

Important role of crystallography in pharmaceutical development

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Drug solubility has been a recurring challenge in the pharmaceutical industry. Among the various techniques used to enhance the solubility of drugs are physical and chemical modifications such as salt formation, solid dispersion, use of surfactant etc. Polymorphic forms of drugs provide interesting solutions to the solubility issue since they have differing solubilities as well as stabilities, the latter playing an important role in determining the shelf life of the formulation. Generally the solubility of metastable forms is kinetically greater than the thermodynamically stable form thereby offering solutions at least in theory to the bioavailability issue. The stabilization of metastable forms in the formulation often has proved to be a challenge. The predictable scale up of these metastable polymorphs through the development of robust processes has also been extremely challenging. This area has become an area of focus for the generic pharmaceutical industry since by the discovery and stabilization of alternate polymorphs through innovative formulations has often successfully challenged innovator pharmaceutical and led to the early introduction of cheaper drugs. The focus of this talk will be to highlight some of these challenges as well as raise the need for more academic -industry collaboration to enhance the quality of the solutions provided.

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