Seat No. _____

HQ-BP804ET

B. Pharm. (Sem.-VIII) Examination

April - 2023

Pharmaceutical Regulatory Science : BP804ET

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

Instructions : (1) Figure to the right indicates marks.
(2) Draw neat and clean diagrams as required.

1 Answer the following questions. **10x2=20**

(a) Explain the term pharmaceutical drug regulation.

(b) What are the different phases of drug discovery and development?

(c) How clinical trials are different from non-clinical trials?

(d) Comment: Generic drugs are of substandard quality compared to innovator products.

(e) In India, which regulatory authority gives approval for the marketing of drugs in the Indian market?

(f) Give the name of regulatory agencies of the US, India, Australia, and Canada.

(g) What is the objective of CTD?

(h) How CTD and ACT'D are different?

(i) Comment: IRB is associated with the manufacturing aspects of drugs.

(j) What is Orange book?

2 Answer any **two** out of the following questions. **2x10=20**

(a) Why pharmaceutical product registration is important? Discuss in detail, NDA and ANDA with their flowchart.

(b) Give a detailed account of the regulatory authority of India, the US, and Europe.

(c) What are CTD and eCTD? Discuss different modules of both documents and discuss their advantages and disadvantages.

3 Answer any **seven** out of the following questions. **7x05=35**

(a) Explain the term: CFR 21, SUGAM, Purple book, PMDA, and DCGI.

(b) Write an informative note on IND.

(c) What are the objectives of the drug master file? Give its important content.

(d) Differentiate classical and reverse pharmacological approaches of drug discovery.

(e) What is clinical research protocol? Discuss briefly.

(f) Explain the role and responsibilities of IRB.

(g) Write a detailed note on GCP.

(h) How clinical trials and pharmacovigilance are different? Discuss.

(i) Write a note on ASEAN common technical document.

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