

CASE STUDY

Successfully Formulating A Poorly Soluble
And Highly Variable API

CHALLENGE

Formulate a highly complicated tablet product with a poorly soluble API that has highly variable bioavailability. An initial formulation with a matching dissolution profile, failed its pilot bio-study.

SOLUTION

- Initially attempted to find suitable dissolution medium.
- The product is pH-dependent water soluble, limiting media sources available.
- Used the physical behavior of the formulation to our advantage.
- Reformulation utilized a lubricant-based wet granulation method.
- Used to slow down the tablet's disintegration time.
- Matched the DT/physical behavior and achieved compliance of dissolution to USP.

OUTCOME

Reformulation was successful in slowing down the initial burst of the tablet and its disintegration time. The product passed its second bio-study and six months stability test. The product was filed by our customer in the first quarter of 2019.