

Lyo-Bead Production & Post-Lyophilization User Guideline



The guidelines in this document can help users avoid problems in lyophilization for Lyo-bead production. For storage and stability, expiry and general handling of these product pre-lyophilization, please refer to the individual Product Handling Guides.

Safety precautions:

Read and understand the SDS (Safety Data Sheets) before handling the reagents. Copies of these SDSs are available on our website or upon request.

There are several advantages for lyophilization, including room temperature shipping and storage, extended shelf-life and increased flexibility in sample volume. In order to be compatible with lyophilization however, enzyme preparations must be glycerol-free and include specialized lyophilization-excipients that preserve the mixture as it is exposed to various lyophilization conditions including freezing, temperature ramps, vacuum and dehydration. An ideal lyophilization formulation should stabilize an enzyme in a freeze-dried format and allow very fast rehydration and reactivation of the enzyme preparations, without impacting its performance post rehydration.

Lyophilization

- The lyophilization cycle protocols in Table 1 is suitable for lyophilization of Lyo-Ready qPCR mixes and 1-step RT-qPCR mixes in lyophilization beads format. These parameters are provided as a guidance only and should be optimized to different user formats and systems.
- The product already contains excipients, therefore, there should be no need to add any further excipients to assist lyophilization.

Table 1. Lyophilization guidelines

Step	Temperature	Time	Description	Vacuum Set Points
Shelf Pre-Freezing	-40 °C	n/a	Pre-Freezing	
Freezing	-45 °C	0.5 °C/min	Ramp	
	-45 °C	10 min	Hold	
Evacuation	-55 °C (Condenser)			75 mTorr (100 µbar)
Primary Drying*	-45 °C	180 min	Hold	37.5 mTorr (50 µbar)
	-40 °C	0.5 °C/min	Ramp	
	-40 °C	900 min	Hold	
Secondary Drying	+22 °C	0.5 °C/min	Ramp	37.5 mTorr (50 µbar)
+22 °C	240 min			Hold

*Primary drying time could be extended to up to 24h depending on quantity of sample that is lyophilized

Post-Lyophilization

- Lyophilized qPCR and 1-step RT-qPCR mixes must be handled in a humidity-controlled environment of <5% humidity to ensure storage stability.
- For maximum shelf-life, we suggest packaging lyophilized material under inert gas conditions (e.g. nitrogen or argon) and insert a desiccant sachet to improve stability.
- Pouches should be heat-sealed and labelled.