PROGRESSION IN TABLET COMPRESSION

by Dale Natoli

The most common problem encountered in tablet manufacture would have to be granulation adhering to the tool face, commonly known as 'sticking'. Tablet manufacturers often have to struggle through compressing a batch of sticky product, and sometimes – due to the severity of the sticking – are unable to compress any tablets at all. Typically, sticking is unnoticed or unrecognised during product development and so will often commence and/or worsen once the product reaches production when the dynamics of weight, friction, heat, powder flow, segregation and dwell time – to name but a few, come into play.

For most companies, sticking can be difficult, if not impossible to avoid. At the production level, this can affect operating efficiency and productivity, and dramatically increases manufacturing costs – not to mention the effects on tablet quality, that can affect consumer confidence and the perceived effectiveness of a product.

All too often, tablet manufacturers will revert to a punch coating that promises to eliminate sticking by promoting enhanced product release. In general, these coatings are costly and, in our experience, are less than 50 per cent effective. Also, adding a punch coating to the equation introduces a variable that is difficult to monitor and virtually impossible to troubleshoot. Thus, before deciding on a coating, it is better to explore the many different steel grades that can offer improved product release. These steels will typically be higher in chromium than standard tool steels and much easier to troubleshoot than a punch with a coating – when and if sticking continues.

Consistency

The most important factors for consistent tablet production are tablet press cleanliness and proper maintenance. Improperly set or maintained lower punch retainers is a common cause of variable tablet weight and hardness, whereas improper or inconsistent tool working length would typically be responsible for any deviation in tablet hardness and thickness.

Improper fill cams can also be responsible for inconsistencies in tablet production; if the fill cams are too deep, excessive granulation is taken into the die, then discharged at the weight cam and re-circulated. If the feeder cannot reclaim this granulation, it will bypass the feeder and accumulate at the neck of the turret; hence, the centrifugal force of the spinning turret will propel the granulation outward and refill the dies after passing over the weight cam – resulting in weight variation.

Proper product flow is also crucial to uniform tablet compression; granulation that flows evenly is conducive to higher-quality tablets.

Speed

The most important contributor to tableting speed – or indeed to tablet production – has been the acceptance of multi-tip tooling. This has been used for decades in the industrial, food and confection industries, but only in the last 10 years has multi-tip tooling been accepted and used in the pharmaceutical industry on rotary tablet presses. Tablet manufacturers producing micro-tabs are experiencing speeds of over 5,000 tablets per second. The main concern with using multi-tip tooling is the ability to compress consistent-quality tablets and – if not – then the ability to validate the tablet reject system to ensure that out-of-spec tablets are discharged.

We expect to see faster press speeds in the future, as this is the long-term scope for virtually all premium tablet press manufacturers. Frank Stokes is believed to be the engineer responsible for designing the rotary tablet press during his employment with Parke Davis in the late 1800s. The same basic design – using cams to vertically move the tooling through the various cycles of tablet compression in a turret, with upper and lower punches and dies – is still used today. The first rotary tablet presses produced 400 to 600 tablets a minute, whereas the modern tablet

