

QP Code: 722006

Reg. No.....

**Seventh Semester B. Pharm Degree Supplementary Examinations  
May 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 pilot plant scale up techniques with special emphasis on personnel and space requirements.
2. Write a note on various technology transfer agencies in India

**Short Notes**

**(7x5=35)**

3. Discuss drug development process.
4. Write the role and responsibilities of regulatory affairs professional.
5. Write a note on organization and functions of CDSCO.
6. Write a note on Industrial hazards and safety.
7. Outline the regulatory requirements and approval procedures for new drugs.
8. CTD and eCTD.
9. Write a note on platform technology

**Answer Briefly**

**(10x2=20)**

10. What is packaging
11. Significance of pilot plant study
12. Write the various phases of clinical trials.
13. ANDA.
14. INDA
15. What is COPP
16. Define Validation
17. Define overages
18. What is fire Hazard
19. Write the role of documentation in pharmaceutical industry.

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