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

**Time: 3 Hours**

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**Total Marks: 75**

**Note:** Attempt all Sections.

**SECTION A**

1. **Attempt all questions in brief.** <https://pharmacyindia.co.in/> **2 x 10 = 20**

- Differentiate NDA and ANDA.
- What is placebo trial?
- What do you mean by a randomized design?
- Define clinical trial and explain Phase II.
- Write about Timeline and types of IND. <https://pharmacyindia.co.in/>
- How many people will be selected for Phase-I trial?
- What is the significance of pharmacovigilance?
- Importance of DMF.
- Write a brief note on 21 CFR.
- Differentiate Generic vs Innovator.

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**SECTION B**

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

- Discuss the various modules and requirements of electronic Common Technical Document (eCTD)? Compare it with ASEAN common technical documents (ACTD).
- Write the various stages of Development of new drugs.
- Discuss the application and approval process of ANDA.

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**SECTION C**

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

- Explain organization structure and functions of USFDA.
- What are various GCP obligations of investigator and sponsor?
- Explain the salient features of orange book and purple book.
- Explain the organization and functions of CDSCO. <https://pharmacyindia.co.in/>
- Discuss the organization structure and functions of Australian drug regulatory body.
- Explain the safety monitoring in clinical trials.
- Discuss the importance of pharmaceutical regulatory affairs in industry.

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