White Paper

Multi-Tip Tooling for Tablet Compression: Separating Fact from Fiction

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The Specialist.

Introduction

The prospect of using multi-tip tools to dramatically increase production output on a single tablet press has long been considered by process engineers who seek additional capacity with minimal capital investment. The math is simple – a press tool design with 2 or 3 tips will produce 2 or 3 times the output of a press running with single-tip tools. While this is absolutely true, there are technical and validation challenges that are often very difficult to navigate. This paper examines multi-tip tool technology and the process control and validation issues that must be carefully evaluated to assess the potential for success.

Single and Multi-Tip Tools

Rotary tablet presses are configured with press tools consisting of an upper punch, lower punch, and die. For most applications, the upper punch has just a single tip, which is configured to match the geometry of the tablet being produced. Tablet press tooling geometry is governed by several standards (TSM and EURO) that define the tooling length, tool head geometry, and related tolerances. Most modern tablet presses offer an exchangeable turret capability that permit tablets of different sizes (using different tool standards) to be produced on the same press. In general, turret options for most press models include:

Turret Specification	Maximum Tablet Diameter	Nominal Punch Barrel Diameter	Nominal Die Diameter
TSM or EU D	25 mm	25 mm	38.10 mm
TSM or EU B	16 mm	19 mm	30.16 mm
TSM or EU BB	13 mm	19 mm	24.00 mm
TSM or EU BBS	11 mm	19 mm	21.00 mm

For all tablet press designs, the pitch circle of the die table for a given press is fixed, and the number of punches is different to meet varying tooling standards; this allows, for example, an increased number of punch stations when the die size is smaller. For a single-sided tablet press, which produces one tablet per revolution, a typical turret offering is as follows:

Turret Specification	Maximum Tablet Diameter	Number of Punch Stations
TSM or EU D	25 mm	29
TSM or EU B	16 mm	35
TSM or EU BB	13 mm	44
TSM or EU BBS	11 mm	47

At any given press speed, the output is then:

Output (tablets / hour) = Press speed (rev/min) X (number of punch stations) X 60 min/hour

Many customers leverage exchangeable turret technology to maximize output based on tablet size. For example, let's consider an 8 mm tablet running on a standard 35-station B turret at 80 RPM. The output is calculated as follows:

Output = (80 rev/min) X (35) X (60 min/hour) = 168,000 tablets per hour

If we run the same tablet on a 47-station BBS turret at the same press speed, the output would be:

Output = (80 rev/min) X (47) X (60 min/hour) = 225,600 tablets per hour

The use of the BBS turret, with identical processing parameters including press speed, compression dwell time and feeder dwell time, has resulted in an output improvement of 34.3%.

For double-sided rotary presses, which produce 2 tablets per revolution and which are designed for very high volume production, the nominal turret sizes are as follows:

Turret Specification	Maximum Tablet Diameter	Number of Punch Stations
TSM or EU D	25 mm	59
TSM or EU B	16 mm	71
TSM or EU BB	13 mm	87
TSM or EU BBS	11 mm	95

At any given press speed, the output is then:

Output (tablets / hour) = Press speed (rev/min) X (number of punch stations) X (2) X 60 min/hour

For the same 8 mm tablet running on a standard 71-station B turret at 60 RPM, the output is calculated as follows:

Output = (60 rev/min) X (71) X (2) X (60 min/hour) = 511,200 tablets per hour

If we run the same tablet on a 95-station BBS turret at the same press speed, the output becomes:

Output = (60 rev/min) X (95) X (2) X (60 min/hour) = 684,000 tablets per hour

The use of the BBS turret, with identical processing parameters including press speed, compression dwell time and feeder dwell time, has resulted in an output improvement of 33.8%.

Running a product on a turret that maximizes production output is an excellent strategy for maximizing tablet compression capacity. However, whenever a significant increase in tablet production capacity is required, the issue of multi-tip tools is often at the center of the discussion.

Based on the tablet size and tool specification, it is often possible to configure the upper and lower punches with multiple tips that will compress and eject multiple tablets at each punch station. In theory, the use of multi-tip tools can dramatically increase production capacity by the multiple of the tips that can be fit on the press tool. In general, the number of tips that can be incorporated on a single punch is a function of the tablet size and the turret being utilized, as follows:

Turret Specification	Maximum Tablet Diameter (Single-Tip)	Tablet Diameter (Multi-Tip)	Number of Punch Tips
TSM or EU D	25 mm	6 mm	7
TSM or EU D	25 mm	8 mm	5
TSM or EU D	25 mm	10 mm	3

Returning to the example of the 8 mm tablet, why not run a 5-tip tool configuration on the 59-station turret, and achieve an output as follows:

Output = (60 rev/min)* (59) X **(5)** X (60 min/hour) = 1,062,000 tablets per hour

This represents an improvement of 107% of the nominal output achieved with single-tip tools on the 71-station B turret, and an improvement of 55% over the nominal output achieved with the 95-station BBS turret. This appears to be a very easy decision and a slam dunk ROI, as outputs can be doubled and only a single set of multi-tip tools is required. Unfortunately, there are constraints and challenges that make this seemingly simple calculation extremely complicated to implement.

