DR. BABASAHEB AMBEDKAR TECHNOLOGICAL UNIVESITY LONERE-RAIGAD-402103

End Semester Examination – Winter 2024

Course :Master of Pharmacy (Pharmaceutics) Branch : Pharmacy

Semester : SEMESTER - 1

Subject Code & Name: MPH104T -REGULATORY AFFAIR

Date:

Time : 3 Hours] **[Total Marks : 75**

Instructions to the Students:

1.All questions are compulsory.

2.Draw diagrams / figures wherever necessary

3.Figures to right indicate full marks

Q.1 Attempt any FIVE questions of the following (5 x 2) = 10

A) State the importance of an Investigational Medicinal Product Dossier (IMPD). 2

B) Recall the meaning of Scale up Process Approval Changes (SUPAC) and explain its need. 2

C) Summarize the key contents of a Master Formula Record (MFR). 2

D) Outline the regulatory requirements specified by the Therapeutic Goods Administration (TGA). 2

E) Define 180-days market exclusivity. 2

F) List reasons why bioavailability/bioequivalence (BA/BE) studies are outsourced to Contract Research Organizations (CROs). 2

G) Explain the purpose of the Code of Federal Regulation (CFR). 2

Q.2 Attempt any FOUR questions of the following (5 x 4) = 20

A) Write a note on CTD and eCTD and its usefulness in regulatory affairs. 5

B) Explain the structure and purpose of a Drug Master File (DMF) and describe its importance in regulatory submissions. 5

C) Describe various activities of the Medicines and Health care products Regulatory Agency (MHRA). 5

D) Explain in detail Post marketing surveillance. 5

E) Write a note on generic drug product development. 5

F) Discuss the importance of Pharmacovigilance for safety monitoring in clinical trials. 5

Q.3 Attempt any THREE questions of the following (15 x 3) = 45

A) Describe in detail stability guidelines as per ICH. 15

B) Describe the regulatory approval process for ANDA. 15

C) Explain the steps involved in carrying out a clinical trial. Write the responsibilities and functions of Institutional Review Board (IRB). 15

D) Discuss Hatch- Waxman Act and their impact on drug development process. 15

E) Discuss Health Insurance Portability and Accountability Act (HIPAA) and its significance in clinical trials. 15