TEDOR

CASE STUDY

Successfully Formulating A Poorly Soluble And Highly Variable API

TEDOR helped a mid-size pharma company develop a manufacturing process for a highly complicated product that was both poorly soluble and possessed highly variable bioavailability.

Our team succeeded by transforming the product's weakness into a strength.

The Challenge

A mid-size pharma company has been working with TEDOR to manufacture a highly complicated product with a large market value.

TEDOR was asked to devise a formulation which accommodates a difficult API that is poorly soluble and features highly variable bioavailability.

The in vivo variability was a major challenge for the product as not only could each patient react differently to the tablet, but the same patient could also react differently if taking the tablet at different times of day or on alternate days.

An initial formulation was developed with a desired dissolution profile and dosed as a three-way replicate in fasting and fed conditions. This pilot biostudy failed in most of the categories, so TEDOR helped the customer embark on a fact-finding mission to discover why, and to ensure that the reformulation's physical behavior (time to disintegrate, disintegration pattern etc.) is as desired while maintaining the desired dissolution profile.

The Solution

TEDOR conducted experiments to obtain the desired physical behavior of the formulation. Our team knew we needed to find a dissolution medium that ensures the new product's dissolution predicts formulation behavior in vivo. However, because the product is pH-dependent water soluble, there were not many media sources available.

TEDOR had to think outside of the box and use the physical behavior of the formulation to our advantage. We reformulated the product utilizing an unconventional granulation method that used a lubricant during the wet granulation stage. This unusual method helped match the DT/physical behavior and achieved desired dissolution profile.

The Outcome

The manufacturing process developed by TEDOR was successful in producing a consistently uniform product which was dosed as a fully replicate design for both fasting and fed condition and behaved as expected in vivo.

To find out more about how TEDOR can help make your next project a success, contact Terry Novak, Chief Operating Officer, at (862) 207-1262