



Optimization of Freeze-Drying Cycles Using Modulated Differential Scanning Calorimetry.

ABSTRACT:

Historically, freeze-drying has been treated more as an art than a science, and the optimization of lyophilization parameters was accomplished empirically through a trial-and-error process. As such, failure of the lyophilization process was common, resulting in loss of time and valuable product.

More recently, pharmaceutical scientists have begun characterizing the structure of the freeze-concentrated solution, so that critical transition temperatures such as T_g and T_m can be accurately determined. Understanding these temperatures and their impact on structure is critical to the success of a freeze-drying cycle. However, the structural transitions typical of these complex solutions are often difficult to characterize through traditional DSC analyses.

Modulated Differential Scanning Calorimetry (MDSC) is the industry-standard thermal analysis technique for the characterization of complex transitions. MDSC effectively separates heat flow into a reversing component associated with heat capacity and structural changes, and a non-reversing component which arises from latent heat of these processes. MDSC is well-accepted as a primary tool for the characterization of freeze-concentrated solutions, and the subsequent optimization of lyophilization cycles. MDSC is also used to characterize lyophilized product providing additional information regarding product stability.

In this webinar, the theory of Modulated DSC will be reviewed. Application of MDSC to lyophilization science, and specific applications examples regarding characterization of freeze-concentrated solutions and lyophilized product will be presented. Finally, techniques for using MDSC results to optimize freeze-drying cycles will be discussed.