

QP Code: 722006

Reg. No.....

**Seventh Semester B. Pharm Degree Supplementary Examinations
December 2025
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. Elaborate in detail about documentation, premises and equipment's for TT as per WHO guidelines.
2. Describe the organization and responsibility of the State Licensing Authorities in India with respect to regulatory affairs.

Short Notes

(7x5=35)

3. Describe about pilot plant scale-up for semi solid dosage forms.
4. Write briefly on SUPAC guidelines.
5. Explain the role of regulatory affairs in drug approval.
6. Elaborate in detail about Investigational New Drug (IND) application.
7. Discuss the approval procedures for New Drugs.
8. Enumerate the functions of CDSCO.
9. Elaborate about Fire hazards.

Answer Briefly

(10x2=20)

10. List out the advantages of pilot plant studies.
11. Define Validation.
12. List out the approved regulatory bodies.
13. Define Quality Risk Management.
14. Write a note on Investigator's Brochure.
15. List out the Technology Transfer agencies in India.
16. Describe the role of Drug control laboratory.
17. Write a note on COPP.
18. Define NDA.
19. List out the types of hazards.
