Sl.No: M2142 **Course Code: BP702T**

VINAYAKA MISSION'S RESEARCH FOUNDATION
(DEEMED TO BE UNIVERSITY), SALEM

B.PHARM. DEGREE EXAMINATION – July 2021
Seventh Semester

INDUSTRIAL PHARMACY II

Time : Three hours Maximum: 75 marks

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

1. Describe in detail about Good Laboratory practice.
2. Explain the WHO guidelines for Technology Transfer.
3. Summarize the Investigational New Drug Application and New Drug Application.

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

4. Describe the responsibilities of State Licensing Authority.
5. Explain about TT related documentation.
6. Give an account of Investigator's Brochure.
7. Explain the concept of Total Quality Management.
8. Draw the organization chart for Central Drug Standard Control Organisation.
9. Describe about the pilot plant scale up considerations for Semi Solids.
10. Give an account of Commercialization.
11. Explain about Bio Equivalence Studies.

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

12. What is quality by design?
13. Write the responsibility of Regulatory Affairs professionals.
14. Give an account of APCTT.
15. What is the function of State Licensing Authority?
16. How will you review the formula in pilot plant scale up?
17. What is NABL Standard?
18. What is the role of CDSCO in India?
19. Write about Drug Development Team.
20. State briefly about TIFAC.
21. What are the items should be examined during process Evaluation?

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