DAO-BP804ET

Seat No. _____

B. Pharm (Sem. VIII) Examination

April / May - 2022

Pharmaceutical Regulatory Science : BP-804ET

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

Instruction : Figure to the right indicates full marks for the respective question.

1 Answer the following. **10×2=20**

(1) Define: Clinical trials.

(2) What is Orange Book?

(3) Enlist the types of DMF.

(4) Give the fullform of ANDA, ASEAN, CTD and GCP.

(5) Enlist the stages of drug development.

(6) Give any 4 examples of changes- being made to an already approved NDA by pharmaceutical product manufacturers.

(7) Differentiate CTD & ACTD.

(8) Give the name of regulatory authorities of India and Australia.

(9) What are generic drugs? Explain with suitable example.

(10) What is CFR?

2 Answer the following. (Any TWO) **2×10=20**

(l) Write a detailed note on constitution and procedures of Institutional Review Board.

(2) When one can file for NDA? Explain with suitable example and discuss in details about the approval process of NDA with flowchart.

(3) Describe in detail about pre-clinical studies.

3 Answer the following. (Any SEVEN) **7×5=35**

(1) Write a note on Clinical trial protocol.

(2) Describe in detail about the federal register.

(3) Write a note on eCTD.

(4) Explain in brief about the Generic drug product development.

(5) Give the details of managing and monitoring of clinical trials monitoring.

(6) Describe in brief about organizational structure of Indian regulatory authority.

(7) Write a detailed note on organizational structure and types of applications of USA.

(8) Describe in detail about GCP obligations of Sponsor.

(9) Give a detailed note on Pharmacovigilance.

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