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Back-to-basics on tablet press efficiency

How an objective assessment of equipment's efficiency can make a big difference

As the pharma manufacturing industry continues to increase its focus on optimizing operational efficiency, high-volume tablet production should not be an exception.

In many instances, there is a tendency to investigate new trends or developments in automation and the fundamentals — the basic blocking and tackling of efficient tablet production — are overlooked. But in most production environments, there is potential to materially improve overall efficiency by focusing on the key parameters that drive overall equipment effectiveness (OEE); namely, production output, yields, uptime and labor requirements.

Here, we will take a back-to-basics approach to highlight actionable improvements applicable to any solid dose production environment.

Optimizing tablet press output

For most tablet products, the press speed range, including maximum press speed, is defined in the process validation protocol. Considering this, any effort to increase production speeds must incorporate an understanding of this constraint. While the press speed range should have been established on the basis of process capability, in some cases the values are historic.

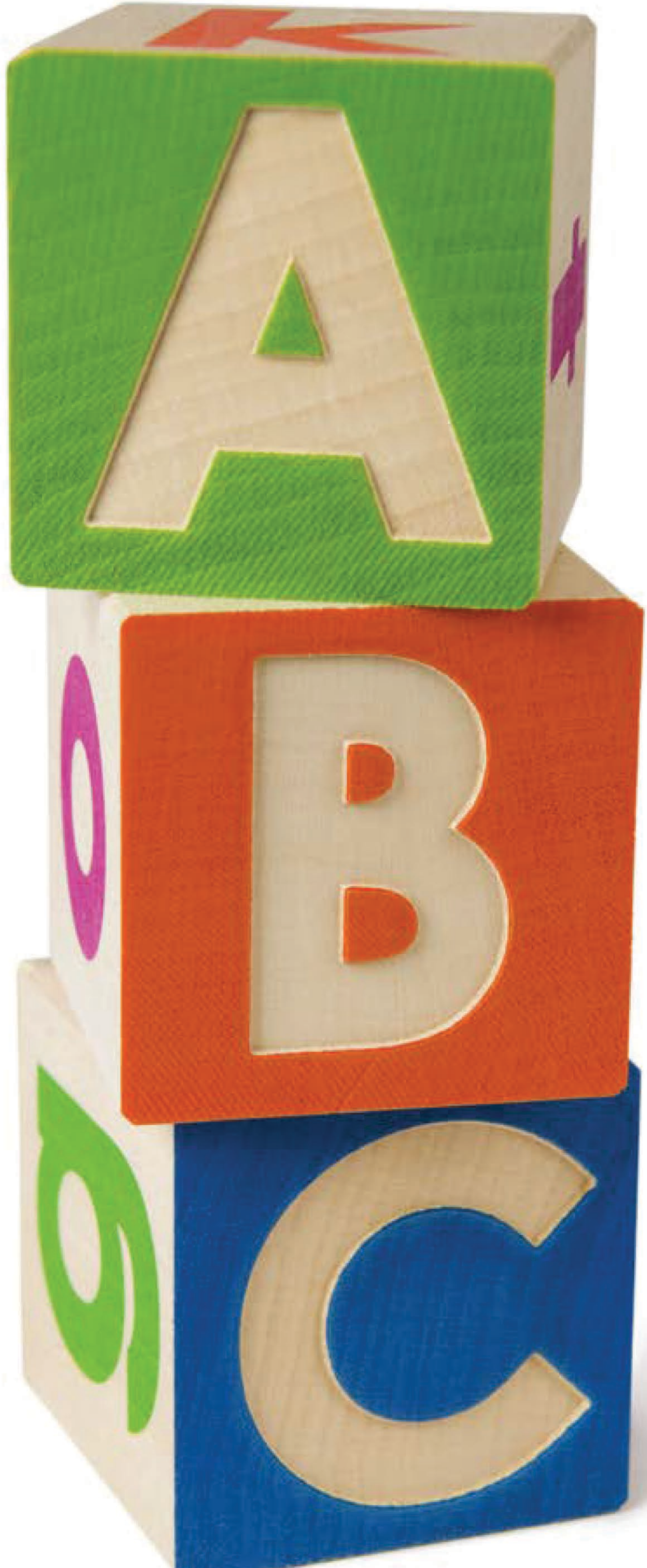
Knowing this, assessing the current process capability is always a good place to start determining how well the process is under control, and what the potential is to increase turret speed (and therefore production) while maintaining critical quality attributes.

