M.PH1.5C STABILITY OF DRUGS AND DRUG PRODUCTS THEORY **3 Hrs/Week**

UNIT – I

1. Overview of kinetic concepts – First, second and pseudo orders.
2. Complex order kinetics – concepts; equations and their application.
   Series, consecutive and reversible reaction, steady state approximation.
3. Stability prediction by pharmacist and calculation protocols.
4.

UNIT – II

5. Temperature as a stress : Arrhenius theory, activation energy calculations, Q10 value calculations.
6. Interpretation of kinetic data : Transition state theory, media effects, catalysis, pH effects. Some practical applications.

UNIT – III

7. Drug decomposition mechanisms :
   (a) Hydrolysis and acyltransfers : Nature of reaction, structure and utility, stabilization of pharmaceutical examples.
   (b) Oxidation : Nature of oxidation, kinetics of oxidation, oxidation pathways of pharmaceutical, Interest Inhibition of oxidation
   (c) Photolysis : Energetics of photolysis, kinetics photolysis, photolytic reactions of pharmaceutical interest, prevention of photolytic reactions.
8. Solid state chemical decomposition
   Kinetic of solids state decomposition, Pharmaceutical examples of solid state decomposition, Pure drugs, drug excipient and drug-drug interaction in solid state methods of stabilization.

UNIT – IV

9. Physical stability testing of dosage forms :
   (1) Solids – tablets, capsules, powder and granules
   (2) Disperse systems
   (3) Microbial decomposition
   (4) Over-view, physical stability of novel drug carriers, liposomes, niosomes, nano-particles.
10. Strategy and tactics of stability testing :
    (1) Regulatory requirements (2) Stability protocols
    (3) Experimental Design (4) Interpretation of data