Formulation strategies

• properties associated with drug
  – bulk properties
  – physicochemical properties
  – stability considerations
  – biopharmaceutical considerations
• marketing considerations
• economic considerations
• company expertise

Preformulation

• bulk properties
  – organoleptic
  – crystallinity and polymorphism
  – water adsorption
  – particle size, shape, and surface area
  – bulk density
  – adhesion
  – powder flow
  – compressibility

Preformulation

• physico-chemical properties
  – solubility analysis
  – ionization
  – partition coefficients
  – dissolution
• stability
  – solid state (RH, oxygen, light, compatibility)
  – solution (pH, buffers, solvent, temperature)
  – compatibility with excipients

Preformulation

• biopharmaceutical properties
  – absorption (route, rate, extent, mechanism, absorption windows, food effects)
  – metabolism (first pass metabolism, enzyme induction, metabolism in GIT)
  – duration of action (dosing, controlled release)
  – dose