M. Pharm 1st year 1st semester 2025

Regulatory Affairs

Time: 3 hours **Total marks: 75**

Answer any five (05) questions taking at least one (01) from each group

Group - A

1. Enlist the various toxicological studies in pre-clinical trials. Explain any two in detail. **15**
2. Explain in detail the NDA approval process. **15**

Group – B

3. Write briefly on the decentralized drug approval process in EU. **15**
4. What is CMC? Write objectives of CMC. Define combination products as per CFR. What are CTD and ECTD? Write their benefits. (2+3+5+2+3)=**15**

Group – C

5. a) What is a non-clinical trial, why do we need this? classify non clinical trials.
   b) Write a note on NDA and ANDA 2+2+2+9=**15**

6. a) What is IRB, write the composition and responsibilities of IRB.
   b) What is HIPPA?
   c) Classify the types of HIPPA, Elaborate the Contents of HIPPA
   [(2+3+3) = 8+ (1+1+5) =7] =**15**

7. a) What is Informed Consent? Why is the informed consent necessary?
   b) Explain the protocol writing with its importance.
   (2+2) + (5+6) =**15**