Total No. of Questions : 8] *[Total No. of Printed Pages : 2*

Roll No .....

BP-804T(A)/PY-804 (A)-CBGS

B.Pharmacy VIII Semester (PCI Scheme)/ (Non-PCI Scheme)

Examination, June 2020

Choice Based Grading System (CBGS)

Pharmaceutical Regulatory Science

Time : Three Hours

Maximum Marks : 75

Note: i) Attempt any five questions.
ii) All questions carry equal marks.
iii) Subparts of the question should be attempted in continuation.

1. Elaborate the following.
   a) Timeline and types of IND.
   b) Institutional review board.

2. Describe in detail new drug approval process along with its documentation requirements as per USFDA.

3. What is the general procedure for export of pharmaceutical product? Discuss the requirement of Common Technical Document (CTD).

4. Compare the documentation requirements of ANDA and NDA submissions. How innovator drug is different from generics drugs?

5. Give a brief overview of the regulatory authorities with reference to their organizational structure with special reference to USFDA and European union.

6. Explain the role of pharmacovigilance in clinical trials monitoring. What are various GCP obligations of investigator and sponsor?

7. What are various modules and requirements of electronic Common Technical Document (eCTD)? Compare it with ASEAN common technical documents (ACTD).

8. Write short notes on any two of the following.
   a) Drug Master File
   b) Investigator brochure
   c) Orange and Purple book

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