

Biopharma Group

Transitioning from Liquid to Lyophilised RT-LAMP Assay to Improve Stability

Preserving Excellence: Your Global Partner for Freeze Dried & Liquid Formulations

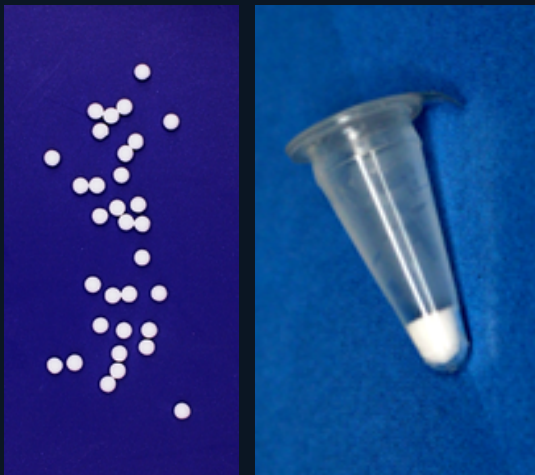
AT A GLANCE

A diagnostics company providing a rapid diagnostic assay for SARS-CoV-2, partnered with Biopharma Group (BG) to transition from liquid detection mixes to lyocake and lyobeads, aiming to improve product stability and eliminate reliance on cold chain logistics.

The company faced significant challenges with high batch rejection rates caused by low product stability and dependency on cold chain logistics.

The main objective was to develop lyophilised assay using the technology reverse transcription, loop-mediated isothermal amplification (RT-LAMP).

The overall aim of this transition is to optimise the sample's stability whilst avoiding the cold chain, leading to a more time and cost-effective process.



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CHALLENGES



- **Low Product Stability:** Resulted in increased operational costs.
- **Cold Chain Dependence:** Increased shipping complexity and costs due to temperature-controlled logistics.

PROPOSED SOLUTIONS



- **Formulation and Cycle Audit:** Conducted a comprehensive audit of the existing formulation to identify stability bottlenecks.
- **Freeze-Drying Microscopy:** Used to determine the critical collapse temperature of the formulation, enabling optimal freeze-drying parameters.
- **Lyocake vs Lyobead Trial:** Tested both formats to identify the most suitable option for high stability, scalability, and efficiency in production.

BENEFITS



1

Significant Moisture Reduction and Improved Stability

The moisture content decreased from 4.33% (w/w) in the first cycle using the initial formulation in a lyocake format to 1.41% (w/w) in the last cycle with the developed formulation in a lyobead format, enhancing product stability.

2

Reduced Shipping Costs

Eliminating cold chain requirements reduced overall shipping costs and simplified global distribution.

3

Improved Structural Integrity

The optimised formulation enabled the production of robust lyobeads, allowing for pick-and-place manufacturing.

Through expert formulation development, cycle optimisation, and close collaboration, Biopharma Group enabled the diagnostic company to achieve exceptional product stability, eliminating the need for cold chain logistics. This transformation not only reduced costs but also accelerated the delivery of critical COVID-19 diagnostic kits to the market.