

Optimization of API Drying Via Hemi-solvate Conversion Kinetics

Dr. Kimberley Allen (speaker)

Dr. Nandkishor Nere

Dr. James Marek

Abbott Laboratories, North Chicago, IL 60064

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Abstract:

Drying of an early stage API candidate required excessively long cycle times in the pilot plant filter dryer. Investigation of the drying curve revealed the rate-limiting step was desolvation, as opposed to removal of unbound ethanol solvent. Intrinsic kinetics were then developed for the ethanol hemi-solvate as a function of temperature, and compared to the apparent kinetics derived from the pilot scale drying. Mass Spectrometry and Raman Spectroscopy PATs supplemented the kinetic study to elucidate a more fundamental understanding of the form conversion. The results were combined to optimize drying conditions on scale and model the time needed to reach an API dryness of 0.1wt%.