MedPharm

CASE STUDY

Stabilizing a Biologic for Nail Delivery

Correcting development strategy and excipient selection to enable a viable formulation pathway

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The Challenge

A sponsor developing a biologic for topical nail delivery encountered significant stability challenges with an existing formulation developed by another CRO. The product was designed to achieve two-year room temperature stability, but early data indicated substantial risk to program success.

Approach

MedPharm applied a biologic-focused formulation strategy to identify the root cause of instability and optimize the formulation:

- Conducted forced degradation studies under biologically relevant conditions
- Evaluated the impact of pH, temperature, metal ions, and solvents on stability
- Assessed excipient compatibility, identifying buffer and emollient incompatibilities
- Removed incompatible excipients and introduced biologic stabilizers
- Optimized formulation to improve stability and support IND-enabling studies

Outcome

- Identified root cause of instability
- Improved stability by ~70% over four weeks
- Established a biologic-appropriate formulation strategy
- Enabled progression to IND-enabling studies
- Reduced formulation risk moving forward
- Accelerated development timeline and increased likelihood of clinical success

Why This Matters

Biologic formulations require specialized development approaches that differ from traditional small molecules. By applying targeted stability assessments and excipient optimization, MedPharm transformed a failing formulation into a viable development pathway, reducing risk and enabling continued program progression.