QP Code: 722006 **Reg. No……**

Seventh Semester B. Pharm Degree Regular/Supplementary Examinations February 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. Explain general consideration of pilot plant scale up techniques for solid dosage forms.
2. Explain role and responsibility of regulatory affairs professionals.

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

3. Explain the requirements for plant location and layout of a pharmaceutical industry.
4. General considerations of Investigational New Drug (IND) application.
5. Describe about COPP.
6. Explain in detail about APCTT.
7. Regulatory requirements and approval procedure for new drugs.
8. Explain pharmaceutical hazards and their safety.
9. Explain technology development and transfer for granularity of TT process.

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

10. What are SUPAC guidelines.
11. Mention TT agencies in India.
12. What are Data presentation for FDA submissions.
13. Explain CDSCO.
14. What is platform technology.
15. Define commercialization and problems.
16. What are confidentiality agreements.
17. List out the five modules of common technical document.
18. Components of an investigators brochure.
19. Define transfer of technology.

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