

Freeze Drying Diagnostics

Ensuring the Stability and Longevity of Your Products



Magnum® Pilot Freeze Dryer
Diagnostic Applications

rev 4/11/2024

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Diagnostics Innovations Rely On Freeze Drying

Freeze-drying is essential for diagnostic products due to their sensitivity to light, oxygen, and temperature. By freeze-drying these materials, they become more stable for long-term storage, have quick reconstitution rates, and are ready for immediate use or storage. This process is particularly important in the field of diagnostics as it allows for precise replication of reagent combinations in PCR tests and diagnostic kits ensuring accuracy and reproducibility in results. However, freeze-drying of diagnostics and reagents can be tricky. It's important to choose the right freeze-dryer to properly process your products.

The Role of Freeze Drying in Diagnostics

- **Stability and Longevity**

By removing water, freeze drying prevents the degradation of reagents and biomolecules, extending the shelf life of diagnostic kits without the need for refrigeration. This stability is crucial for the transport and storage of diagnostic kits

- **Preservation of Functionality**

The process maintains the chemical functionality of the components, ensuring that the diagnostic kits perform as intended when reconstituted and used.

- **Consistency and Reliability**

Lyophilized diagnostic reagents offer consistency in performance, which is critical for obtaining reliable and reproducible results.



Freeze dryers can process diagnostic materials from the basic reagents to "labs-on-a-chip". Quite often the diagnostic kit container type produces challenges for the freeze drying process. Knowledge of heat transfer and experience solving these unique problems is critical to configuring the proper freeze dryer for product quality.

Freeze drying is also crucial when it comes to PCR (polymerase chain reaction) diagnostic procedures, which usually involve multiple reagents mixed together. When the reagents are freeze dried, they're stabilized for a reproducible process and protected for storage and extended shelf life.

How it Works

Freeze drying, or lyophilization, is a sublimation process crucial for preserving sensitive materials used in diagnostic kits. It involves a series of stages—freezing, primary drying, and secondary drying—each integral to maintaining the integrity and efficacy of diagnostic reagents.

Freezing

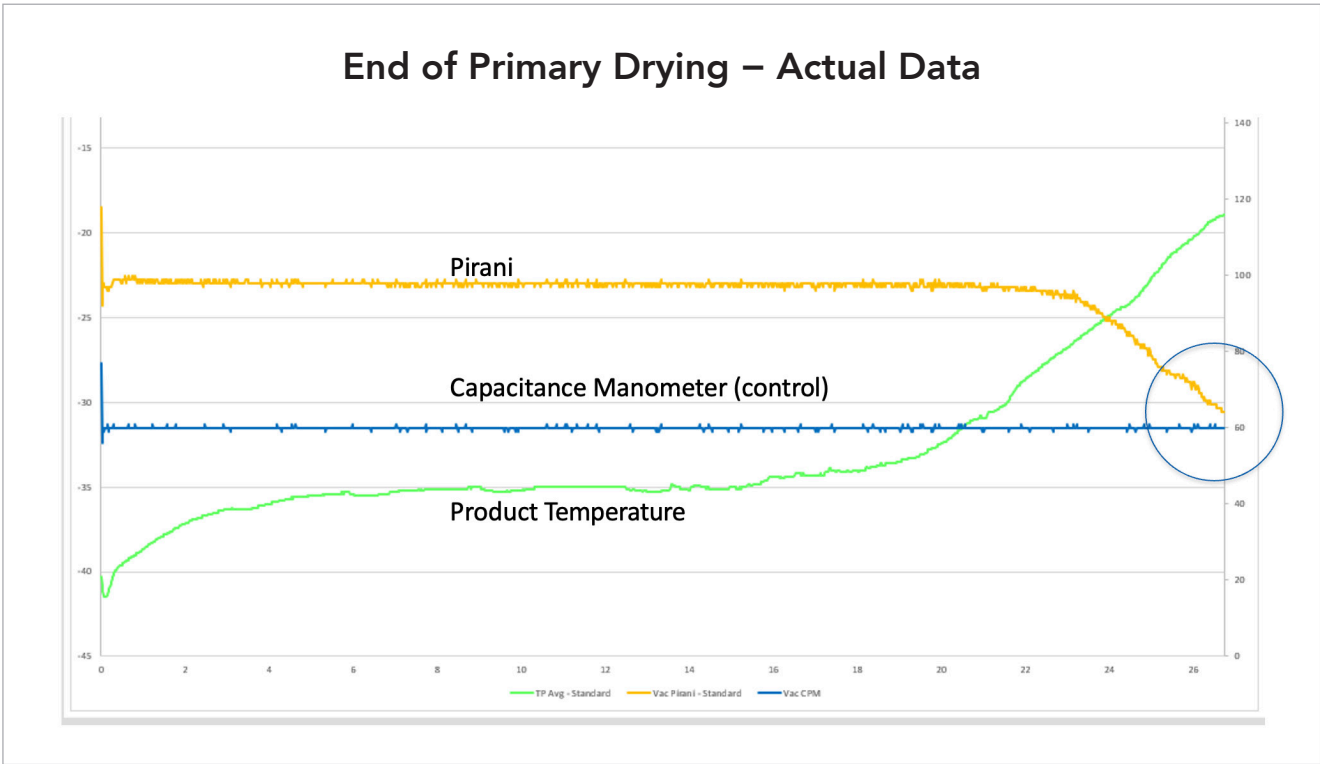
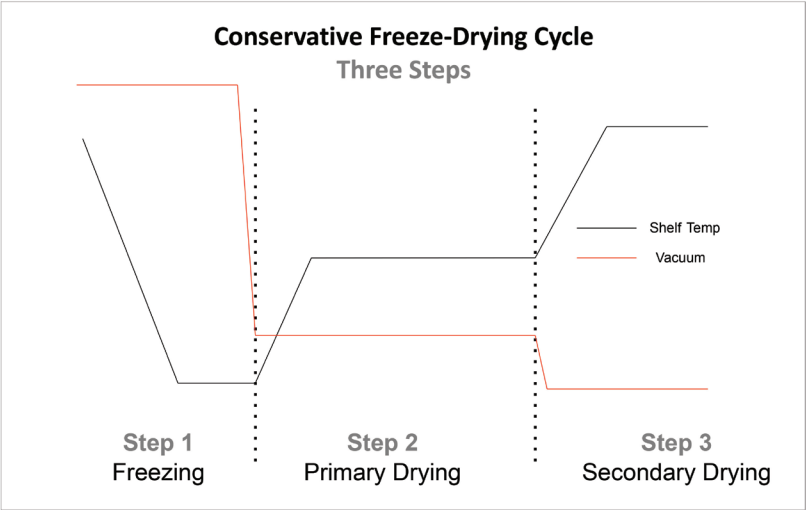
The initial phase involves freezing the material, typically reagents, at very low temperatures. This step is critical for preserving the structural integrity of the materials. The freezing process converts all the water content into ice, thereby stabilizing the material in preparation for drying.

