

GEA Lyophil *Controlyo*[™] Nucleation On-Demand Technology

Controlyo[™] nucleation on-demand technology licensed from Praxair can deliver improved product uniformity, quality, and yield, while reducing cycle times by up to 40%. This proprietary technology can control the nucleation temperature of a solution to within 1°C of its freezing point, delivering exceptional control to a previously uncontrolled freezing process.



Take control of your time, your costs, your product

Until now, the freezing step of lyophilization was uncontrolled due to the random nature of the nucleation process. In a typical pharmaceutical lyophilization process, the contents of individual vials nucleate over a broad range of temperatures, usually spanning 5°-20°C below the formulation's freezing point.

Cooperation between Praxair and GEA Lyophil

Today, Praxair's patent pending process technology implemented on GEA Lyophil's freeze dryers, offers a novel and scalable method for controlling nucleation of the freezing step in commercial lyophilization without requiring any changes to existing drug formulations.

Technology Benefits:

Improved product quality

- Improves vial-to-vial uniformity
- More homogenous cake
- Reduces protein aggregation
- Aligned with FDA's QbD initiative

Increased lyophilization capacity

- Reduces primary drying times by up to 40%
- Lowers operating costs
- Lowers capital costs

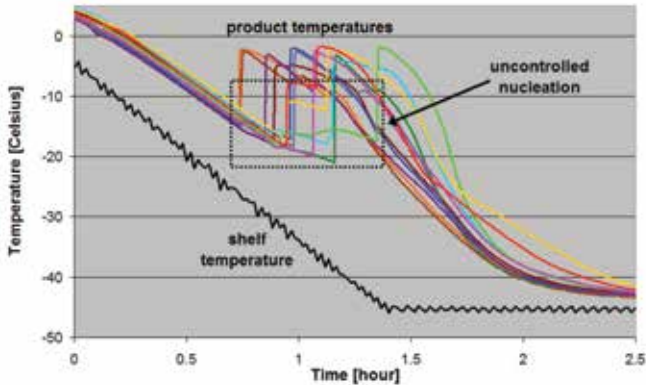
Improved product yield

- Reduces freeze damage for some APIs
- Reduces vial cracking



Nucleation Comparison

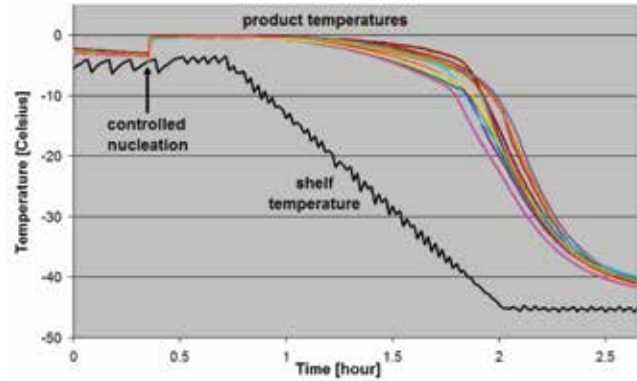
Uncontrolled Nucleation



Problems

- Very cold nucleation
- Widely varying product temp paths

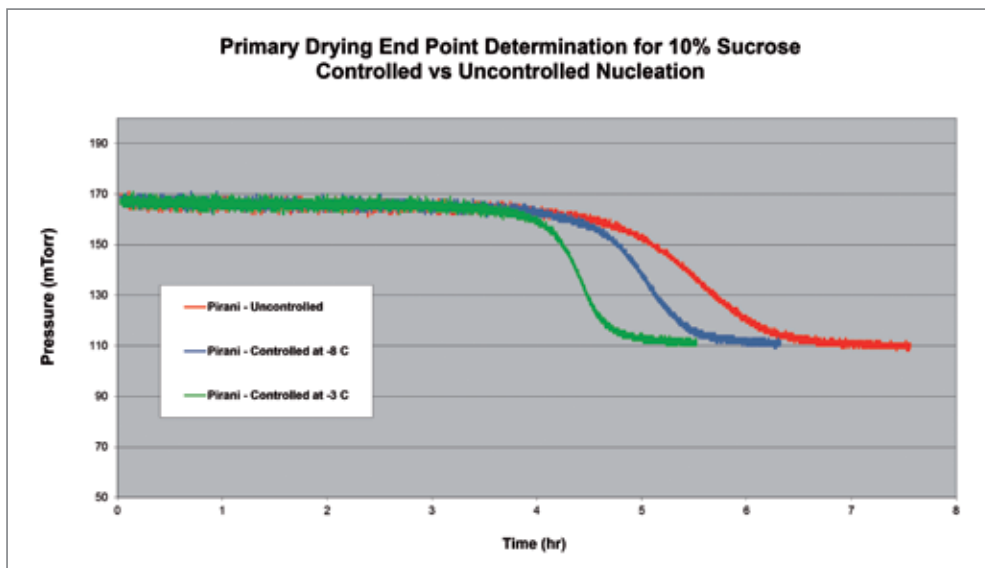
ControlLyo™ Technology



Improvements

- Warmer nucleation
- More uniform product temp paths

Nucleation Temperature Impact on Drying Time



This technology is available for existing and new units



Data provided by Praxair

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