QP Code: 824006 **Reg. No…….**

Eighth Semester B. Pharm Degree Regular Examinations May 2022
Pharmaceutical Regulatory Science

(2017 Scheme)

Time: 3 Hours **Max. Marks: 75**

- ***Answer all questions to the point neatly and legibly • Do not leave any blank pages between answers • Indicate the question number correctly for the answer in the margin space***
- ***Answer all parts of a single question together • Leave sufficient space between answers***
- ***Draw diagrams wherever necessary***

Essays **(2x10=20)**

1. Write about New drug Application registration in US . Classify its sections. Mention NDA forms.
2. Write in detail about pre-clinical and clinical studies conducted for Innovator drug registration.

Short Notes **(7x5=35)**

3. What are the stages of Generic drug product development.
4. Explain the procedure for export of pharmaceutical products.
5. Explain the approval process of investigational new drug (IND).
6. Structure of eCTD.
7. Explain the role of placebo in clinical trials.
8. Drug safety monitoring
9. Contents of Orange book and its applications.

Answer Briefly **(10x2=20)**

10. Write about Drug Master File (DMF) and its type of applications in US and EU.
11. Write the formation and working procedure of Institutional Review Board (IRB).
12. Write the importance of informed consent form.
13. Code of federal regulation.
14. What is abbreviated new drug application.
15. Write the importance of pre-clinical studies in drug development.
16. What are the timelines for ANDA from initial filing to final approval.
17. What is the organizational structure of drug regulatory authority of Australia.
18. What are the different categories and types of applications in US and EU.
19. What are the obligations from sponsors while conducting clinical trials.

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