Sl.No: M21133 **Course Code: MPH104T**

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

M.PHARM. DEGREE EXAMINATION – September 2021
First Semester

BRANCH: PHARMACEUTICAL

REGULATORY AFFAIR

Time : Three hours Maximum: 75 marks

(Draw neat labeled diagrams wherever necessary
your answer should be specific to the questions asked)

SECTION –A

I. Answer any **THREE** questions: **(3 x 15 = 45)**

1. a)Explain the importance of documentation in pharmaceutical industry and add a note on master formula records and distribution records.
   b) Write a notes on CFR.
2. a) What are the regulatory requirement for approval of an API.
   b) ICH quality guidelines.
3. Discuss about regulations for combination products and medical devices.
4. Explain the regulatory requirement of Eu, MHRA and ROW countries.

SECTION –B

II. Answer any **THREE** questions**:** **(3 x 10 = 30)**

5. Detail on ANDA regulatory approval process.
6. Write notes on :
   a) Pharmacovigiliance safety monitoring.
   b) Investigator brochure
7. Write notes on:
   a) CTD and ECTD
   b) Industry and FDA liaison.
8. Write notes on:
   a) Informed consent process and procedures
   b) Investigation of medical products dossier.

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