Primary Drying (Sublimation)

In the primary drying phase, the ice in the frozen material is directly sublimated, turning it from a solid to a gas without passing through a liquid phase. This is achieved under a vacuum at controlled temperatures. The sublimation process removes the majority of the water content while preserving the biological and chemical structure of the material.

Secondary Drying (Desorption)

The final phase involves the removal of the remaining bound water molecules. This stage is carried out at higher temperatures than sublimation and still under vacuum conditions. Secondary drying further reduces the residual moisture content to 1% or lower, which is critical for the long-term stability and shelf-life of the diagnostic materials.



Common Challenges in Freeze Drying for Diagnostics

Freeze drying in the realm of diagnostics encompasses a variety of challenges that stem from the need to maintain the integrity and efficacy of diverse diagnostic materials. The choice of the right freeze dryer is crucial and is influenced by several factors, from temperature control to the physical configuration of the drying setup.

1 Temperature Measurement and Process Control

A primary challenge in freeze drying for diagnostics is the accurate measurement of product temperature and its subsequent impact on process control. Precise temperature control is vital for regulating sublimation rates during the freeze drying process. However, this becomes complex in diagnostics due to the variability in product composition and volume. Achieving a balance between maintaining the desired temperature and managing vacuum levels to control sublimation can be intricate, especially when dealing with diverse diagnostic materials.

2 Process Control

For consistent results it is critical that a proper protocol be implemented to freeze and dry the product. The protocol needs to ensure that the product is frozen in a consistent manner and that all of the product is frozen prior to pulling vacuum. Shelf temperature changes need to have a controlled ramp rate to keep the process under control and repeatable. For diagnostic materials, where consistency is key, uncontrolled freezing and/or uncontrolled temperature ramps can negatively impact the quality and reliability of the freeze-dried product.

3 Container Type and Shelf Contact

The type of container used for freeze drying and its contact with the shelf is another factor to consider. Different containers may have varying levels of thermal contact with the shelf, affecting the freeze drying process. This is particularly challenging when dealing with minimal product volumes, where obtaining a direct measurement of the product temperature is difficult.

4 Volume Considerations

In diagnostic applications, the volume of the product can vary significantly. Larger volumes might present challenges in achieving uniform drying and temperature control. Conversely, minimal product volumes pose challenges in temperature measurement and monitoring, making the process control more complex.

Addressing these challenges requires a comprehensive understanding of the freeze-drying process and the specific requirements of diagnostic materials. Choosing the right freeze dryer, one that offers precise control over temperature and vacuum levels, and accommodates different product volumes and container types, is essential. Overcoming these challenges is crucial for ensuring the production of high-quality, reliable diagnostics, where the accuracy and stability of the freeze-dried materials are of utmost importance.

Selecting the Right Freeze Dryer

Selecting the right freeze dryer for diagnostic purposes is crucial to ensure the integrity, efficacy, and reliability of the diagnostic products. The following key considerations should be kept in mind to make an informed decision:

Temperature Control Precision

Look for freeze dryers that offer precise temperature control. This is vital to maintain the integrity of sensitive diagnostic materials during the freeze drying process.

