



Bilcare

Global Clinical Supplies

Formulation Development

Company Restores Client's Formulation to Fast Track

In February, 2007, a major pharmaceutical company's liquid-capsule formulation was supposed to be on a fast track, but it wasn't proceeding as planned. The supplier that developed the formulation couldn't prepare clinical supplies quickly enough, and the formulation showed signs of decomposition. Recognizing that the chemistry, manufacturing, and controls portion of the project was rate-limiting, the project team sought help from another supplier, Bilcare Global Clinical Supplies, Americas ("Bilcare GCS") of Phoenixville, PA. Bilcare GCS specializes in development and production of clinical supplies.

After evaluating the formulation on paper, Bilcare GCS determined that the decomposition of the active ingredient stemmed from oxidation of another component in the formulation. The two companies agreed that an antioxidant was needed to improve the formulation, and the supplier offered to conduct a situational analysis and draft a project proposal.

In addition to adding an antioxidant, Bilcare GCS staff modified an existing manufacturing line, tightening controls to minimize oxygen and thus decomposition. They also quickly assembled a group of people to produce a demonstration batch, which would serve as a walk-through of the entire process before moving onto a full-scale production run. Making the demonstration batch minimized potential surprises down the road and allowed the company to collect early stability data to support the clinical trial material. In short-term accelerated stability testing, the batch showed virtually no decomposition.

The success of the demonstration batch paved the way for the remainder of the project.

Bilcare GCS reassembled the resources and manufactured, packaged, labeled, and distributed the supplies before the client's deadline. Thanks to the quick project turnaround and early positive clinical findings, the client has returned to Bilcare GCS for additional batches.

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Adding an antioxidant and tightening controls reduced decomposition of a liquid-capsule formulation.

To learn more about Bilcare Global Clinical Supplies, please visit our website or contact:

Bilcare Global Clinical Supplies

300 Kimberton Road
Phoenixville, PA 19460

Phone 800-310-4445
610-935-4300

Fax 610-935-4321

Email direct-gcs@bilcare.com

web www.BilcareGCS.com