Time for change

In this article, Dale Natoli (president) and Kevin Queensen (technical service support, Tooling and Tablets), Natoli Engineering, detail the challenges faced by the R&D team when evaluating the ideal compression profile for a tablet and how the right tooling can help.

One of the challenges tablet manufacturers have faced for many years is the lengthy amount of time and high costs associated with pushing a solid dose product through the research and development (R&D) process. Developing and validating a new solid dose product can, therefore, be daunting for the R&D team.

A critical step in any tablet development process is determining the compressibility of the formulation, which means collecting data on how the formulation behaves in relation to variations in compression force and dwell time — both of which affect the final thickness, density and hardness (tensile strength) of the tablet. These parameters help determine the ideal compression profile for a tablet during R&D and ideally will lead to trouble-free mass production.

KEY DIFFERENCES

Transitioning product from an R&D tablet press to a production press during scale-up has been an ongoing challenge in the tabletting industry for many decades. When developing a new formulation, scientists use a small-scale tablet press to study and understand their product's tabletability. These small-scale systems are useful at the research level, but formulations do not always successfully transfer to the larger-scale manufacturing machines due to differences in turret size, turret speed, pitch circle diameter, feeder assemblies and pressure roll diameter. Compression dwell time is a crucial function that can be affected when scaling up from R&D to production.

Generally, R&D presses are 10 to 16 stations whereas a production press ranges from 30 to 100 stations, which represents a significant difference in pitch circle diameter and effective length of the feeder aperture. These differences considerably affect dwell time as it is dependent on head flat diameter, turret speed and turret pitch circle.

So, what is dwell time? Specifically, dwell time, expressed in milliseconds, is the time in which the punches achieve maximum penetration in the die under the main compression rollers and the punches are no longer moving vertically. In other words, dwell time is the time a punch spends in the same position or stage of the tablet compression process.

SIMULATING PRODUCTION PRESS DWELL TIMES

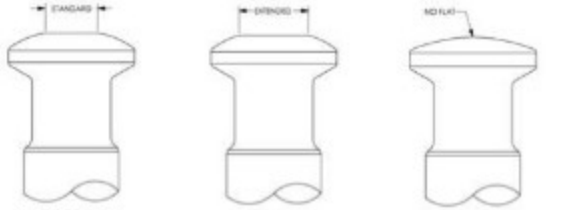
The simulation of production press dwell times on a small rotary R&D press can be accomplished by using punches with a smaller-than-normal head flat. By carefully choosing the head flat and press speed on the small-turret R&D press, one can simulate the dwell times experienced on a production-scale press at a given speed. As many tabletting issues are related to dwell time, this can help mitigate and resolve issues that often get overlooked in the development stage.

However, changing tooling in an R&D tablet press to test which head flat will produce the most robust tablet and possibly solve potential tabletting issues in R&D can be a lengthy and labour-intensive process. For example, the research team can face significant downtime when changing out different sets of tablet compression tooling on the tablet press. An additional challenge is the cost of purchasing these different sets of tooling, each with a different punch head configuration.

The newly available Quick-Release Tooling (Figure 1) from Natoli Engineering was designed to mitigate the operational differences between R&D and production presses. Each tooling set comes with a punch barrel, three interchangeable heads (standard head flat, extended head flat and complete dome — Figure 2) and one customisable punch tip. The three interchangeable heads can be swapped without tools of any kind. R&D teams can test different dwell times during the research process without needing to buy additional equipment.

FIGURE 2

Natoli Quick-Release Tooling comes with a set of three interchangeable punch heads. Punch heads are available to meet TSM or EU specifications in either B or D sizes.



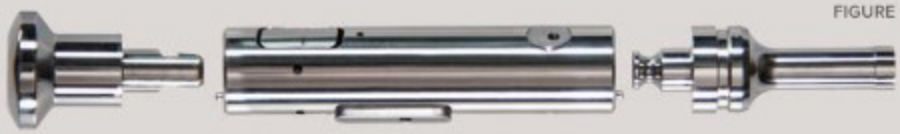


FIGURE 1

By being able to change the punch heads with speed and ease, the R&D team can evaluate dwell times with respect to both press speeds and head flat profiles — critical components of dwell time. This in turn allows for a more detailed analysis of a formulation's compressibility as well as greater troubleshooting capacity in the early development stages.

Once this detailed analysis has been performed in the early development stages it will enable the R&D team to determine the ideal dwell time for a specific formulation or product. In some studies, it has been suggested that the length of the dwell time can help with tabletting issues, such as picking/sticking and capping. However, in recent studies performed at the Natoli Institute at Long Island University it has been shown that some formulations respond negatively to longer dwell times. The results of these studies are set to be published soon.

Additionally, the ability to achieve a specific dwell time is invaluable for continuous manufacturing because as the powder is fed at a specific rate, there is little ability to adjust press speed to achieve the ideal dwell time or to resolve related tablet defect issues. By changing the head, it is possible to achieve the ideal compression profile for the product while keeping the press speeds at the specific requirement relative to powder feed and desired tablet output.

Other tablet considerations, such as size, shape, and cup configuration, can be evaluated when changing the punch tips in the early development stages. Once these considerations are assessed then the optimal tablet shape and cup geometry can be discerned. Not only does this afford the teams the opportunity to examine different tablet geometries for post-compression processes, such as coating, but also means that the various tablet geometries can be assessed for potential defects, such as sticking/picking, capping and edge erosion/chipping.

> **By resolving tabletting issues that are typically overlooked at the development stage manufacturers can speed time to production and reduce costs.**

SUMMARY

Tablet manufacturing issues arise from a multitude of variables such as operator training, calibration and maintenance of equipment, quick delivery parts, tooling and tablet design in addition to the formulation to be compressed.

By resolving tabletting issues that are typically overlooked at the development stage manufacturers can speed time to production and reduce costs. As revealed earlier an important consideration is that of being able to simulate production press dwell times during the research stage of development, which can be a lengthy process. Any innovation that could shorten this process and reduce costs would be a great benefit to tablet manufacturers.

The new Quick-Release Tooling affords research teams to be able to test different dwell times with speed and ease and without requiring several different tooling sets. Also, teams are able to simulate dwell times on a small-turret R&D tablet press before scale-up to a production press, which in turn means that tabletting challenges can be mitigated or solved during the early development phase.

Natoli will be introducing the new tooling set during this year's ACHEMA exhibition — the showcase of the process industry.