QP Code: 722006 **Reg. No……**

Seventh Semester B. Pharm Degree Regular/Supplementary Examinations February 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. Explain technology transfer protocol and quality risk management in technology development and also process involved in technology transfer from R and D to production.
2. Explain the general consideration of pilot plant scale up techniques for the development of liquid orals forms with relevant documentation.

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

3. Explain any two hazards and their industrial safety measures.
4. Explain SUPAC guidelines.
5. Explain organization and responsibilities of CDSCO.
6. What are confidentiality agreements and MoUs.
7. Explain the granularity of TT process involved in technology development and transfer.
8. Explain Data presentation for FDA submissions.
9. Explain Certificate of Pharmaceutical Product (COPP).

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

10. List out the major utility and service systems used in pharma industry.
11. Importance of Investigators Brochure (IB) and NDA.
12. Define TIFAC and TBSE.
13. What are regulatory requirements and approval procedure for new drug.
14. List out the different modules of CTD.
15. What are general consideration of Investigational New Drug (IND) application.
16. Format of COPP.
17. Define technology transfer protocol.
18. Define accident records.
19. What are the steps involved in scale up process.

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