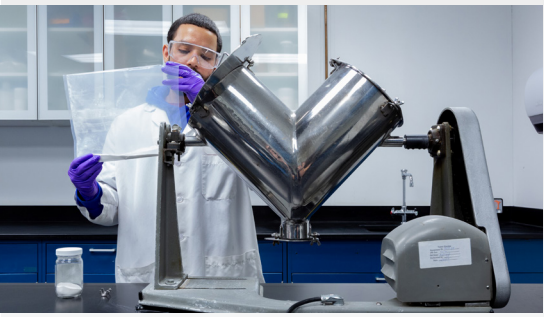
TEDOR PHARMA

CASE STUDY

Successful Encapsulation Involving A Combination of 3 APIs

When a virtual start-up company with a Schedule 3 controlled substance partnered with TEDOR for a formulation, our team was able to overcome multiple APIs with wide strength differences as well as a constrained supply chain.



The Challenge

A virtual start-up company commissioned TEDOR to help formulate a Schedule 3 controlled substance for pain management. The product has three APIs with wide differences in strength. An additional challenge was a vendor's short supply for one of the active ingredients of this product.

The Solution

The fact that the product is a Schedule 3 controlled substance was not a challenge, since TEDOR's facilities are equipped to handle these types of products. The supply chain issue was also overcome easily, with TEDOR's team continuing to work with the original vendor while qualifying a new vendor and validating its batches.

The API combination in this product was particularly disparate, with one API comprising 88% and the other two making up 7% and 4%. To ensure uniformity of the formulation, TEDOR carefully managed every aspect of the excipient used, including selection, amount, grade, and mixing. The screening of the API was another crucial step in obtaining a homogenous mix, with careful attention paid to determining the ideal screen size.

To manufacture the product, Tedor employed a multi-step geometric mixing process, in which the API and excipients were added slowly, with quantities increasing over time.

The Outcome

The manufacturing process developed by TEDOR was successful in producing a consistently uniform product. After roughly 18 months of development, the product was approved and commercialized in 2014. Tedor annually produces 12 to 15 batches, and it has been successfully scaled up from 110,000 to 900,000 capsules.

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