Pro Series: Advanced Tray Freeze Dryers

Efficient and Effective Cycle Development

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MILLROCK TECHNOLOGY

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Efficient and Effective Cycle Development

As a pharmaceutical freeze drying industry professional, you understand the increasing importance of minimizing processing times while decreasing costs, making smarter protocol development crucial to your process. This is especially true for products produced on a large scale, where the cost increases significantly with time spent in the freeze dryer.

The process can be complex and time-consuming, and scaling up your product can be a daunting task. That's why the Pro Series from Millrock is here to help. Our state-of-the-art freeze dryers provide you with the confidence to scale up your product simply and effectively. With our innovative technology, you can achieve reliable and consistent results every time, while streamlining your process and saving time and resources. Whether you are developing a new drug or improving an existing one, the Pro Series can help you achieve your goals with ease.

Three Steps to Faster and Smarter Protocol Development

Our Pro Series Freeze Dryers are perfect for analyzing, optimizing and developing transferable cycles for researchers who want to perform full laboratory tray dryer runs, pilot scale through-put studies, produce the first batch of products for clinical trials, and other research and development needs.

Step 1
Protocol Analysis

Why use outdated technologies that provide only intermittent monitoring and extensive calculations to predict critical process parameters? With the Pro Series you get **real-time, continuous process measurement and unparalleled control.**

Step 2
Cycle Optimization

Save money and time by developing robust products with the shortest freeze drying cycle times. The Pro Series provides you with the tools to optimize both your freezing and primary drying cycles, in order to develop the shortest freeze drying time and critical process parameters for cycle transfer.

Step 3
Cycle Transfer

Scale up, scale down…the future lies in both directions. With the optimized critical process parameters, you can easily use the Pro Series for scale-up of new freeze drying protocols, or scale-down analysis and troubleshooting of existing protocols.

Unlock the Potential of Freeze Drying with LyoPAT®

- ## Process Monitoring for Unparalleled Knowledge

  At the heart of the Pro Series is LyoPAT, state-of-the-art control technologies to monitor and control every possible aspect of the freezing and drying processes. Enhance your freeze drying operations with LyoPAT, the cutting-edge solution for in-situ process analysis and optimization from Millrock Technology. LyoPAT revolutionizes the way you monitor and control freeze drying processes, allowing you to achieve optimal results consistently.

- ## In-Situ and Direct Measurement

  With LyoPAT, you can directly measure critical process parameters without interrupting or altering the freeze drying process. Its in-situ, continuous, non-invasive, and real-time measurement capabilities provide valuable insights into % Frozen, End of Freezing (EOF), Kv, dm/dt, Rp, and End of Primary Drying (EOPD). By leveraging LyoPAT's advanced monitoring and optimization features, you can achieve superior control over the freeze drying process, leading to enhanced product quality, reduced cycle times, and increased operational efficiency. This non-invasive solution ensures that your samples remain undisturbed, preserving their integrity.

- ## Continuous and Real-Time Monitoring

  LyoPAT offers continuous monitoring throughout the entire freeze drying cycle, from freezing to primary and secondary drying. By capturing data in real-time, you can identify process deviations, detect anomalies, and take proactive measures for process optimization.

- ## Batch Size Independence

  Whether you're processing a partial or a full load, LyoPAT adapts seamlessly. Its versatility allows it to work effectively across various batch sizes, ensuring consistent performance regardless of the scale.

- ## Unparalleled Freezing Process Analysis

  LyoPAT is the only known method for analyzing the freezing process during freeze-drying. By closely monitoring and analyzing this crucial stage, you can understand and optimize the formation of ice crystals, leading to improved product quality and stability.

LyoPAT empowers you to achieve superior results, streamline operations, and advance your freeze drying capabilities. Stay ahead in the industry with LyoPAT and revolutionize your freeze drying processes today.

Process Monitoring and Control

FREEZING
End of Super-cooling
Nucleation
% Frozen by Nucleation
Post-Nucleation Crystal Growth
End of Freezing

PRIMARY DRYING
Shelf Temperature
Vacuum Level
Product Temperature
Heat Flow
Mass Flow
Vial Conductivity
Cake Resistance
Percent Dry
End of Primary Drying

Features of LyoPAT® include

- **Accuflux™** - This patented method of process monitoring and control provides a direct measurement of heat flux with AccuFlux provides a new and valuable tool to understand the thermal events occurring during the freezing and primary drying steps. With direct and continuous measurement, AccuFlux provides a continuous stream of your critical process parameters, for use in protocol improvement and transfer. Two Accuflux sensors are provided standard, one at shelf center and the other on the shelf edge. As an option, up to 4 sensors can be installed. Other sensor placements may be considered.

- **AutoDry™** - A patented method to control primary drying based on the product temperature. Optimize your cycle early for the highest through-put in the lab and in manufacturing with AutoDry.

