

VINAYAKA MISSION'S RESEARCH FOUNDATION
(Deemed to be University) , SALEM

B.PHARM. DEGREE EXAMINATION – October 2021
Seventh Semester

INDUSTRIAL PHARMACY - II

Time : Three hours

Maximum: 75 marks

I. Write essays on any **TWO** questions: (2 x 10 = 20)

1. Discuss pilot plant scale up consideration for liquid orals.
2. Discuss stage involved in technology transfer in pharmaceutical industry.
3. Discuss general consideration of Investigational New drug Application.

II. Write short answers on any **SEVEN** questions: (7 x 5 = 35)

4. Discuss the role and responsibilities of RA professional.
5. Discuss the Investigator's Brochure (IB).
6. Discuss the various Modules in CTD.
7. Discuss about qualification and validation for technology transfer as per WHO guidelines.
8. Explain SUPAC guidelines.
9. Outline six sigma concept.
10. Describe the quality management systems.
11. Responsibility of CDSCO.

III. Write short notes on : (10 x 2 = 20)

12. Define pilot and scale up.
13. What is the difference between pilot scale and scale-up?
14. Define quality risk management (QRM) and write its principle.
15. What do you mean by intercompany and intracompany?
16. What is clinical trial protocol?
17. What are BE & BA studies? Why they are required?
18. The functions of state licencing authorities.
19. What is OOS?
20. What is NRDC?
21. Define IND.
