

**Verta Life Sciences | Molecule to Market Consulting.**  
**Supporting Life Science Companies; Develop, Manufacture,**  
**Register, Launch, and Supply their Products.**

## FORMULATION DEVELOPMENT #2 - CASE STUDY

### ISSUE:

Prior studies indicated that a topical drug may be effective in treating an unmet medical need based on limited clinical studies. However, the drug product was not physically stable and the formulation not acceptable for progression to further investigations.

### OBJECTIVE:

To develop a safe, effective and stable formulation of a drug for treatment of the unmet medical need.

### DELIVERABLE:

- To identify a formulation and method of manufacture for a drug product for topical administration with demonstrated safety, efficacy and stability based on Quality by Design (QbD) principles.
- Selection of appropriate primary packaging components.
- Development of product and ingredient specifications and methods based on scientific data, supported by method validation.
- Manufacture Clinical Trial Supplies for with appropriate documentation (batch records, batch release documentation).
- Stability studies to support shelf life stability of drug product.

### Contact Us

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