detailed note on CTD. |
| c. | Describe the objective of GLC |
| d. | Define Pharmacovigilance. |
| e. | Illustrate the pre-clinical studies. |
| f. | Explain different phases of clinical trials. |
| g. | Discuss Abbreviated New Drug Application. |
| h. | Explain the working and formation of Institutional Review Board. |
| i. | Define Federal Register. |
| j. | What is orange book? |

**SECTION B**

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

| | |
|---|---|
| a. | Explain the Investigational New Drug (IND). |
| b. | Discuss in detail about Drug Master Files (DMF). |
| c. | Illustrate the Generic drug product development. |

**SECTION C**

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

| | |
|---|---|
| a. | Discuss the different Stages of drug discovery. |
| b. | Write the Overview of regulatory authorities of India. |
| c. | Discuss in detail about New Drug Application (NDA). |
| d. | Write the procedure for export of pharmaceutical products. |
| e. | Elaborate the clinical trial protocol. |
| f. | Explain Code of Federal Regulatory. |
| g. | Discuss about Pharmacovigilance - safety monitoring in clinical trials. |