The process capability (C_p) can be calculated for tablet weight, thickness and hardness for any product, as follows: $C_p = (USL – LSL) / 6 * \sum$

Where:

C_p = process capability index
USL = upper specification limit
LSL = lower specification limit
$\sum$ = standard deviation

Nominal process capability values of 1.33 or 1.50, or higher, are generally indicative of a process that is under control, and process capability indices of greater than 2.0 would suggest that an increased press speed is possible while maintaining process quality. Increasing press



speed will decrease both feeder dwell time — the time that the punches are beneath the feeder — and compression dwell time, which is the time it takes for the punch head flat to travel across the compression rollers. This means higher press speeds have the potential to create expanded tablet weight variation due to reduced die fill time, as well as lower tablet hardness due to a shorter dwell time in which compression force is applied.

If it is possible to increase the press speed within the validation process range and maintain an acceptable level of process capability, then this is a logical first step toward optimized press efficiency.

A second option for materially increasing output performance comes with leveraging multiple turrets to maximize output for every tablet size. Most modern production machines offer a series of interchangeable turrets. With knowledge of the different tooling sizes and standards, the selective use of multiple turrets can have a considerable impact. (See sidebar)

By aligning tablet size to turret selection, the output can be maximized across the product portfolio without increasing the validated speed range. In addition, the use of multiple turrets — which entails the potential to clean, prepare and tool turrets offline for fast change — also can have a material impact on efficiency by significantly reducing overall downtime.

Maximizing tablet press yields

Across all batch sizes, a clear, consistent objective is to maximize the number of good tablets that can be produced while minimizing inevitable product loss. In general, product losses can be categorized as follows:

- Startup scrap
- In-process losses
- Sampling losses
- Batch end scrap

For most products — and those with highly potent APIs in particular — it is necessary to generate a complete reconciliation to account for the total batch weight. This means the total of all loss sources plus the total good tablet weight must align with the total starting weight of the batch. For most modern tablet presses producing a single-layer tablet, production yields in the range of 95-99 percent are achievable.

Startup scrap is generated when the machine is being setup with process parameters to achieve the required product weight, thickness and hardness. Often, and certainly at higher press speeds, considerable losses can be generated if the operator must make an iterative series of adjustments before settling upon the proper settings.

The best way to minimize startup scrap is to utilize a product recipe capability in which a comprehensive list of optimized machine parameters is stored and retrieved automatically. Most modern tablet presses offer such a capability; one where the product recipe system will automatically configure the tablet press, including settings for press speed, dosing position, tablet thickness, press force settings, punch lubrication system settings and sampling/parameters settings for an inline tablet tester.

In-process losses include material lost from the feeder and either recovered or not recovered in the dust collection system. Most modern tablet presses have advanced feeder seals designed to maximize production yields. These seals eventually wear out and require replacement based on the processing parameters and the nature of the material being produced. The granulation particle size also can have an impact, as fines will always be harder to contain in the feed frame. In addition to inspecting and intermittently replacing feeder seals as required, the dust extraction volume — the amount of air pulled from the compression zone through dust extraction nozzles — is also a critical parameter. In many applications, the tablet press is connected to a central house dust extraction system, and the dust extraction volume can be impacted by the number of machines connected at any given time.

Especially in these instances, it is beneficial to install a sensor to measure the dust extraction pressure in the compression zone or dust extraction main duct and to maintain this indicator at an optimal level that ensures extended operation and minimal material losses. Many modern tablet presses offer an integrated system that includes a pressure sensor that monitors dust extraction and allows control of a motorized damper for consistent, optimized dust extraction volume independent of factors elsewhere in the plant.

In-process losses also can come from tablets rejected by the control system over the course of the batch. Most advanced control systems include an automatic tablet rejection capability permitting single tablets, or a group of tablets, to be rejected based on compression force. Individual compression forces that violate preset upper and lower limits allow tablets to be rejected across the speed range of the machine. In general, these systems are intended to identify and reject outliers associated with a poor die filling or overfilling of the dies with fines.

