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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

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| a. | Define innovator. |
| b. | Define generics. |
| c. | Define IND. |
| d. | Write the application of CTD. |
| e. | Define GCP obligations of investigators. |
| f. | Write the purpose of purple book. |
| g. | Define ASEAN. |
| h. | Write the importance of clinical trials. |
| i. | Which pharmaceuticals are exported from India? |
| j. | Write the responsibilities of research sponsors. |

SECTION B

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

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| a. | Write the basic requirements of preclinical studies. |
| b. | Write the concept of abbreviated new drug application. |
| c. | Write the contents of drug master file. |

SECTION C

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

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| a. | Describe generic drug product development. |
| b. | Write the organizational structure of regulatory authorities in United States. |
| c. | Write the procedure of export of pharmaceutical products. |
| d. | Discuss the role of safety monitoring in clinical trials. |
| e. | Describe eCTD. |
| f. | Write the organizational structure and responsibilities of regulatory authorities in japan. |
| g. | Explain the non-clinical activities involved in new drug discovery. |