

Biopharma Group

Troubleshooting For High Batch Rejection

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

AT A GLANCE

A leading biotechnology manufacturer partnered with Biopharma Group (BG) to help with transitioning from liquid detection mixes to lyocake. The main objective was to develop lyophilised assay (based on polymerase chain reaction, PCR) which will be used in diagnostic applications for clinical use.

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



During small scale development, Biopharma Group proposed a 40-hour and a 22-hour recipe, with both cycles yielding well-dried product with acceptable activity. However, once this was scaled up to a full-load validation batch in a low-bioburden laboratory, below inconsistencies were observed:

- **Partial Cake Collapse:** Lyocake exhibited a dry top layer, a collapsed middle region, and an intact bottom – as shown in figure 1 below.
- **Root Cause Analysis:** Investigation revealed that the product temperature exceeded the collapse threshold due to higher dry layer resistance and smaller ice crystal formation during freezing.

PROPOSED SOLUTIONS



Biopharma Group proposed reverting to the more conservative 40-hour freeze-drying cycle, maintaining shelf temperature at -40°C throughout primary drying to prevent product overheating. This cycle had previously shown 100% success in the R&D laboratory.

BENEFITS



1

Enhanced Product Stability

Improvements eliminated the need for -80°C cold storage, simplifying logistics and reducing costs.

2

Collaborative Success

The partnership led to efficient R&D processes, aligning with the manufacturer's timelines and performance goals.

By leveraging innovative freeze-drying techniques and comprehensive analyses, Biopharma Group transformed a critical diagnostic product, delivering superior stability, quality, and operational efficiency for the biotechnology manufacturer.