- **FreezeBooster® Option** - This patented method of ice crystal injection is the most versatile and effective controlled nucleation method. Create a homogeneous cake across the batch to improve product quality and reduce primary drying time.

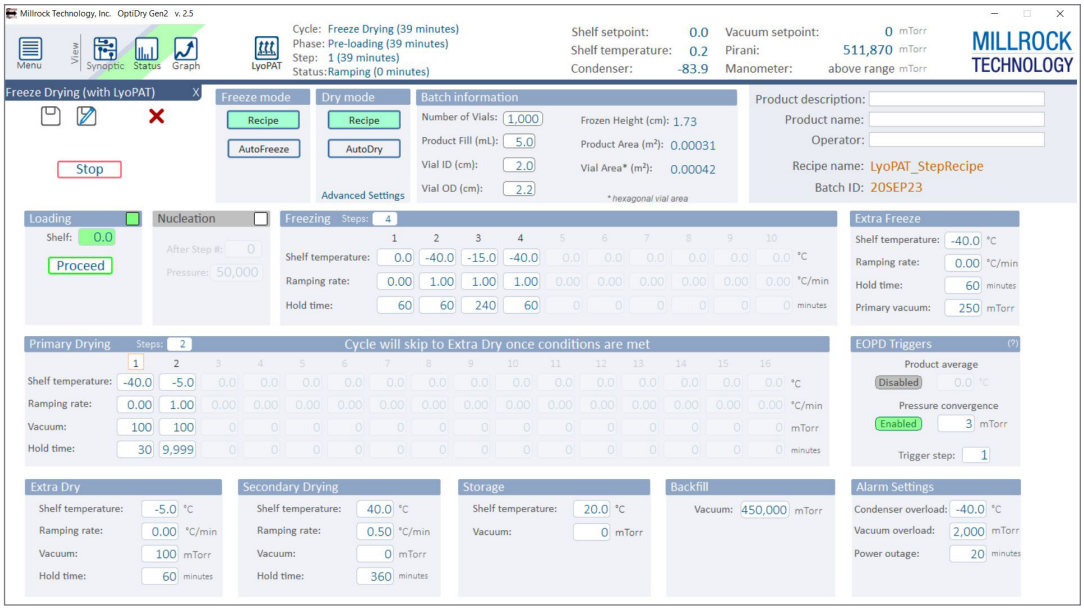
- **Opti-Dry® Gen2** PC/PLC freezing drying control system provides precise and reliable control over the freeze drying process for enhanced efficiency and performance.

Meet Opti-Dry Gen2

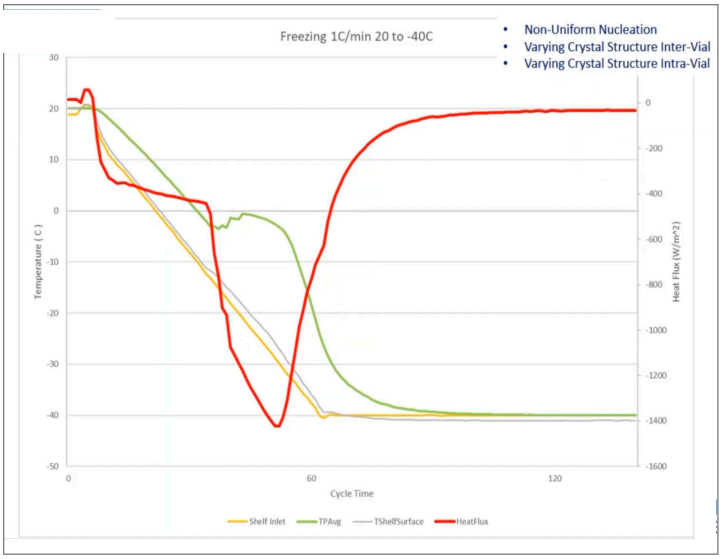
Our new Opti-Dry Gen2 software provides sophisticated and intelligent tools to easily develop and execute both simple and advanced freeze-drying cycles. Select your Freezing method, Primary Drying method, and enable triggers to automatically process and optimize your freeze drying protocol.

Millrock Reporter is included with every system, providing full batch reporting, including recipe, graphs, data, and alarms in a single report. This flexible reporting system enables output to PDF formats and eliminates the need for exporting data to Excel for analysis and reporting.

Predictive maintenance with advanced system monitoring delivers cost-savings and enables maximum uptime by tracking and monitoring the condition and performance of equipment during normal operation. This same control system is used on industrial freeze dryers, allowing scaling to production. All systems are remotely accessible, with customer approval, for troubleshooting process issues.



