

# Characterization of ...

## ❖ Expertise in Freezing / Storing Pharmaceuticals

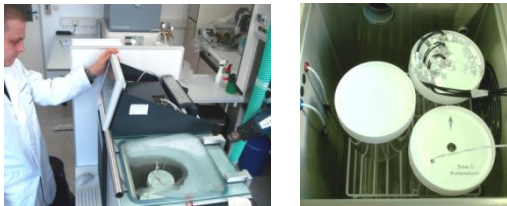
Since 2010, the ILK Dresden is researching cryogenic technologies for the freezing and storage of pharmaceuticals. Based on this research we developed a patented technology for the prediction of product loss.

This enables a full characterization, optimization and validation of final bulk and intermediate bulk freezing processes. To this end, we have developed a wide range of analysis methods to offer a process specific characterization for every freezing technology.

## ❖ Analytical Methods

### Simulation of freezing processes

- Process temperatures down to -180 °C
- Freezing rates up to 60 K / min
- Free choice of package
- Targeted application of mechanical energy

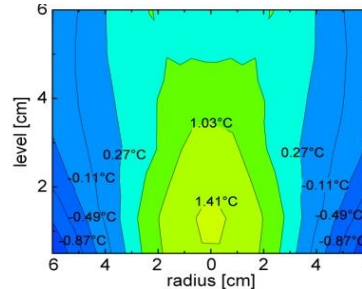


Simulation of typical industrial freezing processes on laboratory scale (left picture) and a view inside of the freezing chamber (right picture)

# Final and Intermediate Bulk ...

## Monitoring of Temperature

- High spatial resolution depending on package size (up to 72 measuring points)
- Determination of cooling rates
- Analysis of the ice growth kinetics

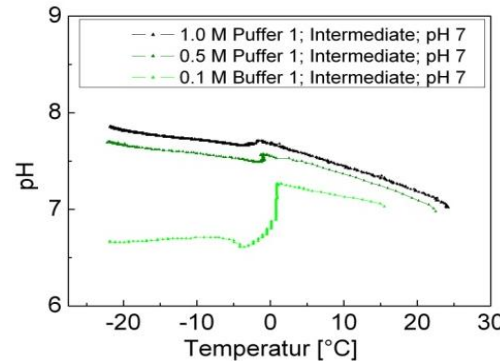


Distribution of temperature in 800 ml of an intermediate bulk after a process time of 30-minutes

## pH Measurement

### Online-Monitoring

- Spatial distribution of the pH
- Profiling the pH down to -30 °C
- Software-based modelling of the pH

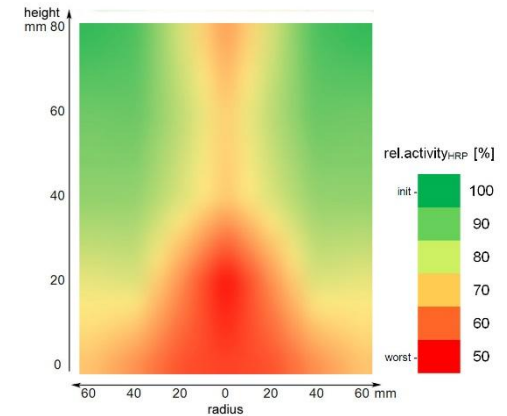


pH-Profile of an Intermediate Bulk during the freezing process. Process temperature: -30 °C; Filling volume: 800 ml

# Freezing processes

## Detecting changes in concentration of bulk composition

- **Spectroscopic Methods**
  - Optical emission spectroscopy (ICP-OES)
  - Spectrophotometry (UV-VIS)
  - Molecular spectroscopy (IR)
- **Chromatographically separation methods**
  - High pressure chromatography (HPLC)
  - Ion chromatography (IC)
  - Gas chromatography (GC)



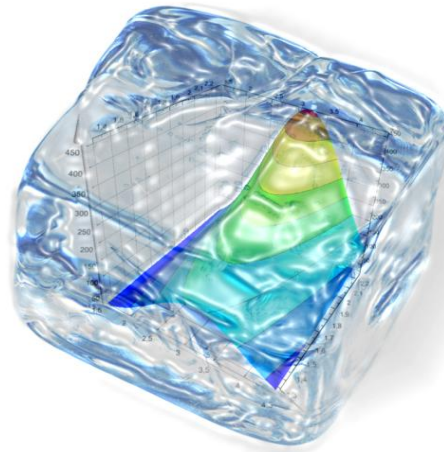
Spatial distribution of relative HRP activity within a frozen intermediate bulk  
green: low concentration (min.)  
red: high concentration (max.)

## Determining the quality of product

- High throughput screening
- Software-based modelling of product loss
- Software-based optimization of yield

## ❖ Range of services

- Online process monitoring
- Characterization of product specific processes
- Optimization of product yield and process time
- Material pick-up analysis
- Choice of product specific packages
- Analyses of freeze/ thaw stability
- Determine the influence of long time storage
- Analyses of protein aggregation



**Product Specific  
Characterization  
and Optimization  
of  
Final Bulk and  
Intermediate Bulk  
Freezing Processes**

**Please contact:** Dipl.-Ing. Johannes Heidingsfelder  
Phone +49 (0)351 40 81 618  
Fax +49 (0)351 40 81 635  
[johannes.heidingsfelder@ilkdresden.de](mailto:johannes.heidingsfelder@ilkdresden.de)

Center of Cryo-Competence in Life Sciences  
Institut für Luft- und Kältetechnik gemeinnützige Gesellschaft mbH  
Hauptbereich Kryotechnik und Tieftemperaturphysik  
Bertolt-Brecht-Allee 20 • 01309 Dresden, Germany  
[www.cryolifesciences.de](http://www.cryolifesciences.de)