

QP Code: 722006

Reg. No.....

**Seventh Semester B. Pharm Degree Supplementary Examinations
January 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. Write in detail about SUPAC guidelines. Discuss the impact on pharmaceutical industry.
2. What is quality risk management Write a note on platform technology

Short Notes

(7x5=35)

3. Discuss the regulatory landscape of approval of new drugs in India.
4. Write a note on non-clinical drug development.
5. Discuss the general considerations of IND applications.
6. How does the Investigator's Brochure evolve throughout different stages of clinical development
7. Write the role and responsibilities of state licensing authority.
8. Discuss in detail chemical hazards in pharmaceutical industry.
9. Importance of plant location and layout of a pharmaceutical industry

Answer Briefly

(10x2=20)

10. Significance of pilot plant scale up techniques.
11. Various modules of CTD.
12. APCTT
13. What is accident record
14. Data presentation for FDA submission.
15. Establish relationship between state licensing authority and CDSCO.
16. Define qualification and validation
17. How are overages utilized in drug formulation
18. How does a confidentiality agreement protect sensitive information during technology transfer
19. Write a note on electrical hazards in pharmaceutical industry.
