



Celsius[®] CFT : Safeguarding Your Drug Substances in Controlled-rate Freeze & Thaw Manufacturing

- Maximum Product Security
- Excellent Process Reliability
- Creates Process Flexibility
- Scalable



Celsius[®] FT100 System

Celsius® CFT



Celsius® CFT is a platform technology for controlled-rate freezing and thawing of biopharmaceutical products.

Celsius® CFT features Celsius®-Paks that are pre-sterilized single-use bags made from 360-micron S71 film purposely engineered to fit into reusable structural frames.

Celsius® CFT defeats cryo-concentration during freeze and thaw cycles.

Celsius® CFT processes up to 100 L of product per cycle, and offers well-qualified shipping solutions for transferring the frozen drug substances around the world.



Maximum Product Security

Proven Bag, Robust Frame

Celsius®-Paks are secured in structural frames for robust handling – even at low temperatures – as proven through extensive functional qualifications.



Optimized Logistics

Control of the entire process logistics from filling to dispensing, including frozen transport, to easily and safely manage large frozen volumes.

Stabilize Drug Substance

Fast, reproducible thermal cycling preserves product stability and mitigates the major adverse effects of large-scale freezing and thawing of biologics.



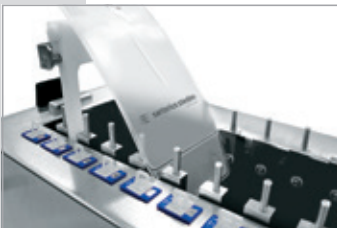
Creates Process Flexibility

Improves Production Management

Decouple process steps, extend product shelf-life, stockpile and enable batch processing.

Efficient Transfers

Easy transfer between DS & DP sites, facilitate management of multi-product facilities, leverage benchtop data for production scale-up. Same system for the same performances everywhere.



Optimizes Freeze and Thaw Operations

Reduce overall process time with fast freeze and thaw processes (5 hours to freeze 100 L of product down to -60°C, everytime).

Excellent Process Reliability

One Supplier

Total integration with monitoring of freeze & thaw process critical quality attributes Process control with 21CFR Part 11 & cGMP compliance.

Pre-Qualified Shippers

Mechanical robustness assured by ASTM D4169 AL1. Thermal performance ensures <-40°C for more than 72 hours against ISTA 7D Extreme Summer profile.

Excellent Reproducibility

Reproducible freeze and thaw cycles from Celsius®-Pak to Celsius®-Pak, from batch to batch and from F-T module to F-T module.

Scalable

Benchtop to Production

Quickly and easily verify product compatibility with 30 mL product in the Celsius® S³ Benchtop System

Flexibility within the Platform

All Celsius®-Paks (30 mL through 16.6 L) have the same film, materials and quality metrics. The production-scale F-T Module is modular from 33 L to 100 L to grow with your process.

Consistent Film

All Celsius® products are built from 360 micron S71 film for easy scale-up from Celsius® FFT to CFT. Film stability development transfers between Celsius® platforms to save time and money.

Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen, Germany

Phone +49.551.308.0
Fax +49.551.308.3289

www.sartorius-stedim.com

