TEDOR PHARMA

CASE STUDY

Solving Compression Issues with Change in API for an NDA

When a small US-based biopharmaceutical company needed to manufacture their first oral solid dose product for an upcoming clinical trial, they turned to TEDOR to overcome their formulation challenges.

The Challenge

A small US-based biopharmaceutical company has selected TEDOR to manufacture their first oral solid dose product for clinical trials.

Following the successful completion of their Phase I clinical trial, the company decided to change the API manufacturing site and process. This was done to reduce API impurities, which has led to differences in physical properties of the API. During R&D trials with the new API, the tablets showed lamination and capping with the new formula as compared to the previous formulation, which could be compressed using direct compression.

The Solution

Our teams ran several experiments to see if a change in excipients level or grade could resolve the issue; the formulation was already dosed for Phase I clinical study and the customer did not want to change the formulation significantly. However, with the major component of the formulation being the API (50%), the issue could not be resolved using the direct compression approach.

It was decided to evaluate non-aqueous wet granulation, adding a small level of a binder while keeping the formulation excipients and their level similar. This non-aqueous wet granulation resulted in an acceptable formulation.

Compaction was also evaluated as an alternate approach, which we explored to avoid the addition of a new excipient. The amount of API was limited, therefore a slugging trial on a compression machine was evaluated instead of roller compaction. A successful formulation was also achieved with this slugging trial, which also meant there was no need to add a new excipient.

The Outcome

These two alternative solutions have been provided to the customer, both the non-aqueous wet granulation approach and the slugging approach (via roller compaction). The ultimate decision on the formulation will be finalized based on an evaluation from the customer and a phase IB clinical batch that will be manufactured.

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