

In-line monitoring of anti-solvent co-crystallization based on NIR spectroscopy

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Co-crystals are being intensively studied nowadays primarily due to the potential of improving pharmaceutical properties including the dissolution behavior for BCS class-II drug substances such as indomethacin (IMC). Recently, we discovered a new method using anti-solvent addition method to prepare indomethacin-saccharin (IMC-SAC) co-crystals. In this study, we investigated the kinetic pathways in the phase solubility diagram during the cocrystallization process. The process monitoring was carried out using in-line NIR spectroscopy, which predicted the concentrations of both IMC and SAC in solution. Actual concentration of the two components was determined using UV-Vis spectroscopy and high performance liquid chromatography (HPLC). The correlation between NIR spectra and analysis data of sampled solutions was evaluated through partial least squares (PLS) calibration model.