Celsius® Product Lines

Discover our Freezing Capabilities

Simplifying Progress

SARTORIUS

Overview of the Freezing and Thawing Operations

Total solution provider in freezing solutions

Sartorius Stedim Biotech offers comprehensive solutions, using either patented freeze-thaw technologies or conventional freezers, for the handling, storage, transfer and shipping of biopharmaceuticals.

Celsius® Controlled Freeze & Thaw (CFT)

The Celsius® CFT systems use a proprietary heat transfer technology to freeze and thaw biopharmaceutical solutions, scalable from process development to commercial scale production products.

Celsius®-Pak

Volumes: 1 L, 2 L, 8.3 L and 16.6 L

1. Filling operation

Celsius® Filling Station FS16-S2

2. Controlled freezing operation

Celsius® FT33 | 66 | 100

3. Storage & logistics

Celsius® Shippable Storage Module (SSM)

Celsius® SSM Shipper

4. Controlled thawing operation

Celsius® FT33 | 66 | 100

Celsius® Flexible Freeze & Thaw (FFT)

The Celsius® FFT single-use assemblies are designed to provide the freezing container used in conventional freezer. The associated logistics for frozen storage and shipping of biopharmaceuticals is also available.

Celsius® FFT

(Volumes: 2 L, 4 L, 6 L and 12 L)

Freezing & storage in conventional freezer

Celsius® FFT Shippers

Celsius® S³ Overview

The Celsius® S³ Benchtop system is the only laboratory instrument available on the market to evaluate the Freeze and Thaw processes of new drug candidates in single-use containers with full scalability to production scale.

This tool allows generation of consistent samples library useful for evaluating stability, storage conditions and formulations.

Samples frozen in the Celsius® S³ Benchtop system may be stored at different temperatures to investigate the drug substance stability, using final scale-like conditions.

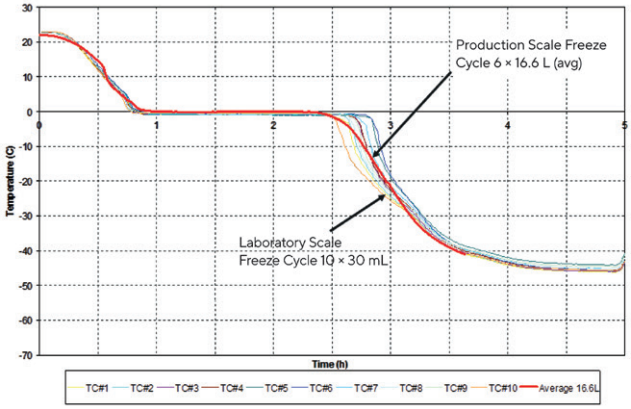
Celsius® FFT

Celsius® S³ Benchtop system

Celsius® FFTp

Celsius® CFT

16.6 L Process Scale vs. 30 mL S³



We Provide Our Support in Your Freezing Operations

Security of supply
Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes. The expertise of designing Single-Use solutions based on collaborative supplier management and customer demand planning assures a state of the art and robust supply chain that can cope with strong market growth.

Quality assurance
Single-Use Products follow applicable ISO and FDA regulations for Medical Devices. Design, Manufacture and Sterilization processes are conducted under conditions that mirror biopharmaceutical operations and meet cGMP requirements.

Validation
Celsius® Bags have been qualified applying the most complex and innovative test regimes. Biological, chemical and physical tests combined with extensive extractable testing provide users of Celsius® with data representing the widest range of process fluids in a variety of processing conditions.

Full compliance with ISO11137 allows sterility assurance level validation of 10^{-6} for each Single-Use System over its entire shelf life.

Application support Development studies
Feasibility studies are enabled using Sartorius Stedim Biotech Laboratory Scale Freeze and Thaw Technologies to assess the characteristics (quality, activity, robustness) of a drug substance.

The studies are designed to replicate the freeze | hold | thaw profiles of the Production Scale Controlled Freeze-Thaw Systems.

Biological entities have their own intrinsic characteristics that call for the development of product specific studies. Our applications group will work with clients to develop studies that will address the unique requirements of their biological entity.

Find out more
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