



Case Study

Quick to Clinic™ – Release of Clinical Batches in Only Seven Weeks

The Challenge The customer came to Patheon needing 50 mg capsules of neat API for Phase I clinical trials.

The Solution First we validated their assay and dissolution methods. Then we manufactured a prototype batch, which we subjected to a one-month stability test to confirm the suitability of the approach. Disposable manufacturing equipment was employed to eliminate the requirement for cleaning verification.

The Outcome The clinical batches were manufactured and released in just seven weeks – including a four-week stability test.

