

Iftimia, Daniel X. Hammer, Kristin Galbally-Kinney, Phillip Mulhall and Ankit Patel and The University of Connecticut: Kristyn Greco, Puneet Sharma and Michael J. Pikal.

Partial financial support for the development and application of the Optical Coherence Tomography Freeze Drying Microscopy (OCT-FDM) and Tunable Diode Laser Absorption Spectroscopy systems was provided by the National Institutes of Health, National Institute of Biomedical Imaging and Bioengineering and National Cancer Institute Small Business Innovative Research Programs (awards R44EB010317 and HHSN261200900023C). The content of this chapter is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

References

1. Buera MP, et al. State diagrams for improving processing and storage of foods, biological materials, and pharmaceuticals (IUPAC Technical Report). *Pure Appl Chem*. 2011;83(8):1567–617.
2. Terakita A, Matsunaga H, Handa T. The influence of water on the stability of lyophilized formulations with inositol and mannitol as excipients. *Chem Pharm Bull (Tokyo)*. 2009;57(5):459–63.
3. Sundaramurthi P, Burcusa MR, Suryanarayanan R. Physical characterization of pentamidine isethionate during freeze-drying—relevance to development of stable lyophilized product. *J Pharm Sci*. 2012;101(5):1732–43.
4. Colandene JD, et al. Lyophilization cycle development for a high-concentration monoclonal antibody formulation lacking a crystalline bulking agent. *J Pharm Sci*. 2007;96(6):1598–608.
5. Schersch K, et al. Systematic investigation of the effect of lyophilizate collapse on pharmaceutically relevant proteins I: stability after freeze-drying. *J Pharm Sci*. 2010;99(5):2256–78.
6. Patel SM, Pikal MJ. Lyophilization process design space. *J Pharm Sci*. 2013;102(11):3883–7.
7. Mockus LN, et al. Quality by design in formulation and process development for a freeze-dried, small molecule parenteral product: a case study. *Pharm Dev Technol*. 2011;16(6):549–76.
8. Nail SL, Searles JA. Elements of quality by design in development and scale-up of freeze-dried parenterals. *Biopharm Int*. 2008;21(1):44–52.
9. Sundaram J, et al. Design space development for lyophilization using DOE and process modeling. *Biopharm Int*. 2010;23(9):26–36.
10. Pikal MJ, Roy ML, Shah S. Mass and heat transfer in vial freeze-drying of pharmaceuticals: role of the vial. *J Pharm Sci*. 1984;73(9):1224–37.
11. Greco K, et al. Accurate prediction of collapse temperature using optical coherence tomography-based freeze-drying microscopy. *J Pharm Sci*. 2013;102(6):1773–85.
12. Mujat M, et al. Optical coherence tomography-based freeze-drying microscopy. *Biomed Opt Express*. 2012;3(1):55–63.
13. Tang X, Pikal MJ. Design of freeze-drying processes for pharmaceuticals: practical advice. *Pharm Res*. 2004;21(2):191–200.
14. Giordano A, Barresi AA, Fissore D. On the use of mathematical models to build the design space for the primary drying phase of a pharmaceutical lyophilization process. *J Pharm Sci*. 2011;100(1):311–24.
15. Gieseler H, et al. Evaluation of tunable diode laser absorption spectroscopy for in-process water vapor mass flux measurements during freeze drying. *J Pharm Sci*. 2007;96(7):1776–93.
16. Kuu WY, Nail SL, Sacha G. Rapid determination of vial heat transfer parameters using tunable diode laser absorption spectroscopy (TDLAS) in response to step-changes in pressure set-point during freeze-drying. *J Pharm Sci*. 2009;98(3):1136–54.
17. Schneid SC, et al. Non-invasive product temperature determination during primary drying using tunable diode laser absorption spectroscopy. *J Pharm Sci*. 2009;98(9):3406–18.