QP Code: 722006 **Reg. No…….**

Seventh Semester B. Pharm Degree Supplementary Examinations
June 2023
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. Describe the steps involved in the pilot plant scale up techniques for the development of semisolid dosage forms with relevant documentation
2. Discuss the WHO guidelines followed for Technology Transfer in the introduction of drug product for marketing.

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

3. SUPAC guidelines.
4. Discuss the responsibilities of State Licensing authority.
5. Quality risk management.
6. Describe briefly about platform technology.
7. Investigator's Brochure.
8. Discuss the regulatory requirements for drug approval.
9. Plant location and layout of a pharmaceutical industry.

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

10. Types of hazards.
11. What is CTD (common technical document).
12. Different phases of clinical trials.
13. TT agencies in India.
14. Explain INDA.
15. Organization of CDSCO.
16. Define Validation.
17. Define overages.
18. Confidentiality agreement in technology of transfer.
19. What are the contents of NDA application.

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