Vacuum Control

Vacuum control plays a critical role in the sublimation phase and is essential for the consistency and quality of the product. Vacuum has a direct effect on the product temperature and variation of vacuum levels changes the process and can result in inconsistent processing. Vacuum control systems vary. Select the vacuum control system that suits your application. Control to $\pm 1\text{mT}$ is available.

Robustness

The robustness of a freeze dryer in diagnostic applications is crucial because it ensures the consistent preservation of sensitive diagnostic reagents and samples, maintaining their integrity and efficacy. This reliability is essential for accurate and dependable diagnostic results.

Scalability and Flexibility

The freeze dryer should accommodate varying volumes and types of diagnostic materials. Scalability is crucial for adapting to different batch sizes and production demands.

Data Logging and Process Monitorings

Advanced data logging capabilities are essential for quality control and process optimization. Freeze dryers that allow real-time monitoring and recording of the drying process parameters can be invaluable.

Compatibility with Various Container Types

The freeze dryer should be versatile enough to handle different types of containers used in diagnostics, ensuring uniform drying regardless of the container type.

Reliability and Durability

Choose a freeze dryer that is known for its reliability and durability, ensuring consistent performance over time with minimal maintenance.

After-Sales Support and Service

Consider the level of technical support and maintenance services offered by the manufacturer. Good after-sales support can be crucial for the long-term successful operation of the equipment.

By thoroughly evaluating these factors, diagnostic laboratories and manufacturers can select a freeze dryer that not only meets their current needs but also adapts to future requirements, ensuring the high-quality production of diagnostic products.



Why Choose Millrock's Magnum Freeze Dryer?

The Magnum Freeze Dryer from Millrock Technology is not just a piece of equipment; it's a gateway to enhanced efficiency, reliability, and precision in the field of freeze-drying diagnostics. Its unique combination of flexibility, high-pressure stoppering capability, optimized shelf area, impressive condensing rates, robustness, advanced vacuum control, and the high pressure stoppering option make it an unparalleled choice for scientists seeking to push the boundaries of diagnostic research and development.

Flexibility for Diverse Applications

The Magnum Freeze Dryer offers unmatched flexibility, adeptly handling various vehicles. This adaptability is essential in the ever-evolving field of diagnostics, where versatility can significantly enhance research and development processes.

Optimized Shelf Area

The well-designed shelf area in the Magnum Freeze Dryer maximizes the space for your diagnostic materials, allowing for efficient and organized processing. This feature is crucial for handling large batches or multiple projects simultaneously, increasing productivity and throughput.

Impressive Condensing Rates

The Magnum Freeze Dryer boasts exceptional condensing rates. This efficiency is vital in maintaining the stability and quality of freeze-dried diagnostic products, ensuring that they meet the stringent requirements of the scientific community.

Robustness for Flash Handling

Millrock's Magnum Freeze Dryer is engineered to handle flash with robustness. This durability is crucial in a laboratory setting, where the reliability and longevity of equipment directly impact research outcomes and operational costs.

Advanced Vacuum Control

The Magnum employs a sophisticated vacuum control system that avoids direct contact on the shelf. This feature ensures that your diagnostics are processed under optimal conditions, minimizing the risk of contamination or damage during the freeze-drying process.

High Pressure Stoppering Option for Difficult to Seal Containers

The availability of a 21 PSI option further underscores the Magnum's versatility. This feature is especially beneficial for specialized diagnostic applications that require higher pressure to seal.



Offering up to 30 sq ft (1.85 sq M) of shelf area with a condensing rate of 20 liters and a capacity of 30 liters, the MAGNUM Pilot Freeze Dryer stands out amongst the competition. This lyophilizer offers 30% more shelf area than most other units in its class.

Additional Options Available

The Magnum is available in either a 20 square foot shelf area for higher water content products or a 30 square foot shelf area version for low water content products. Options include stoppering, clean room configuration, clean in place, 21CFR Part 11 capable software, and controlled nucleation.



NEW! We now offer 'Magnum NitroLyo' LN2 cooled systems. LN2 cooled systems provide all of the performance of mechanically refrigerated systems while eliminating the global warming potential of fluorinated refrigerants and eliminates the flammability dangers of 'natural' refrigerants. Other advantages of LN2 include reduced electrical consumption while eliminating the need for additional air conditioning that is typically required for mechanically systems.

Learn more about our [Magnum Pilot Freeze Dryer](#) for [Diagnostic](#) Applications.

About Millrock Technology

Millrock Technology is a leader in the innovation, design and manufacturing of freeze drying solutions. Since the 1950s, the Millrock team has been solely focused on advancing the science of freeze drying for the pharmaceutical, biotech, diagnostics, tissue and related industries. We work in partnership with you to innovate products that deliver performance and optimize your processes all while preserving your invaluable materials. We are dedicated to offering you the most responsive support services in the industry and to ensuring product performance in real world scenarios.

Experience the Millrock Difference

When you purchase a Millrock product, you get more than a freeze dryer. You get a long-term partner delivering industry-changing innovations, high-performing products, and on-call expert support.

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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