Automatic Tablet Weight Control

Tablet weight is the critical quality attribute for virtually all tablet compression applications. Precision tablet weight control ensures that each tablet delivers the prescribed dosage of active ingredient. Even with the most advanced tablet testing technology, tablet presses can still produce tablets faster than the tablet weight can be measured. Periodic samples and statistical control methods are fine, and there is a secondary parameter – the press force required to produce each tablet – that can be measured in real-time as the basis for automatic tablet weight control. This system permits the real-time, in-process measurement of tablet weight, and the ability to reject individual tablets that exceed indicated quality control limits.

In general, press force control theory can be explained as follows:

1. If a die is filled with a certain volume of material, and then the volume is reduced by bringing the upper and lower punch tips closer together during compression, there will be a resulting press force.

2. If the volume of material in the die is constant, and the final thickness at compression (distance between the upper and lower punch tips) is constant, then the compression force also will be constant.

3. If the volume of the material in the die is constant, and the final thickness at compression (distance between the upper and lower punch tips) is reduced, then the compression force will increase.

4. If the volume of the material in the die is constant, and the final thickness at compression (distance between the upper and lower punch tips) is increased, then the compression force will decrease.

5. Correspondingly, if the final thickness at compression is fixed, and the amount of material in the die is increased, then the compression force will increase; if the final thickness at compression is fixed, and the amount of material in the die is decreased, then the compression force will decrease.

6. With the vast majority of tablet presses, compression rollers are fixed during compression – that is, the upper and lower punches are driven to the same position by the upper and lower compression rollers. At a constant thickness during compression, the press force is thus determined by the amount of material in the die – which is the tablet weight.

Along with a high speed encoder, press force instrumentation, which is generally mounted on the compression roller shaft, permits the peak compression force of each tablet to be measured. This allows the real-time inspection of each and every tablet that is produced. Once the tablet press has been set up to achieve the specified tablet weight, thickness, and hardness, the resulting press force is measured and established as the press force setpoint. In order to set up press force limits, the tablet weight is adjusted to the high average limit, and the resulting compression force is then established as the high average limit. For the high single value press force limit, the tablet weight is adjusted once again to the maximum individual tablet weight, and the resulting compression force is then established as the upper reject limit. The same procedure is then utilized to establish the lower average and lower reject limit.

The press force control loop will then measure the press force associated with each and every tablet produced. An average force will be calculated (usually using a moving average algorithm) and compared to the press force setpoint. A low average compression force would indicate that the weight is slightly low, and the tablet press makes a closed loop correction to the dosing cam to increase the amount of material in the dies. A high average force would indicate that weight is slightly high, and the tablet press makes a closed loop correction to the dosing cam to decrease the amount of material in the dies. The adjustments are very precise and configured such that the system is tuned to return to the desired press force without hunting or overshooting the adjustment. If the average compression force violates the upper and lower limits, then the press is stopped instantaneously. This general press force control algorithm has been in use for more than 30 years.

The measurement of individual press forces permits the detection of out-of-spec tablets, which present as a high or low force – and which violate the upper and lower tablet rejection limits of the force control system. Most modern rotary tablet presses offer a single-tablet rejection system, which will reliably remove a single tablet from the product stream. A mechanical gate, or more commonly, a very short burst of compressed air, will remove an individual tablet across the full operating speed range of the machine.

Constraints of Multi-Tip Tools

The key constraint in the utilization of multi-tip tooling is the validation question pertaining to press force measurement and the ability to reject individual tablets that may be out of specification. Press force control theory, which matches an individual press force measurement to a corresponding tablet weight, encounters significant challenges when multi-tip tools are utilized. In essence, multiple tablets are being produced but only a single force is being measured.

In theory, a press force associated with multiple perfect tablets may be the same as the press force associated with a combination of overweight and underweight tablets. As such, the use of multi-tip tools does not permit the measurement of the individual press force for each tablet, which completely eliminates the ability to reject individual tablets. In most cases, this is enough to derail any consideration of the use of multi-tip tools.

There are also additional process constraints that must be considered. When a punch is configured with multiple tips, the force exerted by the head of the punch on the compression roller is cumulative. That is, if one 8 mm tablet requires a 10 kN compression force, then a press tool with 5 tips will measure 50 kN. In general, products that required higher compression forces will run at a slower press speed than products that require low compression forces. Indeed, in many cases, whatever output gain may be realized with multi-tip tools is quickly offset by the speed reduction associated with the comparably high cumulative compression force requirement.

