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.
- 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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