PURDUE UNIVERSITY | Department of Industrial and Molecular Pharmaceutics

Industrial & Molecular Pharmaceutics Seminar

IMPH 69600

Monday, February 5, 2024
4:30 PM in RHPH 164

"Effects of Buffer Systems on Spray Freeze-Dried and Lyophilized High-Concentration Protein Formulations"

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First Seminar

Solid-state protein formulations are known to have enhanced stability than their liquid counterparts. pH is one of the many factors affecting the stability of protein formulations. The pH of protein formulations in the solution state is influenced by the buffer system used, directly impacting their solid-state stability. During lyophilization, buffer systems may interact with components present in the protein formulations, causing pH changes. This study aimed to investigate the effects of phosphate buffer and amino acid buffers (histidine or arginine, either alone or in combination) on the physical properties and long-term storage stability of spray freeze-dried or lyophilized protein formulations. A model protein, bovine serum albumin (BSA), was used to prepare high-concentration protein formulations. The formulations consisted of BSA, trehalose, and mannitol in an 80:15:5 ratio, respectively. Different buffers were utilized for the preparation of protein formulations, and these solid formulations were screened for their long-term stability using size exclusion chromatography (SEC). Specific combinations of these buffers resulted in increased monomer loss during long-term storage stability. Future studies will concentrate on understanding the mechanisms through which these buffers induce aggregation.