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Characterization of phase separation and re-crystallization of amorphous solid dispersions

Shawn Yin

Bristol-Myers Squibb, USA

Recently, we have developed a system containing screening techniques capable to assess physical stability risks of spray dried disperse (SDD) materials. The objective of this screen is to give formulators a warning when phase separation and crystallization of the dispersion may be likely. Better understanding of phase separation risk should impact choice of API loading in the dispersion and polymer selection. Ultimately, a more complete understanding of the phase separation and crystallization risk should enhance our ability to assess the API crystallization risk of SDD materials during product stability, performance evaluation studies and product storage. The physical characterization techniques in this screen include powder X-ray diffraction (PXRD), total scattering pair distribution function (TSPDF), isothermal calorimetry (TAM), differential scanning calorimetry (DSC), moisture sorption, Fourier transform infrared spectroscopy (FT-IR), solid state nuclear magnetic resonance (ssNMR) and other common pharmaceutical physical characterization techniques. Illustrated by case study examples in this presentation are, capturing SDD material phase separation sign and understanding crystallization risk enabled robust pharmaceutical SDD materials.

shawn.yin@bms.com