

**M. Pharm 1<sup>st</sup> year 1<sup>st</sup> semester 2024**

**Regulatory Affairs**

**Time: 3 hours**

**Total marks: 75**

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

**Group - A**

1. What are Generic drugs? Differentiate between generic and branded drugs. Give a flowchart for ANDA for product development. **15**
2. Explain the various paras under Hatch- Waxman Act in general. What leads to delay in entry of generic drugs to the market? Elaborate **15**

**Group – B**

3. i. What is a clinical trial, why do we need this? classify non clinical trials.  
ii. Explain the protocol writing with its parts. **2+2+2+9**
4. i. What is IRB, write the composition and responsibilities of IRB. **(2+3+3) =8**  
ii. What is HIPPA? Classify the types of HIPPA, Elaborate the Contents of HIPPA.  
**(1+1+5) =7**
5. i. What is Informed Consent? Why is the informed consent necessary? **(1+2)**  
ii. Write the process of Informed consent? When should the ICP be conducted?  
**(6+6)**

**Group – C**

6. Write briefly on the centralized drug approval process in EU. **15**
7. Enumerate New Drug Application procedure in USA. **15**