# Enhanced Formulations

**CASE STUDY** 



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## CASE STUDY Enhanced Formulations

## Solubility Enhancement

Increase bioavailability for dose escalation study

#### THE CHALLENGES

- ➔ Low bioavailability observed with existing neat API-in-Capsule.
- Severe side effects were observed with 72mg dose, so the dose was reduced to 63mg, however, a further reduction in strength was required.

### **ITHE SOLUTION**

Produce an amorphous form of solubilized material with surfactant using hot melt granulation (high shear granulation with jacketed bowl). Fill the granules into capsules using Quantos technology.

#### THE RESULTS

- Successfully achieved an increase in bioavailability. PK study showed 32mg dose was equivalent to 63mg dose.
- Currently evaluating 9mg dose in Covid study, 26mg dose in prostate cancer study, and 32mg dose in three triple negative breast cancer trials.

