**Sl.No: M21953** **Course Code: BP702T**

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

## B.PHARM. DEGREE EXAMINATION – JANUARY 2020
**Seventh Semester**

## INDUSTRIAL PHARMACY II

Time : Three hours Maximum: 75 marks

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

1. Explain in detail about pilot plant scale up considerations for solids.
2. Describe about TT agencies in India.
3. Explain about central drug standard control organization (CDSCO).

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

4. Explain about platform technology.
5. Describe the quality by Design (QBD).
6. Give an account of analytical method transfer.
7. Describe about management of clinical studies.
8. Explain the pilot plant scale up considerations for liquid orals.
9. Describe about NDA regulatory approval process.
10. Explain about six sigma concept.
11. Summarize the biostatistics in pharmaceutical product development.
12. Describe about the responsibilities of state licensing authority.

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

13. Write about GMP considerations in pilot plant scale up.
14. Give a brief account on Technology Transfer protocol.
15. What is the role of Regulatory affairs?
16. Define clinical trial according to CDSCO.
17. What are the three aspects of TQM?
18. State about slugging.
19. Define Transfer of Technology.
20. What are the components of non-clinical drug development?
21. What is ISO 9000?
22. What was given in the CDSCO regarding academic Research.

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