Sl.No: M21756a **Course Code: MPH104T**

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

M.PHARM. DEGREE EXAMINATION – July 2019
First Semester

BRANCH: PHARMACEUTICS

REGULATORY AFFAIRS

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. Discuss about various documentation done in pharmaceutical industry.
2. Give note on independent ethics committee formulation and procedure for informed consent process.
3. Enumerate the regulatory requirements of EU, MHRA and ROW countries.
4. Write about:

   i) Post approval regulatory affairs ii) Pharmacovilgilance in drug safety

SECTION –B

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

5. Write on investigation of medicinal product dossier.
6. What is HIPAA and its usefulness in clinical trials.
7. Brief on ANDA approval process for generic drugs.
8. Describe the regulation used in approval of medical devices.

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