



CASE STUDY

# Overcoming Solubility Challenges in Small Molecule Formulation

Resolving solubility limitations to eliminate precipitation and enable a stable formulation strategy

# The Challenge

---

A sponsor developing a small molecule formulation faced significant stability challenges with a formulation developed by another CRO. The product required improved chemical and physical stability, but performance issues were limiting progress and creating regulatory risk.

## Approach

---

MedPharm applied a structured, science-led formulation strategy to identify the root cause of instability and improve solubility:

- Conducted drug solubility studies to understand formulation limitations
- Identified mismatch between solvent capacity and drug loading
- Evaluated excipient compatibility and screened alternative excipients
- Designed new formulations from first principles to improve solubility
- Developed systems that maintained drug solubility at target concentrations
- Replaced the original formulation approach with an optimized strategy

## Outcome

---

- Identified root cause of drug precipitation
- Achieved improved chemical and physical stability
- Developed a formulation that maintained solubility at target levels
- Eliminated formulation risks related to instability
- Reduced regulatory risk from excipient limitations
- Enabled progression with a robust, scalable formulation
- Accelerated development timeline and increased likelihood of successful approval

## Why This Matters

---

Solubility challenges are a common barrier in small molecule development. By applying targeted solubility studies and formulation design, MedPharm transformed an unstable formulation into a robust, scalable solution, reducing risk and enabling successful program progression.