QP Code: 722006 **Reg. No…….**

Seventh Semester B. Pharm Degree Supplementary Examinations
February 2022
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 a note on the historical overview of regulatory affairs, regulatory authorities and their role & responsibilities in controlling the introduction of newer drug molecules.
2. Discuss the plant location and layout and other requirements for starting a Pharma Industry.

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

3. Discuss the chemical hazards and their prevention.
4. Explain in detail about SUPAC guidelines.
5. Granularity of TT Process.
6. Describe briefly about platform technology.
7. What are the regulatory requirements and approval procedures for New drugs in India
8. What are the role of TBSE in Technology transfer.
9. What are the responsibilities of CDSCO.

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

10. What are the unit operations involved in pilot plant scale up of solid dosage forms
11. Define Technology transfer.
12. Different phases of clinical trials.
13. What are innovation and invention.
14. Different types of licensing agreement
15. Define regulatory authority.
16. Briefly Explain TIFAC.
17. Briefly Explain COPP.
18. Steps of drug development process.
19. What is the structure of CTD

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