If the tablet rejection system is working constantly, then the process is clearly not in control and adjustments to the machine setup, including a reduction in press speed, may be warranted. Most single-tablet rejection systems

Typical turret options for a modern, single-sided rotary press

Per the various press tool standards, it is critical to understand that the EU/TSM B, the EU/ SM BB and the EU/TSM BBS press tools are identical – only the die diameters are progressively smaller. With identical upper and lower punch tool geometry, the compression dwell time is equivalent at the same press speed for these tool sizes. The feeder dwell time is also the same, since the punch is traveling at the same linear speed across the same feeder opening.

For example, a 10 mm diameter tablet running on a TSM B turret with 35-stations at 80 RPM will produce 168,000 tablets per hour. If the same tablet is produced at the same press speed with a 47-station TSM BBS turret, the output becomes 225,600 tablets per hour, an increase of 34 percent. The ROI on the additional turret and transport cart is then a simple calculation – and typically well worth it.

Turret specification	Number of stations	Maximum tablet diameter
EU or TSM D	29	25 mm
EU or TSM B	35	16 mm
EU or TSM BB	44	13 mm
EU or TSM BBS	47	11 mm

are complemented by an electronic audit trail capability that tracks the number and source (punch station) of the tablets being rejected. Excessive rejects from the same punch station can point to a problem with the press tooling — such as picking, sticking or damage to the face of the tool — that can be resolved by replacing the affected punch station.

Sampling losses occur based on sample size and frequency. Certain advanced presses offer the capability to sample on demand from the HMI, which, based on press speed, will provide a sample of the appropriate size with minimal losses. Sampling to an automated tablet tester for tablet weight, thickness and hardness measurement can automate the sampling process, but is unlikely to have any material impact on the magnitude of sampling losses, which are typically very minor.

Most advanced presses have a low material level sensor that will stop the machine when the material is almost empty; typically, there is material remaining in the feed pipe above the feeder. Depending on the volume of the feeder and the geometry of the feed pipe, some machines offer the ability to override the low material level sensor and run the press under automatic control, producing an incremental quantity of good tablets for as long as the remaining material quantity will support. In this case, the low average compression force alarm will eventually stop the machine before any reject tablets are produced. For exceedingly small tablets, the incremental quantity of good product produced after the initial low-level alarm can be considerable, adding favorably to overall production yield.

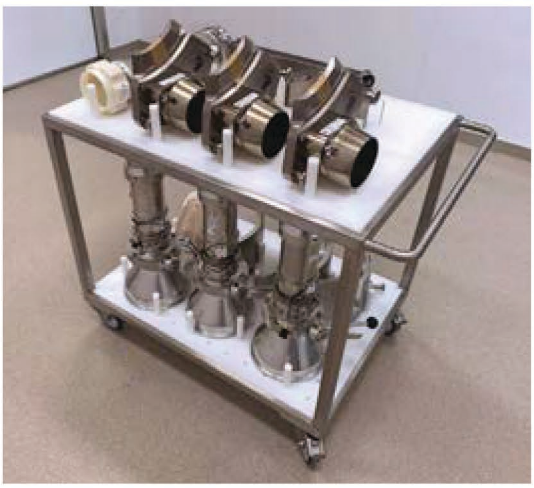
Increasing production uptime

To provide the basis for uptime improvement, it is first necessary to understand the sources of downtime. Most advanced production control systems are equipped with electronic audit trails that track both machine adjustments (event log) and machine diagnostics (alarm log). An analysis of the alarm log will permit an assessment of those faults causing the machine to stop, such as punch tightness or violation of press force limits. Analyzing the faults' frequency offers an opportunity to execute a remediation plan. For example, frequent machine stops due to punch tightness may be resolved by increasing lubrication to the upper or lower punches — a simple adjustment made via HMI.