There is also the matter of die fill. Producing a single, 8 mm tablet of a specific tablet weight will permit a higher press speed than a process where it is necessary to fill 5 die holes for every punch station. For products that have less than robust flow properties, again, any output gain associated with multi-tip tooling can be offset by the speed reduction required to achieve consistent die fill.

Multi-tip tools are an excellent solution for food, confectionary, and technical products, where the tablet weight control is not critical. Producing small mints and sweeteners at rates that exceed 1,000,000 per hour is quite common with the use of multi-tip tooling.

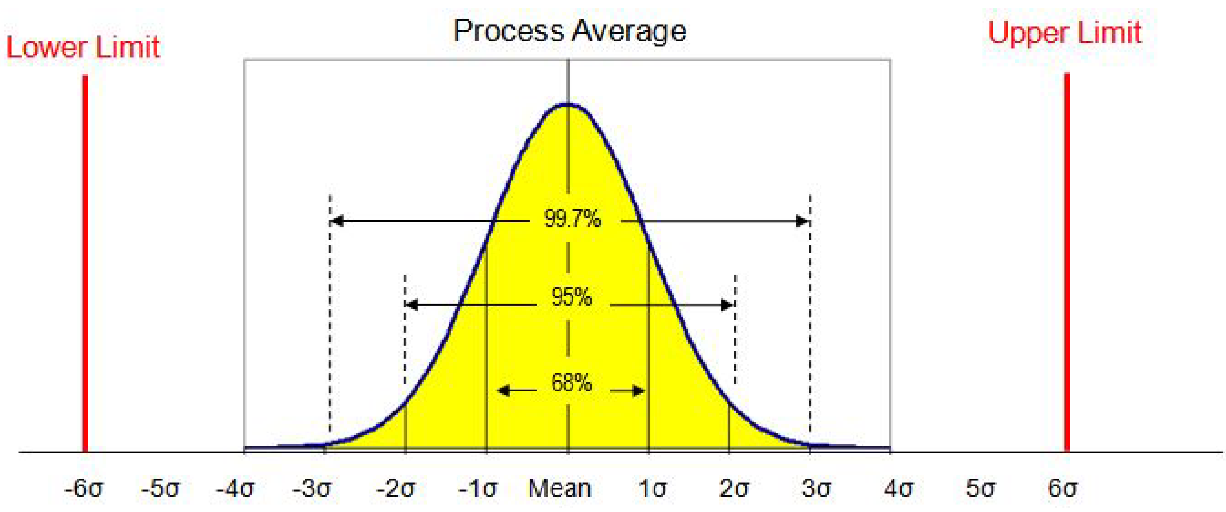
For those who seek to utilize multi-tip tools for pharma and nutra products, the only way to overcome the press force control / tablet rejection validation constraint is to develop a statistical case that demonstrates consistent and superior process capability – one in which all tablets are well within the specification limits at all times. This requires the calculation of process capability for tablet weight, thickness and hardness, as follows:

$$C_p = (USL - LSL) / 6 \times \Sigma$$

Where

C_p = process capability index
USL = upper specification limit
LSL = lower specification limit
Σ = standard deviation

The process capability index is the ratio of the upper and lower specification limit, divided by 6 sigma, which comprehends 99.7% of the process samples. A process capability index of 1.67 or higher is generally considered to be good, but the final determination is a question for the quality control group. In general, the process capability index must be evaluated for all critical process quality attributes, including tablet weight, thickness, hardness, dissolution, and content uniformity.



Conclusion

The use of multi-tip tools does seem to present a compelling opportunity to significantly increase production output on a tablet press. However, critical and technically valid constraints surrounding product quality and process validation have significantly limited the application of this technology in pharmaceutical manufacturing. The inability to reject an individual tablet, or even to recognize a high or lower individual force associated with a tablet reject, remains the key barrier.

For small tablet formats with low compression forces and superior material flow properties, including mini-tablets, it is possible to leverage the use of multi-tip tools based on a substantial statistical analysis of process capability in the context of specification limits. For larger tablets, and higher compression forces, any potential gain with multi-tip tools is usually offset by the need to slow the machine down based on the cumulative press force, and/or the dwell time required to fill multiple die holes on each station. And again, the inability to reject an individual tablet, or even to recognize a high or lower individual force associated with a tablet reject, remains the primary obstacle to successful implementation.

For food, confectionary and technical applications, multi-tip tooling does offer an opportunity for significant capacity increases. However, the high-cost of multi-tip tools as compared to conventional, single-tips must be considered in determining the true ROI.