

Additional Literature

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Freeze – Drying in Practice

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Adapted from slides originally created by and with courtesy of PD Dr. Andrea Allmendinger





Collection 1

Tech Transfer

Cullen, S., Walsh, E., Gervasi, V. *et al.* Technical transfer and commercialisation of lyophilised biopharmaceuticals — application of lyophiliser characterisation and comparability. *AAPS Open* **8**, 14 (2022). <https://doi.org/10.1186/s41120-022-00059-0>

Heat Transfer Mechanism

Arnab Ganguly, Steven L. Nail, Alina Alexeenko. Experimental Determination of the Key Heat Transfer Mechanisms in Pharmaceutical Freeze-Drying. *J.Pharm.Sci.*, Volume 102, Issue 5, 2013, <https://doi.org/10.1002/jps.23514>

Ramp rate of shelf temperature in the primary drying proces

1. Ryo Ohori, Tomomi Akita, Chikamasa Yamashita, Investigation of lyophilized formulation susceptible to the ramp rate of shelf temperature in the primary drying process, *Journal of Drug Delivery Science and Technology*, Volume 61, 2021. <https://doi.org/10.1016/j.jddst.2020.102285>
2. Ryo Ohori, Tomomi Akita, Chikamasa Yamashita, Mechanism of collapse of amorphous-based lyophilized cake induced by slow ramp during the shelf ramp process, *International Journal of Pharmaceutics*, Volume 564, 2019, <https://doi.org/10.1016/j.ijpharm.2019.04.057>



Collection 2

Moisture increase in product via moisture from stopper

1. Pikal MJ, Shah S. Moisture transfer from stopper to product and resulting stability implications. *Dev Biol Stand.* 1992;74:165-77; discussion 177-9. PMID: 1592166.
<https://pubmed.ncbi.nlm.nih.gov/1592166/>
2. P.D. Donovan, V. Corvari, M.D. Burton, N. Rajagopalan. Effect of Stopper Processing Conditions on Moisture Content and Ramifications for Lyophilized Products: Comparison of “Low” and “High” Moisture Uptake Stoppers. *PDA Journal of Pharmaceutical Science and Technology.* Jan 2007, 61 (1) 51-58 <https://journal.pda.org/content/61/1/51>
3. M. Le Meste, D. Simatos, J.M. Préaud, P.M. Precausta, Factors influencing changes in moisture content during storage of freeze-dried vaccines in vials, *Journal of Biological Standardization*, Volume 13, Issue 3, 1985, [https://doi.org/10.1016/S0092-1157\(85\)80001-9](https://doi.org/10.1016/S0092-1157(85)80001-9)