

Roll No _____

END-TERM EXAMINATION
Odd Semester 2024-25

Course Code: MPH104T

Course Name: Regulatory Affairs



Programme Name: M.Pharm (Pharmaceutics) Sem: Ist

Time: 3 Hours

Maximum Marks: 75

Instructions: The question paper consists of 07 questions out of which any Five has to be attempted.

Section A (15 x 5 = 75 Marks)

1	What is the role of documentation in the pharmaceutical industry? Explain the Hatch-Waxman Act and its amendments. How have they impacted generic drug development?	CO-1	L-2
2	Describe how the organizational structure and functions of the Drug Regulatory Authority of India affect drug approval processes.	CO-3	L-3
3	Describe Clinical Trials. Analyze the composition and functions of the Institutional Review Board (IRB). How does it contribute to ethical oversight in clinical trials?	CO-4	L-4
4	Evaluate the guidelines set by the International Council for Harmonisation (ICH) and discuss their effectiveness in promoting global standards in drug development.	CO-3	L-5
5	Discuss the different stages involved in pre-clinical studies and their importance in the drug development process.	CO-5	L-3
6	How does the regulatory approval process for New Drug Applications (NDA) and Abbreviated New Drug Applications (ANDA) function?	CO-2	L-3
7	Define common technical document (CTD) and electronic common technical document (eCTD). Explain different modules in CTD and eCTD.	CO-1	L-1

