

a resource. **RESULTS:** The proper design and formulation of a dosage form requires consideration of the physical, chemical, and biological characteristics of all of the drug substances and pharmaceutical ingredients (excipients) to be used in fabricating the product. The drug and pharmaceutical materials utilized must be compatible and produce a drug product that is stable, efficacious, palatable, easy to administer, and well tolerated. Preformulation factors include physical properties such as particle size, crystalline structure, melting point, solubility, partition coefficient, dissolution, membrane permeability, dissociation constants, and drug stability. **CONCLUSIONS:** Successful development of a formulation includes multiple considerations involving the drug, excipients, compliance, storage, packaging, and stability, as well as patient considerations of taste, appearance, and palatability.

Baghel, S. et al. (2016). "Polymeric amorphous solid dispersions: A review of amorphization, crystallization, stabilization, solid-state characterization, and aqueous solubilization of biopharmaceutical classification system class II drugs." *J Pharm Sci* 105(9):2527–2544.

Poor water solubility of many drugs has emerged as one of the major challenges in the pharmaceutical world. Polymer-based amorphous solid dispersions have been considered as the major advancement in overcoming limited aqueous solubility and oral absorption issues. The principle drawback of this approach is that they can lack necessary stability and revert to the crystalline form on storage. Significant upfront development is, therefore, required to generate stable amorphous formulations. A thorough understanding of the processes occurring at a molecular level is imperative for the rational design of amorphous solid dispersion products. This review attempts to address the critical molecular and thermodynamic aspects governing the physicochemical properties of such systems. A brief introduction to Biopharmaceutical Classification System, solid dispersions, glass transition, and solubility advantage of amorphous drugs is provided. The objective of this review is to weigh the current understanding of solid dispersion chemistry and to critically review the theoretical, technical, and molecular aspects of solid dispersions (amorphization and crystallization) and potential advantage of polymers (stabilization and solubilization) as inert, hydrophilic, pharmaceutical carrier matrices. In addition, different preformulation tools for the rational selection of polymers, state-of-the-art techniques for preparation and characterization of polymeric amorphous solid dispersions, and drug supersaturation in gastric media are also discussed.

Chadha, R. and S. Bhandari (2014). "Drug-excipient compatibility screening—Role of thermoanalytical and spectroscopic techniques." *J Pharm Biomed Anal* 87:82–97.

Estimation of drug-excipient interactions is a crucial step in preformulation studies of drug development to achieve consistent stability, bioavailability and manufacturability of solid dosage forms. The advent of thermoanalytical and spectroscopic methods like DSC, isothermal microcalorimetry, HSM, SEM, FT-IR, solid state NMR and PXRD into pre-formulation studies have contributed significantly to early prediction, monitoring and characterization of the active pharmaceutical ingredient incompatibility with pharmaceutical excipients to avoid expensive material wastage and considerably reduce the time required to arrive at an appropriate formulation. Concomitant use of several thermal and spectroscopic techniques allows an in-depth understanding of physical or chemical drug-excipient interactions and aids in selection of the