CASE STUDY

Devising An Extended Release Dosage Form Using A Ribbon Blender

CHALLENGE

Carry out the tech transfer of an extended release product from a Big Pharma client, which required a bio-equivalence study. The product failed the bio-equivalence study when initially manufactured with a ribbon blender.

SOLUTION

- Inspection of every manufacturing step to eliminate potential causes.
- The amount of isopropyl alcohol (IPA) in the formula needed to be reduced for ribbon blending.
- Avoided change in formula thus avoiding fed Bio-study and prevented delay in FDA approval.

OUTCOME

After reformulation, the product successfully passed the bio-equivalence study and was approved by the FDA.

Commercialized in the first quarter of 2019.