QP Code: 722006 **Reg. No…….**

Seventh Semester B. Pharm Degree Special Supplementary Examinations July 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. Explain general consideration and significance of personnel requirements, space requirement of pilot plant scale up techniques.
2. Explain in detail about WHO guidelines for technology transfer.

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

3. Explain the regulatory requirement for non-clinical drug development.
4. Describe the factors influencing the location of the pharmaceutical industry.
5. Explain approved regulatory bodies and agencies.
6. Explain detail about Common Technical Document (CTD).
7. Mention some important consideration to platform technology.
8. Introduction and historical overview of regulatory affairs.
9. Explain APCTT and BCIL.

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

10. What are accident records.
11. What is NDA.
12. Write the importance of risk management principles.
13. Define transfer of technology.
14. What are fire hazards and electrical hazards.
15. What are regulatory requirements and approval procedure for new drugs.
16. Significance of SUPAC guidelines.
17. Differentiate between process layout and product layout.
18. List out the responsibility of regulatory affairs professionals.
19. Define commercialization.

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