MedPharm

CASE STUDY

Resolving Scale-Up Stability Challenges Through Process Development

Identifying and controlling critical parameters to enable robust, reproducible manufacturing

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The Challenge

A sponsor encountered instability during scale-up despite having a confirmed formulation composition. As manufacturing progressed, variability increased and product stability issues emerged, creating risk for continued development.

Approach

MedPharm applied a process-focused strategy to identify the root cause of instability and improve manufacturing consistency:

- Evaluated manufacturing parameters and their impact on stability
- Focused on process-driven root causes rather than formulation alone
- Conducted Design of Experiments (DoE) to assess excipient ratios and process parameters
- Investigated the impact of PEG ratios, glycerol, ethanol, and cooling rate
- Identified interactions between excipient ratios and process conditions
- Defined optimal formulation and process parameters for scale-up

Outcome

- Identified root cause of syneresis during scale-up
- Established critical process parameters (CPPs)
- Reduced variability between manufacturing runs
- Enabled consistent, reproducible scale-up
- Achieved stable product under optimized conditions
- Avoided the need for full reformulation
- Accelerated development timeline and reduced scale-up risk

Why This Matters

Scale-up challenges are often driven by process conditions rather than formulation alone. By identifying and controlling critical parameters, MedPharm enables robust and reproducible manufacturing processes that reduce risk and support successful program progression.