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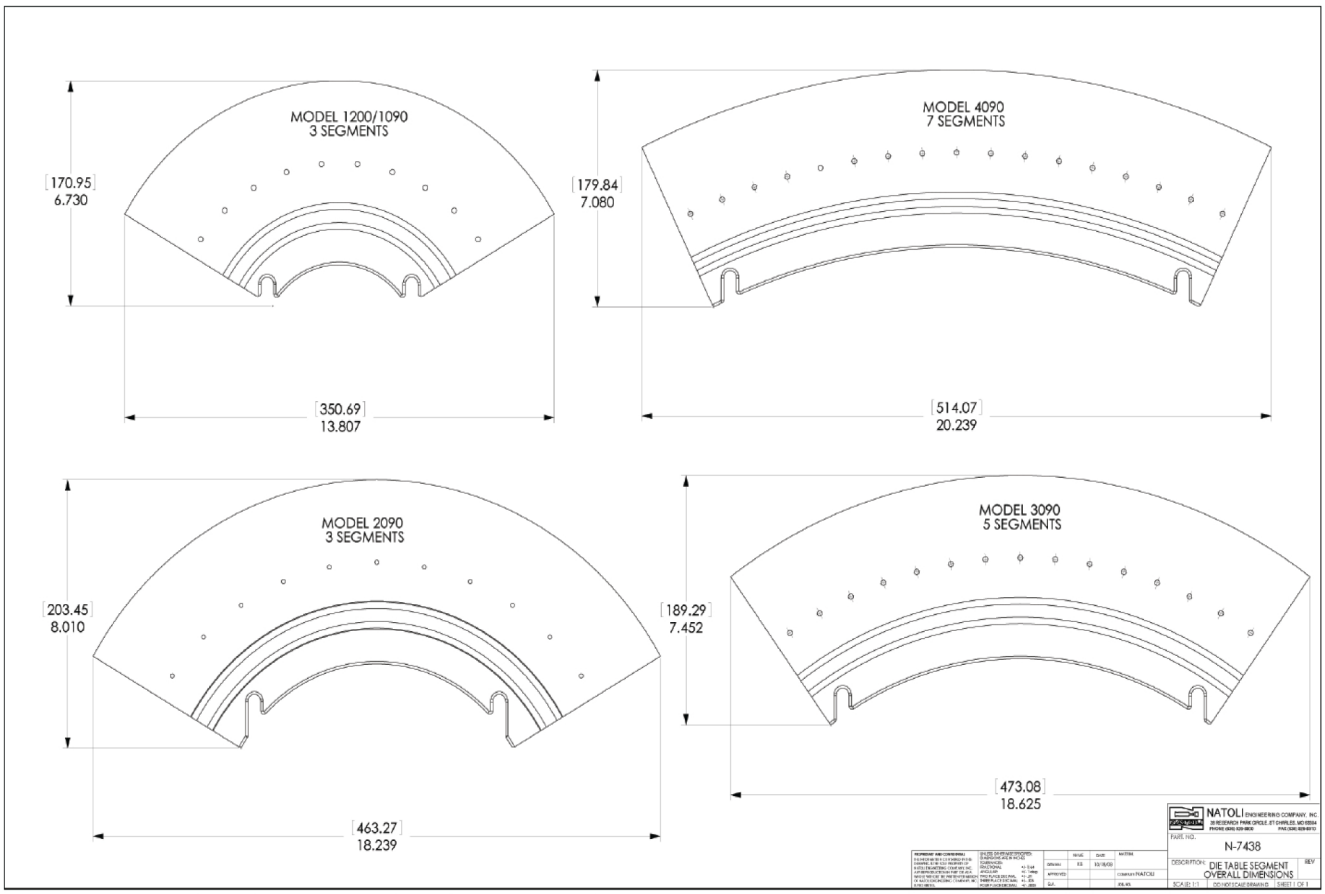

Figure 1. Cross sections of various configurations of Fette die segments.

presses of today can produce more than 100,000 tablets per minute. Innovation is simply matter of time.

Granulation

Having chosen a suitable excipient, proper granulation is essential for overall tablet quality. Problems such as sticking, picking, poor hardness, friability and product flow can result from improper granulating. As a consequence, excessive fines can be formed, resulting in tableting problems such as tool binding, product scorching or discoloration, and excessive tool and press wear. This seems to be a common issue with tablet manufacturers today, as dry direct compression blends have become the preferred method.

Over-blending a granulation is another concern that is generally overlooked and can occur in the tablet press itself. The rotary force feeder of the tablet press should always be considered as a mini blender. The feeder paddles aggressively move the granulation into the die bores, and if the feeders are overfilled and/or run at too high a speed, the granulation continues to be blended. This can result in the over-blending of what may have been a good granulation.

Advances in technology

In the past decade – other then multi-tip tooling as mentioned earlier, the most significant advances have been the Fette Die segments, and the Courtoy die ring and die shells.

