Printed Pages:01 **Sub Code: BP 804ET**

Paper Id: 231064 **Roll No.** | | | | | | | | | | |

B PHARM
(SEM VIII) THEORY EXAMINATION 2022-23
PHARMACEUTICAL REGULATORY SCIENCE

Time: 3 Hours ***Total Marks: 75***

Note: Attempt all Sections.

SECTION A

1. Attempt *all* questions in brief. **2 x 10 = 20**

(a) Differentiate NDA and ANDA.

(b) What is placebo trial?

(c) What do you mean by a randomized design?

(d) Define clinical trial and explain Phase II.

(e) Write about Timeline and types of IND.

(f) How many people will be selected for Phase-I trial?

(g) What is the significance of pharmacovigilance?

(h) Importance of DMF.

(i) Write a brief note on 21 CFR.

(j) Differentiate Generic vs Innovator.

SECTION B

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

(a) Discuss the various modules and requirements of electronic Common Technical Document (eCTD)? Compare it with ASEAN common technical documents (ACTD).

(b) Write the various stages of Development of new drugs.

(c) Discuss the application and approval process of ANDA.

SECTION C

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

(a) Explain organization structure and functions of USFDA.

(b) What are various GCP obligations of investigator and sponsor?

(c) Explain the salient features of orange book and purple book.

(d) Explain the organization and functions of CDSCO.

(e) Discuss the organization structure and functions of Australian drug regulatory body.

(f) Explain the safety monitoring in clinical trials.

(g) Discuss the importance of pharmaceutical regulatory affairs in industry.

QP23DP1_290 | 06-01-2023 13:34:49 | 117.55.242.132

QP23DP1_290 | 06-01-2023 13:34:49 | 117.55.242.132