QP Code: 722006 **Reg. No…….**

Seventh Semester B. Pharm Degree Regular Examinations
October 2021
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. Discuss the role of Central Drug Standard Control Organization in controlling the drug distribution in India and write its organization and responsibilities.
2. Describe different types of hazards and their prevention in the Pharmaceutical companies.

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

3. Write briefly about platform technology.
4. Discuss the WHO guidelines for Technology Transfer (TT).
5. Discuss the Non-Clinical drug development.
6. Describe the plant location and layout of Pharma Industry.
7. What are the responsibilities of regulatory affairs personnel.
8. Discuss the practical aspects and problems of commercialization.
9. Responsibilities of TT agencies.

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

10. What is critical equipment variable.
11. Applications of quality risk management.
12. Different phases of clinical trials.
13. What are bioequivalence experimental study design,
14. Define NDA
15. Accident records
16. Define COPP
17. Structure of CTD
18. What are the critical manufacturing steps in direct compression of tablet dosage forms
19. What are the objectives of pilot plant scale up techniques

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