RoSS® shell

Recommended filling volumes for freezing applications

Abstract

This application note provides guidance on filling volumes evaluated when using RoSS® (Robust Storage and Shipping) shell for freezing applications. **It summarizes observed system behavior under defined test conditions and highlights the relevance of bag-to-shell contact** as a key parameter influencing mechanical performance.

The RoSS® shell is designed as a mechanical support structure for single-use bag assemblies during freezing, storage, and handling. Its function is to provide defined positioning and mechanical stabilization of the assembly. The evaluation presented focuses on the interaction between filling volume and system behavior within the shell.

The RoSS® shell does not influence the intrinsic design, material properties, or performance characteristics of the selected single-use bag. Overall system performance results from the interaction between the bag, the shell, and the applied process conditions.

The information presented is based on application testing and is intended for knowledge sharing. It does not replace supplier validation documentation or process-specific qualification.

1. Introduction

During freezing of single-use bag assemblies, mechanical stress can occur due to movement of tubing, connectors, and the fluid mass, particularly at subzero temperatures where materials exhibit reduced flexibility. Such movement is a recognized contributor to mechanical integrity risks in freezing applications. To address this, controlled positioning and immobilization of the assembly during freezing are essential.

The RoSS® shell is a mechanical support structure developed to enable defined positioning of single-use bag assemblies during freezing, storage, and handling. The shell consists of a PE frame, integrated foam inlays, and a stainless RoSS® steel-lid (figure 1).

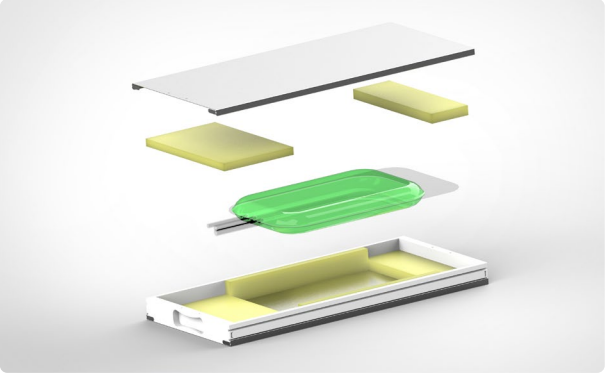

Figure 1: RoSS® shell assembly consist out of a PE frame (1), 3D foam inlays (2) and a stainless steel-lid (3)

The structural components provide mechanical robustness, while the internal foam elements support positioning of the assembly and accommodate volume expansion during freezing. The stainless steel-lid facilitates heat transfer during controlled freezing processes.

As a standalone component, the RoSS® shell is used in combination with a selected single-use bag. The intrinsic properties and functional performance of the bag remain unchanged, and overall system behavior results from the interaction between bag, shell, and process conditions. System performance is influenced by the extent to which the filled bag is in contact with the surrounding RoSS® shell structure, which is directly affected by the applied filling volume.

2. System behaviour during freezing

The filling volume determines how the bag occupies the internal cavity of the shell and establishes the degree of contact with surrounding surfaces. As this contact increases, the assembly becomes more geometrically constrained within the RoSS® shell.

Figure 2: Image showing the clear homogenous freezing in RoSS® shells, whereas uncontrolled slow freezing negatively affects critical quality attributes due to the occurrence of cryoconcentration

During freezing, heat is withdrawn through the shell boundaries, initiating solidification at the interface and progressing toward the core. This results in a moving solidification front (ice front), which defines how the frozen structure develops over time.

Under conditions supporting uniform heat transfer, the ice front advances in a controlled manner. This contributes to consistent formation of the frozen body and maintenance of the assembly geometry.

In combination with the physical confinement provided by the shell, this supports stable positioning of the assembly during freezing and subsequent handling.

The extent of this effect depends on several factors, including heat transfer characteristics, filling geometry, and formulation properties.

3. Test context

General test conditions for RoSS® 1013 and RoSS® 1049 are summarized below. Both configurations were evaluated with a 5 L PALL Allegro™ single-use bag.

The filling volumes were selected to balance bag utilization, contact with the shell heat-transfer surfaces and mechanical robustness during freezing and handling.

3.1 General test conditions

Parameter	Descpription
Bag system	5 L PALL Allegro™ single-use bag
Fill medium	Tap water (worst-case approach due to volume expansion during freezing)[1]
Freezing method	RoSS.pFTU plate-based freezing
Initial fill temperature	10–15 °C
Freezing conditions	Cooling to –80 °C for at least 11 h
Storage conditions	Frozen storage at –80 °C after freezing
Thawing conditions	Thawing to ambient temperature (25 °C) in RoSS.pFTU plate freezer
Handling conditions	Repositioning across six orientations and controlled mechanical stress after freezing

[1] Atkins, P. W., De Paula, J. and Keeler, J. (2023). Atkins' Physical Chemistry. Oxford University Press.

Figure 3: Schematic illustration of RoSS® shell repositioning across six orientations per shell to simulate vertical storage and handling conditions (AI generated)

3.2 Handling procedure and observation

Step / Test	RoSS® 1013	RoSS® 1049
Bag system	5 L PALL Allegro™ single-use bag	5 L PALL Allegro™ single-use bag
Evaluated filling volume	4.0 – 4.2 L	4.3 – 4.5 L
Vertical storage	Yes – on multiple sides (1 h ±10 min per orientation)	Not performed
Repositioning (turning)	All orientations (6 positions per shell)	
Drop test	2 repetitions per side	
Thawing	Ambient temperature (25 °C in RoSS.pFTU plate freezer)	
Visual inspection	After handling and thawing	
Observed behaviour	Stable positioning of the assembly; no visible damage under the applied test conditions	

The filling volumes differ due to configuration-specific design considerations and were verified through freezing, thawing and defined mechanical handling tests.

4. Evaluation

The evaluated filling volumes supported stable positioning during freezing, handling and thawing.

- Repositioning, vertical storage where applicable and drop tests did not result in visible damage to the bag assembly or RoSS® shell
- The tested filling volumes were suitable for the intended freezing application under the investigated conditions

System behavior remains dependent on bag design, filling volume, process parameters and application-specific requirements.

5. Conclusion

The tests indicate that the filling volume is a relevant parameter influencing the mechanical interaction between the bag assembly and the RoSS® shell during freezing. Under the applied test conditions, the evaluated filling volumes resulted in sufficient contact between the bag and the shell structure, supporting stable positioning during freezing and subsequent handling.

The observed system behavior is influenced by multiple factors, including bag design, fill composition, and process parameters. Variations in these factors may lead to different outcomes and should be evaluated as part of process-specific qualification.

The RoSS® shell contributes to system performance by providing mechanical stabilization and defined positioning of the assembly when used within appropriate operating conditions.

Indication of immobilization at subzero temperatures

Figure 4: RoSS® shell 1049 at 4.5 L filling volume after freezing, showing foam impressions generated during freezing

Figure 5: RoSS® shell 1013 at 4.2 L filling volume after freezing, showing positioning of the bag assembly within the shell

5. Outlook

Filling volume optimization is inherently application- and process-specific. Further evaluation under process-representative conditions may support:

- Definition of application-specific operating ranges
- Assessment of compatibility with selected bag systems
- Generation of data aligned with drug substance process requirements

Single Use Support offers support for:

- Process-specific validation studies
- Adaptation of filling strategies and configurations
- System-level evaluation in collaboration with end users and bag suppliers

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