

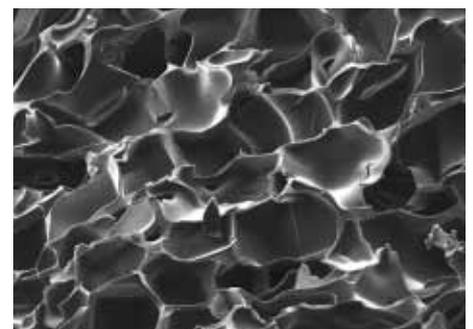
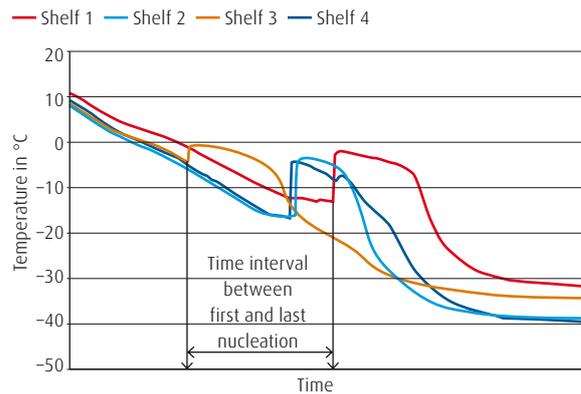


VERISEQ[®] Nucleation for laboratories. Improved lyophilisation through controlled nucleation.



VERISEQ[®] Nucleation is an advanced controlled nucleation technology engineered to significantly improve the quality of the end product. With this innovative system, cryogenic ice fog circulates within a lyophiliser chamber, providing an optimal temperature for reliable and prompt top-down nucleation of the pharmaceutical formulations in the vial. This accelerates overall cycle time by up to 35%, reduces vial-to-vial variance, improves product uniformity and increases ice crystal size, leading to reduced water vapour resistance and less time for reconstitution. The technology is applicable to laboratory-, pilot- and production-scale lyophilisers. By using the same technology from development to commercialisation, VERISEQ speeds up and greatly facilitates the validation process.

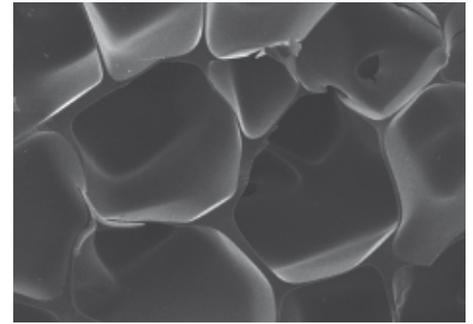
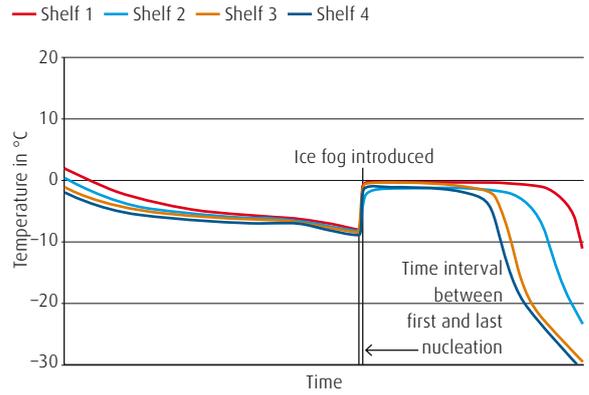
Nucleation variability with traditional lyophilisation



Product temperature profile across trays during freezing step. Actual data from customer test. Colours refer to temperature measurements of the reference vials. Thermocouples mounted on exterior of vials.

Natural nucleation: smaller ice crystals, larger vial-to-vial variability. Same magnification factor used for this photo and the photo on page 2.

Nucleation variability with VERISEQ® Nucleation technology



Product temperature profile across trays during freezing step. Actual data from customer test. Colours refer to temperature measurements of the reference vials. Thermocouples mounted on exterior of vials.

VERISEQ® Nucleation: larger ice crystals, reduced vial-to-vial variance. Same magnification factor as that used for the photo on page 1.

Benefits and operational characteristics

- Suitable for laboratories and pilot facilities, enabling them to test new formulations with controlled nucleation in the lyophilisation process
- Adaptable to all lab-/pilot-scale lyophilisation units; requires 2 x 1-1/2" ports
- Self-contained, fully automated one-button operation
- PLC-controlled with HMI interface
- Data logging

Technical characteristics

Capacity	Lab/pilot lyophilisation units up to 3 m ² shelf space
Power	5 kW
Temperature range	-193 °C to 120 °C
Operating pressure	10 barg max
Services	Liquid and gaseous nitrogen (dewar)
Electrical	230/120 V, 50 or 60 Hz, single-phase, 40 A
Weight	220 kg
Footprint	0.6 m width X 1.1 m depth
Height	1.3 m
Vacuum pump	Edwards RV12 dual-stage rotary; 0.001 mbar

Equipment features



Linde AG

Linde Gases Division, Carl-von-Linde-Strasse 25, 85716 Unterschleissheim, Germany
 Phone +49 89 31001-0, info-pharma@linde.com, www.linde-gas.com