

Successful Cooperation Yields Anti-Stick Rewards

“ The work that I Holland did to troubleshoot this sticking problem and support these trials was fantastic and proved key to moving this project forward. ”

Patrick Daugherty, Pfizer USA

Pfizer is the world's largest research based Pharmaceutical Company - discovering, developing, manufacturing, and marketing branded medicines. However, despite its status as an industry giant, Pfizer still has to handle the common day to day challenges of tablet compression...

The Project

During 2007 Pfizer Product and Process Development (PPD, Freiburg Germany) opened discussions with I Holland regarding compression problems on one of their solid dose products under development. The main objective was to find a coating solution that would prevent sticking and also a design solution that would prevent picking. Additionally, a key objective was to evaluate the use of external spray lubricant against coated tooling options.



Pfizer - Freiburg, Germany



Consequently a compression trial was designed that would test the effects of changes in tablet design and the latest coating technologies available. For this I Holland provided two sets of tooling coated with a selection of PharmaCote coatings from their current and developing range. The embossed detail on both sides of the tablet was also redesigned in addition to a change of the tablet profile. The three pronged approach allowed Pfizer to make

an informed choice of which coating solution/design to use when scaling up this product for commercial manufacture. The three parameters (coating, design and profile) were tested simultaneously.

The trial was run over three days at the Pfizer plant in Freiburg Germany with I Holland present throughout the trial working alongside the PPD team to monitor and analyse the results. Every tablet produced was isolated from each individual station using the capabilities of the press.

Design

During the trial several design parameters were tested:

1. Double radius cup against single radius cup
2. Standard Pfizer logo and product identification against optimised design with increased counter dimensions to reduce the chances of picking.
3. External lubrication against coated tooling



Coatings

As the tricky Pfizer logo was put through its paces several coatings were also tested for their anti-stick performance:

PharmaCote DN A premium coating for combination problem products (sticky, corrosive, abrasive)

PharmaCote CN An excellent all round coating to prevent sticking, corrosion & wear;

PharmaCote NI Bespoke anti-stick coating;

Development Coating 1

Development Coating 2

Results

The premium CN coating proved to be the most effective anti-stick solution, completely eliminating the sticking problem and thus the need for an external spray lubricant. Based on the outcome of the trials, Pfizer elected to adopt I Holland's recommendations for a change in tablet profile to double radius, an optimised embossing design and the CN coating with the additional 'plus' process applied to the tooling. Since the trial I Holland have supplied further tooling for scale up validation batches and all lots have been manufactured successfully without sticking. The test set was also used for additional studies on a second product where the NI coating proved to be the most effective solution. This is now being used in development trials. Significantly, the trials also proved that the use of advanced coating technologies and the matching of correct coating properties to each specific formulation can provide a very cost effective alternative to expensive external lubrication systems. Since the trial, Pfizer have produced over 40 million tablets using the I Holland solution in the course of a product transfer. Patrick Daugherty of Pfizer Inc. Groton, USA states: 'The work that I Holland did to troubleshoot this sticking problem and support these trials was fantastic and proved key to moving this project forward.'



PharmaCote treatments and coatings