

Title: Achieving Desired Polymorphs in API Process Development

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Polymorphism of active pharmaceutical ingredients plays an important role in determining their physical and chemical properties, as well as their suitable use in drug substance application. The search for polymorphs requires thorough and systematic methodologies to gather sufficient understanding of crystal formation and stability in various solvent systems. A compound of interest undergoes multiple phase transformations during material preparations before leading to the desired crystal form. Polymorph control is made possible, from crystallization throughout drying, with knowledge collected in both polymorphism studies and process engineering to ensure consistent generation of the desired product. Our studies will be presented concerning the relation of different polymorphs, crystal form conversions, crystallization techniques and processing needed to tailor crystal morphology, crystallite or particle size, and solid properties.