Fette developed a turret configuration that eliminates the use of traditional dies and die-locks that hold the dies secure in the die table. The die segments have two major benefits. Firstly, they increase the number of stations in a given diameter of a turret, thereby increasing the number of tablets produced per turret revolution. Secondly, they dramatically reduce tablet press set-up time by eliminating the lengthy and painstaking process of setting each die in position. Instead of handling, cleaning and maintaining individual dies, the die segments require two bolts per segment and are locked positively in place, while maintaining the proper alignment of the punches into the segment bore.

The Courtoy die ring also has advantages over conventional dies and is more versatile as it allows the use of traditional dies, or alternatively a unique die configuration called die shells that are held in position without the use of traditional die locks. Unlike the Fette die segments, the Courtoy system uses a single piece replaceable die ring that substitutes for the traditional die table of a turret. To remove and replace the die ring, the turret's upper and lower section separates allowing

unrestricted access to the die ring for removal and installation. Again, increasing the number of stations in a given diameter of a turret increases the number of tablets produced per turret revolution, while use of the die ring instead of conventional dies and die locks dramatically reduces press set-up time.

Tooling sizes and materials

A variety of sizes and configurations are available, with each configuration having a unique benefit. The most common configurations are the 'B' and 'D' types, which are available in the American and European cam format. The 'B' type is smaller in scale than the 'D' type and is considered the most common; it is used by virtually all pharmaceutical tablet manufacturers. In general, the different configurations are determined by the maximum available tonnage, and the output or speed of a tablet press due to fewer tooling stations in a given turret diameter.

Tablet compression tooling is also available in a variety of materials. In order to maintain efficiency, it is advisable to evaluate several steel types to determine which material will be best suited for a particular product. High chromium steels tend to be preferred over standard steel for better product release, but have a tendency to be more brittle – and so are not best suited for some tablet shapes or granulations requiring excessively high compression tonnage.

However, most products are suited to multi-tip tooling technology. Considerations include tablet size, compression force, product sticking, ejection force and the overall condition of the tablet press. Multi-tip tooling provides a substantial increase in production, resulting in a highly efficient tabbing programme. In most cases, a tablet manufacturer can expect an increase in output of approximately 80 per cent for each additional tip. For example, if a press is producing 3,500 tablets per minute, then by adding an additional tip the output will be 6,300 tablets per minute, and the addition of a further tip will raise output to approximately 9,100 tablets per minute.

Micro-tab punches

Micro-tab tooling is a unique tool configuration, engineered to reduce distortion or breaking of the punch tips, as occurs more commonly with the lower punch. The micro-tip configuration should be considered for all tablets under 4mm in diameter, and for tablets of 5mm or smaller requiring an excessively high compression force.

The micro-tab tool configuration shortens the upper and lower punch tips in order to gain strength, making the punch tips more robust. In order to shorten the lower tip, a special undercut must be machined in the bottom of the die to accept a portion of the smaller punch barrel in order to have the proper tip length for tablet ejection.

Cleaning

Proper cleaning of compression tooling can be a long and tedious task. Many tablet manufacturers that need to clean several sets of tooling per day have implemented expensive and automated washing systems equipped with hot air drying to reduce spotting and surface corrosion. Regardless of the method used, the most important factors to use a cleaning agent suited for carbon tool steels. The use of hot water for rinsing elevates the temperature of the tooling to aid in the immediate drying process and reducing the possibility of surface discoloration and spotting.

"Tablet land"

Tablet land generally has the appearance of a small flat ridge around the perimeter of a tablet. Sometimes, it can be confused with poor quality tablets, which have a small raised crown around the tablet perimeter; this is commonly referred to as 'flashing'. Passing tablets through a vibrating machine called a de-duster helps to remove the soft feather edge, reducing dust accumulation during packaging and edge attrition during the coating process. The degree of flashing is dependent on punch and die clearance, tool wear, particle size and tablet design.

There is a misconception regarding land as an undesirable attribute – especially for film-coated tablets, whereas in fact it is just the opposite. Designing land into a tablet design will help to strengthen the edge of the tablet, allowing for easier film coating and extending tool life.

Summary

There are many factors that need to be taken into account to ensure the fast, consistent production of high-quality tablets. Tablet compression can therefore be described as more of an art than a science.

Article based on interview published earlier this year in Innovations in Pharmaceutical Technology.