QP Code: 722006 **Reg. No……**

Seventh Semester B. Pharm Degree Regular/Supplementary Examinations September 2024
Industrial Pharmacy
(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. Discuss the role of good documentation practice in pharmaceutical industry
2. Write a note on technology transfer protocol. Write the salient features of SUPAC guidelines

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

3. What is analytical method transfer
4. What is COPP
5. Write a note on drug development process
6. Write notes on investigator's brochure
7. Write the role and responsibilities of Pharmaceutical Regulatory affairs professionals.
8. Technology transfer agencies in India
9. Importance of plant location and layout in pharmaceutical industry

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

10. What are the contents of NDA application
11. Module III of CTD
12. What is clinical trial protocol
13. Establish the relationship between generics and ANDA
14. How does an INDA application contribute to drug development
15. Functions of CDSCO
16. What is qualification and validation
17. What is confidentiality agreement
18. What is MOU
19. Mechanical Hazards

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