Abstract Submitted
for the DFD16 Meeting of
The American Physical Society

Application of methods for quantifying maximum potential segregation and actual segregation risk to design of powder blends DAVID GOLDFARB, STEPHEN CONWAY, MICHAEL GENTZLER, Merck Research Labs — As described in a recent publication (Gentzler, Tardos, Michaels, *Powder Technology*, 2015), the tendency of pharmaceutical powders to demix due to segregation can threaten the content uniformity of solid dosage forms. Using the methodology established in this publication, examples of analysis and optimization of pharmaceutical formulations to evaluate the potential for segregation during formulation and reduce the risk of content uniformity issues upon scale-up are provided. Modification to active components and excipient properties are considered and a systematic risk assessment approach for multi-component blends emerges. Use of the measurements to understand excipient and raw material sensitivities in lieu of pilot and commercial-scale production tests is described. This approach has the potential for being readily applied to the study of the segregation risk potential outside the pharmaceutical industry.

David Goldfarb
Merck Research Labs

Date submitted: 01 Aug 2016 Electronic form version 1.4