MedPharm

CASE STUDY

Reducing API Concentration While Preserving Topical Drug Performance

Formulation optimization enabled equivalent efficacy with lower drug loading

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The Challenge

A specialty pharmaceutical company developed a 5% cream containing a proprietary drug but sought to reduce API concentration without compromising performance. High drug loading can increase cost of goods and patient exposure, creating both commercial and clinical challenges.

The goal was to lower the API concentration while maintaining the same formulation framework and excipient system.

Approach

MedPharm applied a formulation-first strategy to optimize drug performance at lower concentrations:

- Evaluated drug solubility and stability across existing excipients
- Assessed formulation behavior using a first-principles approach
- Optimized excipient concentrations to increase thermodynamic activity
- Designed and tested revised formulations with reduced API content
- Conducted in vitro permeation testing (IVPT) to compare performance
- Measured skin penetration and permeation to confirm equivalence

Outcome

- Reduced API concentration from 5% to 3.75%
- Maintained equivalent skin penetration and permeation in IVPT studies
- Lowered patient exposure to the active drug
- Significantly reduced cost of goods
- Confirmed efficacy and safety in a Phase 3 clinical trial
- Achieved regulatory approval
- Successfully commercialized the optimized product

Why This Matters

Reducing drug load while maintaining performance can significantly improve both clinical and commercial outcomes. By optimizing formulation design, MedPharm enables more efficient products that reduce cost, improve safety profiles, and support successful development and commercialization.