QP Code: 722006 **Reg. No……**

Seventh Semester B. Pharm Degree Regular/Supplementary Examinations August 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. Explain in detail about pilot plant scale up considerations for solid dosage forms.
2. Discuss in detail about Central Drug Standard Control Organization (CDSCO).

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

3. Discuss about Technology Transfer related documentation.
4. Elaborate Platform technology.
5. Discuss about Investigator's Brochure in clinical studies.
6. Discuss the NDA regulatory approval process.
7. Describe COPP.
8. Enumerate the responsibilities of state licensing authority.
9. Discuss about plant location and layout in relation to Industrial safety.

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

10. Write about GMP considerations in pilot plant scale up.
11. Describe Technology Transfer protocol.
12. List out the role of regulatory affairs.
13. Define clinical trial according to CDSCO.
14. Define SUPAC.
15. List out the drug testing laboratories.
16. Expand BCIL and APCTT.
17. Highlight the components of non-clinical drug development.
18. Define Analytical method transfer.
19. Define ANDA.

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