



COLLEGE OF PHARMACY
PHARMACEUTICAL SCIENCES
UNIVERSITY OF MICHIGAN
Pharmaceutical Sciences Special Seminar

Wednesday, September 11, 2019
2548 North University Building
4:00-5:00 pm

“Intricacies of Freeze-Drying Biologics”



Presented by:

Robin Humcke Bogner, Ph.D., FAAPS

Professor of Pharmaceutics

University of Connecticut

Department of Pharmaceutical Sciences

ABSTRACT Freeze-drying (also called lyophilization) is a cost manufacturing process reserved for pharmaceutical and other products that are not sufficiently stable as liquids over their intended shelf-life. The process consists of freezing most of the water or solvent in the product, sublimation of the frozen water, and finally desorption of the remaining unfrozen water. Sublimation (also called primary drying) is the longest phase in the process and can be modeled as a quasi-steady-state coupled heat and mass transfer process. Due to the design of both lab-scale and manufacturing freeze-dryers, the heat transfer is not uniform for all products on the shelves in the dryer. In addition, the pattern of ice in each vial after freezing is not uniform. Both variations lead to within batch vial-to-vial heterogeneity that has been modeled, experimentally verified and will be discussed. Lastly, the product is reconstituted prior to patient administration. High concentration protein products are known for challenges in reconstitution. Many of the causes of long and variable reconstitution have been recently revealed and can be mitigated to improve product performance.

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