QP Code: 824006 **Reg. No…….**

Eighth Semester B. Pharm Degree Supplementary Examinations
November 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. Explain the various modules of Common technical document
2. Explain the protocol for submission of Investigational new drug application

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

3. What are the risks involved in clinical trials
4. What is the need for drug regulations
5. Procedure for export of pharmaceutical products
6. Post marketing surveillance
7. Approval process of generic drugs
8. Draw a flow chart for ANDA review process
9. Conditions for implementing changes to a new drug application

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

10. Drug master file
11. Define new chemical entity
12. Difference between clinical trial and clinical study
13. Mention the timelines involved in filing a new drug application
14. Who are subjects and what is their role in a clinical trial
15. Functions of CDSCO in India
16. Define law and act
17. Enlist the functions of institutional review board
18. Why clinical research needs to be regulated
19. Name the regulatory authorities of Canada, Australia, European union and Japan

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