Protocol Analysis

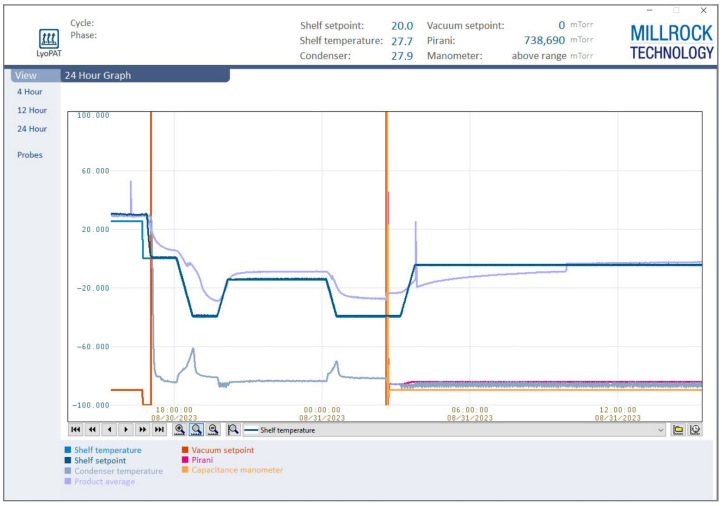


Example of Freezing analysis
Unique ability to measure the heat flow during the freezing process to enable the operator to determine the impact of the cycle on crystal growth.

LyoPAT Data

	Sensor 1	Sensor 2
Heat Flux (W/m²)	200.1	155.9
Product Temp (°C)	-16.5	-16.5
Kv Shelf (W/m²-°C)	17.3	13.5
Percent Q Shelf (%)	100.0	100.0
Heat Flux System (W/m²)	200.1	155.9
Kv System (W/m²-°C)	17.3	13.5
Mass Flow per Vial (g/hr)	0.11	0.08
Total Mass Flow (g/hr)	106.54	83.02
Pressure Over Ice (Torr)	1.08	1.08
Cake Resistance (Torr-cm²-hr/g)	31.72	40.70
Heat in Freezing (J)	-2,808	-2,315
Heat in Primary Drying (J)	4,828	3,965
Mass Loss per Vial (g)	1.70	1.40
Total Mass Loss (g)	1,703.48	1,398.91
Dried Cake Height (cm)	0.59	0.49
Percent Dry (%)	34.07	27.98

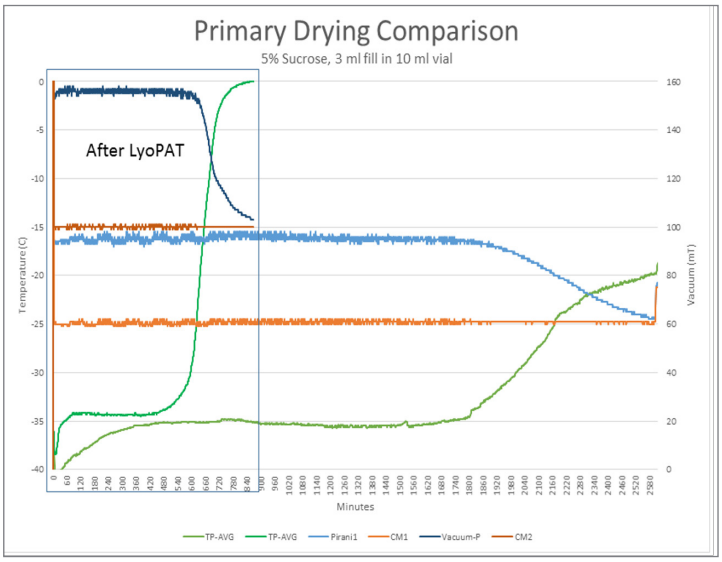
Critical Process Parameters are measured throughout the freeze drying process. The data collected can later be used for process improvement, scale-up or scale-down protocol transfer.

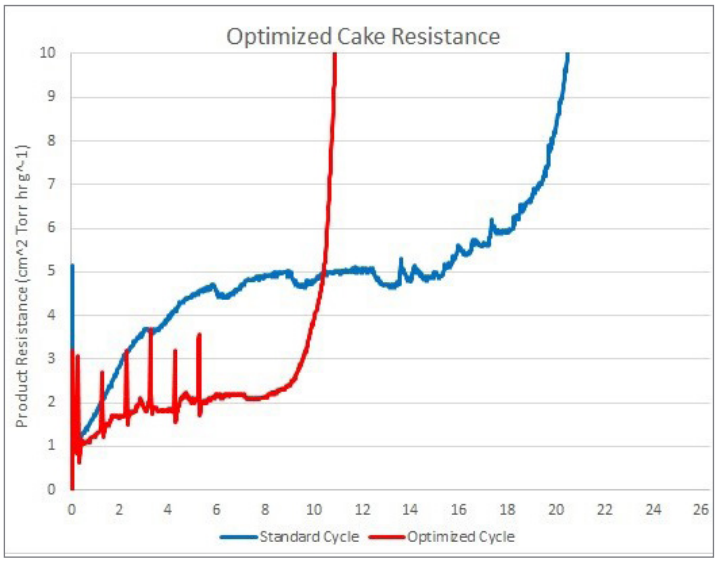


Compare the protocol to the actual run performance.

