QP Code: 824006 **Reg. No……**

Eighth Semester B. Pharm Degree Regular/Supplementary Examinations July 2023
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. Explain in detail about Investigational New Drug (IND) its Modules and sections from I to V in Common Technical Document (CTD).
2. Explain the difference between clinical studies conducted for Generic and Innovator drugs.

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

3. Purple book and its uses.
4. Explain the importance of Pharmacovigilance and its monitoring procedure in post marketing.
5. Drug master file.
6. Differentiate paper submission, eCTD and non e-CTD electronic submissions (NeeS).
7. Regulatory requirements of preclinical studies.
8. Explain the clinical stages of generic drug development.
9. ASEAN common Technical Document (ACTD) with country specific guidance on any two Asian countries.

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

10. General principles applied in clinical research protocol development.
11. Ethics of randomised clinical trials.
12. Reasons and benefits of implementing informed consent in clinical trials.
13. GCP and its importance in clinical trials.
14. What are the timelines for Abbreviated New Drug Application (ANDA) approval.
15. Federal register.
16. Code of Federal Regulations (CFR) 21CFR.
17. Category and types of applications in Australia, Japan and Canada.
18. List of Technical documents required for Export of Pharmaceuticals.
19. What are the obligations from Investigators and monitors while conducting clinical studies.

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