Preformulation in Solid Dosage Form Development (Drugs and the Pharmaceutical Sciences)

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During the onset of any clinical trial there are many factors and variables to consider. Funding, time restraints, and regulatory agency guidelines are factors that often influence which variables will be studied, leaving other important information out of the study. **Preformulation in Solid Dosage Form Development** covers every topic of critical importance to the preformulation stages of drug development. Serving as a handbook or stand-alone reference, this text equips those in academia and the pharmaceutical industry with both basic and applied principles for the characterization of drugs, excipients, and products, and deals with the issues relating to predictability, identification, and product development during preformulation stages through Phase I of clinical trials.

With contributions from an international panel of experts in the field, this guide:

- outlines an updated preformulation program for modern drug development issues that includes particle morphology, characterization, thermal analysis, and solubility methods
- contains rational designs for the structure of formulation studies
- covers the importance of preformulation design using artificial neural networks and computational prediction techniques, and examines the concepts of preliminary-preformulation
- discusses the typical drug-excipient interactions that could occur during the course of development and methods of characterization
- includes novel methods to determine the physical and chemical stability of new formulations
- reviews the structure, content, and format of the preformulation report
- examines the significance of drug substance physiochemical properties, in regulatory quality by design

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