ZETA FREEZE & THAW SYSTEMS
Safe storage and transport of biopharmaceuticals

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**BRIDGING TIME AND DISTANCE**

When storing purified proteins, consider best method to guarantee product stability

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When freezing proteins according to pre-defined parameters a precise process control is a necessary requirement

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**The Challenge**

The biopharmaceutical sector needs to

- respond flexibly to momentary demand and supply,
- distribute production steps between locations, and
- hold intermediate forms of products for some time between processing steps.

This makes it essential to have a method of storing and transporting sensitive products such as pharmaceutical proteins.

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**The Solution**

ZETA offers a solution in the form of a complete range of equipment for controlled freezing, transport, storage and thawing of sensitive biopharmaceuticals. In the frozen state, biopharmaceuticals generally have good stability, and they are also protected against microbial growth.

ZETA Freeze & Thaw Systems are based on transportable stainless steel vessels linked to sophisticated cooling systems. Since the product quality of biopharmaceuticals is often sensitive to the exact conditions of freezing and thawing, ZETA Freeze & Thaw Systems also include lab-scale and pilot-scale devices to ensure rational and economical development of the freezing process.

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**Images:**

- ZETA FreezeContainer PED & ASME
- ZETA LabFreeze
- ZETA PilotFreeze
PRESERVING QUALITY

Best QbD compliant tool and PAT ready system for process development and scaling procedure

More safety due to reproduceable processes in best-in-class stainless steel systems

Kind to proteins
Biopharmaceutical products are usually stable in frozen form, but the process of freezing them is critical. ZETA Freeze & Thaw Systems are specially designed to make the freezing step as safe for your product as possible. Here are some of the features that reduce the stress factor for your proteins:

- Fully automated and controlled temperature profiles
- Highly efficient and homogeneous heat transfer
- Freezing and thawing without agitation
- Process design and process prediction supported by ZETA FreezeSimulation

Advantages of Stainless Steel:
- Safe, reliable, robust
- Free of leachables and extractables
- Long operational life
- Deal process control with inline and online sensors

ZETA Freeze & Thaw Systems

ZETA LabFreeze System
Investigative apparatus for initial studies of protein-specific behaviour (working volume: 200 ml)

ZETA PilotFreeze System
Miniature industry-grade system for testing process methods (working volume: 700 ml)

ZETA FreezeSystem
Production-scale system for freezing, transport/storage and thawing (working volume: up to 300 l)

A scalable product family: Since the exact freezing conditions are critical for avoiding damage to the product, product-specific development of the freezing method is key to success. ZETA Freeze & Thaw Systems are a family of equipment that offer you an economical, logical and reliable path from initial lab experiments through pilot scale to full production volumes of 10 to 300 l.
The dynamics of the freezing process hold significant risks for product quality. However, with a careful and logical approach to process design, these risks can be controlled. ZETA Freeze & Thaw Systems offer you a safe path through the development of product-specific freezing and thawing processes.

Understand your Process

The ZETA LabFreeze is made for initial experiments and maximizes the amount of data you can obtain from a very small volume of product. It can deliver first insights into effects such as cold denaturation, cryoconcentration, pH shifts and surface stresses.

This data can be used to model the freezing process for the specific product and to derive starting conditions for the next stage of testing.

The ZETA PilotFreeze is a step up to a miniature version of the production-grade system. It allows closer simulation of the production process and further refinement of the method. This stage minimizes unpredictable effects when you move up to full production scale.

Expert Support

Scaling up the process is guided by ZETA FreezeSimulation, a process modeling solution that makes each step in development more predictable and also provides a basis for Quality by Design (QbD), opening up the possibility of abbreviated validation of the freezing process.

Gather prior knowledge about behaviour of the specific protein

Plan experiments using the Design of Experiments (DoE) tool

Do experiments in ZETA LabFreeze

Use experimental data for ZETA FreezeSimulation

Transfer protein-specific freezing model to ZETA PilotFreeze

Verify freezing model in ZETA PilotFreeze, optimize process parameters

Transition to production-scale ZETA FreezeSystem
INNOVATIVE SOLUTIONS FOR OUR CUSTOMERS

ZETA Business Activities
Bioreactors & Fermentation Systems
Downstream Systems
Preparation Systems
CIP/SIP Systems
Magnetic Agitators
Freeze & Thaw Systems
Engineering
Automation

Customer Benefits
Deep process understanding
GMP FDA Compliance
Super-Skid Design
Focus on Sterility
High Process Reliability
Scale-up capabilities
Experience in complex biologics
Customized Process Systems

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