292b Supersaturation Monitoring and Control with Atr-Ftir

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Crystallization is a critical step in the production of the solid form of an active pharmaceutical ingredient. Development of a robust crystallization process can be used to simultaneously maximize yield, minimize impurities, and ensure a consistent particle size for formulations. Additionally, a well-designed crystallization can reduce bottlenecks and improve throughput in downstream processes such as filtration, drying, and milling.

Knowledge of the solubility curve and metastable zone width (MSZW) in the appropriate solvent system provides a window of acceptable operating conditions for developing cooling profiles, anti-solvent addition rates, and seeding protocol. Additionally, the level of supersaturation in the vessel is considered the driving force of the process, and the ability to monitor and control the supersaturation in process further improves the capability of designing a robust crystallization process. The application of automated technology to improve the ease, accuracy and efficiency of obtaining the solubility curve, MSZW, and a calibrated supersaturation monitor to be used for monitoring and control is investigated.