QP Code: 824006 **Reg. No……**

Eighth Semester B. Pharm Degree Regular/Supplementary Examinations July 2024
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 in detail about sections and modules under Drug Master File (DMF) and its registration procedure in US and Europe.
2. Explain the generic drug product development.

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

3. Drug master file.
4. Pharmacovigilance

5. Describe certificate of analysis of a drug product, COPP and FSC.
6. Explain the timelines involved in drug approval process.
7. Clinical trials and protocol development.
8. Code of Federal Regulations.
9. Explain about composition, roles, review and approval process by Institutional Review Board.

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

10. Write the names of different countries involved in European Health Authority.
11. Australian Health Authority and its drug applications.
12. Regulatory requirements and approval procedure for Pharmaceuticals in India.
13. Enlist the roles and responsibilities of USFDA in drug approval
14. Registration of Indian drug products in overseas markets.
15. Investigators and monitors.
16. Safety monitoring in clinical trials.
17. What are the stages of drug discovery.
18. Briefly explain the differences between generics and Branded drugs.
19. What is purple book and orange book.

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