

## CASE STUDY

Successful Encapsulation Involving  
A Combination of Three APIs

## CHALLENGE

Develop a Schedule 3 controlled substance using three APIs with wide differences in strength. One API was in short supply at the vendor.

## SOLUTION

- TEDOR facilities are fully equipped for Schedule 3 controlled substances.
- Careful management of excipient selection, amount, grade, and mixing.
- Experiments helped determine ideal screen size for APIs.
- A multi-step geometric mixing process.
- An additional API supplier was qualified, and its batches validated.

## OUTCOME

TEDOR was successful in producing a consistently uniform product. The product was approved and commercialized in 2014. TEDOR has scaled up production from 110,000 to 900,000 capsules.