Cycle Optimization

The Pro series provides the tools for optimizing freeze drying protocols while keeping the product below its critical temperature.





Example of Cycle Improvement for a Protein

Time

Total Elapsed time: 54.1 hrs

Freezing : 6.6 hours

Primary Drying : 37 hours

Secondary Drying: 10.5 hours

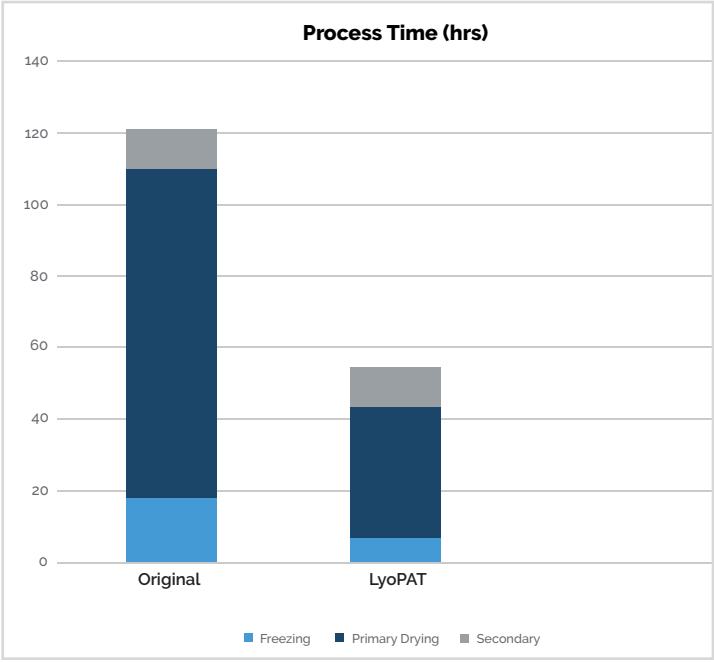
% of Original Processing time = 54.1/121 = ~45%

Reduction in Time: 64 hours

% Reduction in time : 55%

Cake structure visually acceptable

Residual Moisture: 0.61 +/- 0.04%



Revo® Pro Freeze Dryer

Innovation for Your Lab Scale Freeze Drying Needs

Revo Pro with LyoPAT® offers robust, technologically innovative, advanced freeze dryer controls for all of your process needs. This freeze dryer is perfect for researchers who want to perform full laboratory tray dryer runs and is available with 1 to 5 shelves and 2 to 10 sq ft of shelf surface area.

Revo Pro combines the best technology tools and innovations available in the market today for freeze drying analysis, optimization and cycle transfer. LyoPAT technology coupled with our robust and dependable freeze dryers provide researchers with both the innovative tools and the throughput they need for day-to-day operations.

The Pro Series of freeze dryers offer process control and monitoring for both the freezing and primary drying steps, enabling analysis and process optimization like no other system in the world. It's the perfect platform to capture your critical process parameters to make protocol transfer seamless.

Revo Pro Features

CONTROL SYSTEM: Opti-Dry® Gen2

- PC/PLC with ethernet and remote Internet connectivity
- Manual and automatic operating modes
- Graphic and numeric data collection
- Automatic system and leak rate testing
- Options for Protocol Optimization and Controlled Nucleation

SHELF SYSTEM

- 2 to 10 sq ft (0.185 to 0.929 sqM) of shelf area
- Large shelves for more product capacity – 12 x 24 (304mm x 608mm)
- Increased Stoppering Pressure – for 2ml vials
- 316L stainless steel on all wetted parts
- 16 Product Probes

CONDENSER

- 6" vapor port with pneumatic butterfly
- 2" Validation port on the vapor port
- 30L Exposed coil condenser for maximum efficiency
- Hot gas defrost

REFRIGERATION

- High reliability scroll compressors
- Oversized refrigeration components
- CFC-Free, non-proprietary refrigerants

VACUUM

- Pirani vacuum sensor standard
- Capacitance Manometer vacuum sensor
- Advanced Proportional Vacuum Control standard
- Gas backfill standard
- 330 LPM corrosion resistant vacuum pump

OTHER

- Sanitary and KF fittings on all sensor and vacuum ports
- Built-in validation port
- UPS on PLC

Contact us to learn more about how Millrock Technology can partner with your business to provide the highest-performance, advanced freeze drying services.

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