Telstar

Lyotris
High performance in a pilot-scole cGMP freeze dryer

Lyotris

The Lyotris combines industrial equipment performance and small-batch flexibility in a compact envelope.

The focus of new drug development is increasingly on **biotechnology and biopharmaceutical products** with a **high value targeted to a specific population** for the treatment of more rare and complex diseases.

As science advances, the R&D process must evolve to address new requirements. This adds complexity to the drug development process and in turn influences process equipment. This factor is currently driving **an increase in the proportion of new drugs produced aseptically and lyophilized, a reduction in the size of the batches and an increase of the application of barrier technologies and automation** to separate potent but delicate products from human operators.

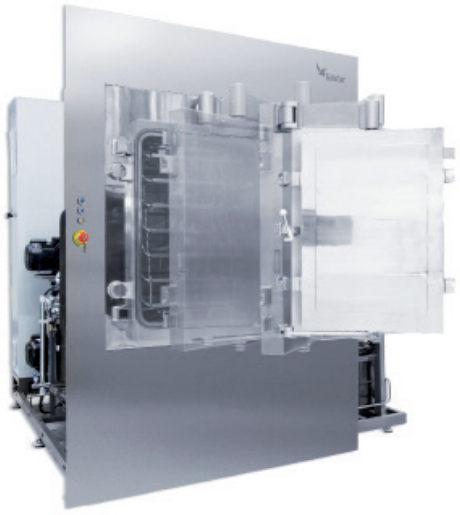
Telstar Lyotris is a cGMP small-scale freeze dryer suitable from early research stages to production stages in vials or bulk under aseptic conditions. It is particularly suited to clinical and small production scale batches of high-value pharmaceutical products such as personalised drugs and pharmacogenomic treatments, vaccines, antibodies and other advanced drugs and therapies which require stabilization.

The standard version includes the complete systems required for automatic cleaning (CIP) and steam sterilisation (SIP) processes and filter integrity testing (WIT). The unit offers critical component redundancy for elements such as the vacuum pumps, compressors and the heat transfer fluid circulation pump. The Lyotris standard unit includes a hydraulically actuated piston to move the shelves for stoppering and a displacement transducer that enables a fine positional adjustment of each shelf to a predetermined loading height for integration with automatic loading and unloading systems. The basic unit is supplied with a stainless steel front fascia for integration through the wall of a clean room or and aseptic isolator and also incorporates an advanced SCADA system for control, supervision and data acquisition.

The comprehensive documentation package includes operation and maintenance manuals, as built drawings and material and instrumentation calibration certificates as standard.

cGMP Compliance

Steam sterilizable Lyotris freeze dryers are designed and manufactured according to ASME-BPE standards: chamber base sloped towards the drain; sanitary type validation ports and connections, and; process pipelines sloped to drain and orbitally welded with certified sanitary components. The unit complies with international cGMP guidelines regarding cleanliness and sterility and all process contact surfaces are made of 316L polished to 0.5 µm Ra, easy to clean and freely drainable. As standard, the Lyotris includes automatic Clean in Place (CIP), Sterilization in Place (SIP) and automatic Water Intrusion Test (WIT) systems.



Compact Design

Lyotris has a compact design for optimal installation, accessibility and maintenance.

Chamber and vertical condenser are mounted on a single frame together with the vacuum system and the heat transfer system. The refrigeration system is supplied on its own skid which can be integrated to the main skid or installed separately depending upon installation location. The skids can be readily separated to facilitate transport through facilities.

The unit is provided with a stainless steel fascia and a novel gimbal door design for compact and **easy isolator integration.** The centre-pivot door has a fully automatic locking system and can rotate 360° to facilitate access, cleaning and maintenance.

Superior Performance

The specifications of the base model meet all cGMP regulatory requirements. Designed in-house by Telstar, the Lyotris combines commercial equipment specifications and performance and small-batch flexibility in a compact footprint.

The refrigeration system is based on hermetic compressors operating in cascade and can achieve a condenser temperature lower than -80°C and shelf temperature lower than -55°C.
The system is duplicated to provide complete redundancy.

