

Industrial & Physical Pharmacy Seminar IPPH 69600

Wednesday, April 12, 2023 3:30PM in RHPH 164

"Understanding the Sources of Variability and Quality in Solid Oral Dosage Forms"



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Abstract:

Solid oral dosage forms are the most common pharmaceutical product, but despite their wide use still have aspects of their formulation that exhibit variability that can impact performance. Magnesium stearate (MgSt) is the most used tableting excipient, and also a problem excipient due to it complex physicochemical nature. MgSt has at least five crystal forms, a composition that is a mixture of fatty acids, and variable surface area, all of which cause measurable differences in the behavior of tablet formulations, specifically powder lubrication and the dissolution rate. In this seminar the impact of fatty acid composition, solid forms, and particle size/surface area on the lubrication and dissolution properties of MgSt formulations will be described. A newly discovered form, the disordered form, will be described, including how its fatty acid content impacts water content and potentially lubrication properties. The potential to follow transformations of the disordered form upon formulation, including disproportionation, will be shown using solid-state nuclear magnetic resonance spectroscopy (SSNMR). Powder bed, binder jet deposition additive manufacturing is an underused pharmaceutical manufacturing technique with formulation aspects that have not been described in literature. Understanding the impact of formulation can go a long way to understanding the critical quality attributes for using powder bed, binder jet deposition additive manufacturing to make solid oral dosage forms.

Presented by Daniel DeNeve, Ph.D. Student. Daniel is a fifth year student in Dr. Eric Munson's lab. He received his bachelors degree in Chemical Engineering from the University of Kentucky. Daniel began working as an undergraduate researcher for Dr. Munson in 2016. He began his Ph.D. in August of 2018, and his research focuses on understanding problematic the sources of variability and their impact on quality in solid oral dosage forms.