From discovery to scale-up to production, Praxair is right there with you. Delivering a continuous supply of gases and time-tested equipment, complemented by a full suite of engineering services and technical support. As well as technologies that help satisfy environmental regulations. Advancing quality, efficiency and reproducibility, not to mention your life’s work. To find out how, call 1.800.PRAXAIR or visit Praxair.com/biopharmaceutical. Praxair Bio/Pharma. Lifecycle technologies.

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Flexible operation and enhanced process control

Lyophilization is a unique process from a refrigeration point of view. Not only does it require ultra-low temperature refrigeration below -50 ºC, but during a processing cycle the refrigeration load is also extremely variable, often requiring a system turn-down in excess of 10:1. Both of these processing characteristics favor cryogenic refrigeration over mechanical systems.

Cryogenic systems are capable of providing a rapid and constant cool-down rate in any temperature range of interest. Mechanical systems typically cannot maintain the initial cool down rate throughout the entire production cycle. Therefore, the increase in operating flexibility and the precision of cool-down and freezing obtainable with advanced liquid nitrogen systems offer manufacturers significantly improved product structuring capability. This is especially important in developing formulation models and lyophilization cycles where the added control over parameters such as freeze rates, shelf and product temperatures and sublimation rates enables manufacturers to determine and employ optimum settings to attain ideal moisture levels and shelf-life for their lyophilized products.

Additionally, the later stages of the lyophilization process call for maintaining ultra-low temperatures in the condenser for extended periods to remove the vapor originating from the sublimating ice from the product. Indirect cryogenic heat exchange systems can hold very low temperatures at a precise point over any period of time without "freeze-up." This heightened level of control makes temperature specifications more easily reproducible. Dependable and precise temperature control can also help with GMP documentation and compliance.

Improved reliability, reduced complexity

Lyophilization typically requires ultra-low temperature refrigeration at temperatures below -50 ºC, sometimes as low as -100 ºC. The reliability of mechanical systems deteriorates as the refrigeration temperature drops. Compressors and related equipment, in fact, account for 80% of service problems associated with mechanical systems. Inherently simple and reliable cryogenic systems, with practically no moving parts, are not subject to catastrophic compressor failure, making them much more reliable than complex mechanical systems. Liquid nitrogen-based systems also provide constant cooling power throughout the temperature ranges of any lyophilization cycle. Finally, these systems can maintain refrigeration during power failures, maintenance and other downtimes, providing additional operational flexibility to support valuable products.

For more information
Contact Praxair at 1-800-PRAXAIR (1-800-772-9247) or log on to www.praxair.com.