The standard **vacuum system** contains oil-sealed rotary-vane vacuum pumps configured with redundancy equipped with gas ballast, anti-suck back valves and oil mist filters. The ultimate vacuum achieved in the chamber is better than 1x 10-2 mbar. The vacuum pump set includes a Pirani type vacuum transducer. When applications dictate, the oil-sealed vacuum pumps can be substituted for **dry vacuum pumps** operating without lubricant in the process cavities.

A **twin-head seal-less fluid pump** ensures smooth operation while providing redundancy. The circuit also includes brazed plate heat-exchangers and an SCR heater to provide a high level of temperature uniformity and heat exchange efficiency.

Microbleed vacuum control system to maintain the desired pressure in the drying chamber, operated by PID control in association with the vacuum measurement instrumentation.

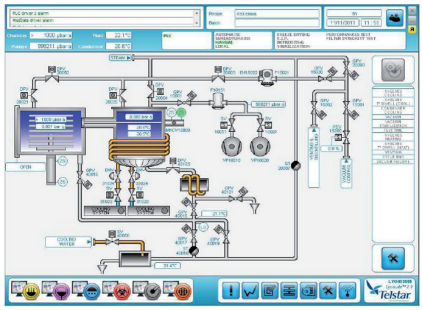
A **hydraulic cylinder** is installed on the top of the chamber to move the shelves. This enables the insertion of the stoppers into the vials at the end of the drying process at a controlled variable pressure as well as facilitating constant level loading for integration of loading and unloading systems. Internal to the chamber, the hydraulic piston is enclosed within a stainless steel **bellows** which is sealed at both ends to avoid any risk of product contamination.

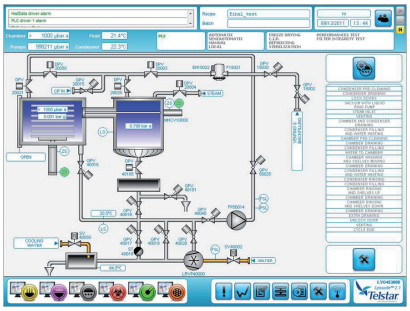
The chamber and condenser are separate vessels connected by means of a duct with pneumatically actuated **mushroom valve**. A **bellow**s fully encloses the shaft between condenser and actuator to eliminate any risk of contamination.

A thermostatically controlled **quench pot** cools the effluents in the drain lines prior to discharge by means of water injection.

Fully automated Control System

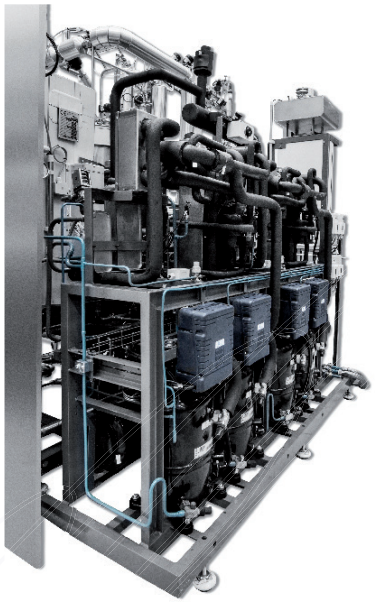
Lyotris freeze dryers are supplied with a fully automated control system based around a programmable logic controller (PLC) that controls all aspects of the equipment supplemented by a Supervisory Control Data Acquisition (Lyosuite SCADA) System to control user access and provide visualization, reporting and management of alarms and events. Lyosuite is FDA 21 CFR Part 11 compliant. The SCADA system is built using InTouch by Wonderware running on the latest compatible version of Microsoft Windows.
The suite of tools available in Lyosuite includes: access level control; building and storing recipes of freeze drying cycles; access to historical data; process visualization graphics; alarms, and; batch reports.





Special configuration for solvents

Lyotris can be configured to be intrinsically safe for processing flammable solvents. A Risk Analysis will be carried out to determine the required safety measures and the unit will be designed accordingly.



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