

SIGNIFICANCE OF PREFORMULATION STUDIES IN DESIGNING, FABRICATING FOR PHARMACEUTICAL DOSAGE FORMS

Prior to development of any formulations the physiochemical properties of drug should be known to the developer.

Preformulation studies have a significant part to play in anticipating formulation problems and identifying logical path in liquid, semisolid and solid dosage form technology. The need for adequate drug solubility cannot be over emphasized. Stability studies in solution will indicate the feasibility of parental or other liquid dosage form and can identify methods of stabilization. In parallel solid-state stability by DSC, TLC and HPLC in the presence of tablet and capsule excipient will indicate the most acceptable vehicles for solid dosage form. Prior to the development of pharmaceutical dosage forms, it is essential that be valid fundamental physical and chemical properties of the drug molecule and other divided properties of the drug powder are determined.

Preformulation is to make available and realize information regarding:

- 1) The degradation process
- 2) Any adverse conditions relevant to the drug
- 3) Bioavailability
- 4) Pharmacokinetics and formulation of similar compounds
- 6) Toxicity.

Preformulation influences

- a) Selection of the drug candidate itself

- b) Selection of formulation components
- c) API and drug product manufacturing processes
- d) Determination of the most appropriate container closure system
- e) Development of analytical methods
- f) Assignment of API retest periods
- g) The synthetic route of API
- h) Toxicological strategy
- i) To establish its compatibility with common excipients by observing caking, liquefaction, colour change, odour formation.

It also gives directions for the development of formulation in choice of drug form, excipients, composition, physical structure, helps in adjustment of pharmacokinetics and bio pharmaceutical properties. In this review article we basically consider the various parameters should be keep in mind before to the fabrication of any formulations.