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BBF-BP804ET Seat No. _____

B. Pharm. (Sem. VIII) Examination

July – 2021

Pharmaceutical Regulatory Science

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 : **10×2=20**

(a) What is the importance of drug regulation ?

(b) Enlist the different phases of drug discovery with their time duration.

(c) How you differentiate clinical and non-clinical trials ?

(d) Why generic drugs are comparatively economical than innovator products ?

(e) Enlist and briefly explain different formats of product registration for approval.

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

(g) How CTD and eCTD are different ?

(h) What is ASEAN and ACTD ?

(i) Give the full name of IRB and GCP.

(j) Briefly explain the term Orange book.

2 Answer any two out of the following questions : **2×10=20**

(a) Why pharmaceutical product registration is important ? Discuss in detail, CTD and eCTD with their advantages.

(b) How NDA, ANDA and IND are different, Give the detailed account for NDA and ANDA.

(c) What is the role of ethics committee ? Give its formation and working. Briefly discuss the informed consent process.

3 Answer any seven out the following questions : **7×5=35**

(a) Explain the term: Code of federal regulation, SUGAM, Purple book, PMDA and DCGI.

(b) What is an investigational new drug ? Discuss the approval process of IND.

(c) Write an informative note on drug master file.

(d) Discuss classical and reverse pharmacological approach of drug briefly.

(e) Enlist the content of clinical research protocol and discuss briefly.

(f) Discuss the role and responsibility of IRB.

(g) Write a detailed note on CDSCO.

(h) Which are the phases of clinical trials ? Discuss the role of pharmacovigilance.

(i) Explain the term with reference to clinical trial : Sponsor, Subject, Investigator, Protocol and NDCT-2019.