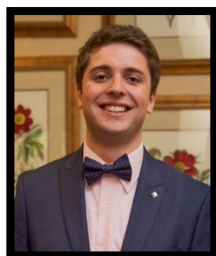


Industrial & Molecular Pharmaceutics Seminar

IMPH 69600

Monday, March 25, 2024
4:30 PM in RHPH 164

“Stabilization of Biologics by Lyophilization: Formulation, Process, and Analytical Development”



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Last Seminar

Lyophilization in the presence of an excipient, typically a disaccharide, is a technique used to prepare solid-state biologic formulations with increased stability. The ability of a disaccharide to effectively stabilize a protein in the solid state is proposed to depend on interactions between the protein and the disaccharide (water-replacement theory) and the ability of the excipient to slow the mobility of the protein (vitrification theory). Solid-state nuclear magnetic resonance (ssNMR) spectroscopy is an analytical technique that was used to assess the homogeneity and measure the mobility of lyophilized human serum albumin formulations prepared with sucrose, trehalose, and/or mannitol. Sucrose and trehalose formulations were found to have similar stability, homogeneity, and mobility, whereas mannitol formulations were less stable than sucrose/trehalose formulations, except at low excipient concentrations.

RF/Microwave irradiation during the primary drying step is being explored as a method to reduce lyophilization times, which often can be several days. We are comparing the stability of protein formulations prepared using conventional lyophilization methods and RF/microwave-assisted methods. Formulations containing either bovine serum albumin or a monoclonal antibody were prepared, and critical quality attributes such as stability and moisture content were analyzed. RF/Microwave assisted lyophilization methods resulted in solids with less moisture and similar or better stability when compared to solids prepared with conventional lyophilization. ssNMR showed slightly higher mobility for samples prepared by RF/microwave-assisted lyophilization.