

Abstract Submitted
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Characterizing dense suspensions: two case studies from the pharmaceutical industry DAVID J. GOLDFARB, NAZIA KHAWAJA, IRINA KAZAKEVICH, HIMANSHU BHATTACHARJEE, MICHAEL HESLINGA, CHAD DALTON, Merck Research Laboratories — Liquid suspensions of Active Pharmaceutical Ingredient powders are present as pharmaceutical dosage forms in the form of oral suspensions and injectables. We present two case studies, both dense ($\sim 30\text{-}40\%$) suspensions, in which the physical characterization of the product, specifically, particle size & shape and rheology were key to understanding the key product attributes as pertaining to the manufacturing process and to patient administration. For the one case study, an oral suspension, identifying variations in particle morphology during the wet milling of the product was key to the product understanding necessary to modify the milling process. Rheological measurements were applied as well. For the second case study, an injectable, results from different particle size measurement techniques and rheological measurements indicated the possibility of flocculation in a formulation. Additionally, measurements were obtained to assess the “injectability” of the product via rheometer and texture analyzer measurements and Poiseuille flow modeling. As a result, the relevant shear rate regime for this drug product administration was identified.

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