

The Impact of the Freezing Stage in Lyophilization: Effects of the Ice Nucleation Temperature on Process Design and Product Quality

Lyophilization is the most common method for manufacturing solid protein pharmaceuticals (1) and is central to the preservation of materials which must be dried very thoroughly (< 1% moisture) in order to ensure stability and require a gentle, sterile process for doing so. However, the multitude of variables inherent in a large batch of individual vials in a complex drying chamber configuration makes process control difficult at best; and a thorough understanding of the process and the materials science of different formulations is necessary to avoid product damage.

Michael J. Pikal, Ph.D., Shailaja Rambhatla,
& Roe Ramot

School of Pharmacy, University of Connecticut Author Company