The review of machine alarms can be complemented by an understanding of what adjustments are being made to the machine by the operator over the course of the batch, which is generally captured in the event log. The event log provides a time-stamped log of all machine adjustments and includes the operator of record, the before value and after value for each parameter. In some cases, incorrect adjustments might be occurring that make the process unstable — or that result in faults causing machine stoppage. When reviewed together, the alarm and event logs can provide insight into what is happening at all times, and can identify training deficiencies and remedial actions that have a dramatic impact on overall efficiency.

Once the batch is finished, there is a major emphasis on changeover time. To start, the cleaning and changeover requirements must be carefully defined. For example, producing the same product at varying strengths may require a different procedural approach than switching to a completely different product and active material. In general, the changeover sequence for a tablet press includes the removal of all product contact parts, the removal of the press tooling, and the cleaning of the press and related peripherals, followed by the installation of new press tools and clean product contact parts. For some machines, this process can take eight hours or longer; however, there are several practical ways to reduce this changeover time.

First, the use of uniform change procedure, and a cart specifically designed to house the product contact parts, can ensure a streamlined and consistent procedure to remove the parts in the proper sequence and place them in a repeatable position. The procedure is then reversed when installing the clean product contact parts back in the press, complete with a regimented SOP, sequence and on-cart part position. To reduce overall change times, some companies employ the use of a second



The KORSCH XL 400 Tablet Press parts cart facilitates a repeatable and fast changeover process.

set of product contact parts, which is cleaned off-line and available immediately when the next batch is finished.

Further, the manual removal and installation of press tools in a turret mounted in the press can be eliminated with the use of an additional turret strategy. Not only can the turret for the next product be tooled off-line (while the press is in operation), the turret configuration can be adapted to the tablet size to maximize production output. Leveraging an additional turret strategy in combination with a second set of product contact parts and a regimented, streamlined change procedure can reduce overall changeover time by 50 percent and condense the process to something less than three to four hours.

Time, of course, is product: More efficient changeovers have an immediate and substantial impact on overall equipment efficiency.

Strategies for semi-attended operation

While leveraging the latest in tablet press automation can certainly present opportunities for improved operational efficiency, this back-to-basics approach should be considered the first course of action. Automation strategies can support a plan to move to semi-attended operation, where a single operator can monitor and operate a number of tablet presses concurrently. First, most advanced control systems permit a configuration where a second HMI may be mounted outside the compression suite, eliminating the need for operators to be present in the room at all times. It is possible to populate a single HMI with a control system overview of multiple machines, allowing the operator to monitor the process remotely on one or multiple machines from outside the compression suite.

Most high-speed tablet compression suites utilize a post hoist, mezzanine or feeding from a second floor, and there is no manual scooping of material into a product hopper. This means that material is fed consistently to the tablet press and no operator intervention is required, at least until a drum or IBC change is required.

In many applications, a full-time operator presence is required in the room to monitor tablet collection and manually replace full containers to permit the press to run continuously. Most modern deduster and metal check combination units offer a lifting height and a tablet diverter that supports the automated feeding of a large IBC or multiple, smaller containers based on a preset tablet count. Based on the container size, these systems can eliminate the need for the operator to manually manipulate collection containers over a period of several hours; and if the operator is not back in time, the press will simply stop when the last container is filled.

More efficient changeovers have an immediate and substantial impact on overall equipment efficiency.

Another opportunity to achieve semi-attended production is through the integration of an inline tablet tester, which will measure tablet weight, thickness, and hardness of individual tablets at preset intervals, and provide closed loop feedback to the press force control system to keep the process centered on the tablet weight target. In most applications, the values for thickness and hardness are monitored without closed loop feedback, and the press will be stopped if the corresponding average or single value limits for tablet thickness and hardness are violated. Tablets are generally conveyed from the discharge chute by gravity or a venturi system, in which a stream of air is used to transport the tablets to a collection hopper on the tablet tester. The key limitations of these systems are the capital investment required and the ability of automated testers to properly align every tablet shape and size in a repeatable fashion for consistent hardness measurement. While significant advances have been made regarding alignment capability, certain elaborate tablet shapes still present challenges.

In general, a tablet compression system that can manage tablet collection and periodic sampling with closed loop feedback opens the door for semi-attended operation, in which a single operator can oversee and monitor the operation of multiple tablet presses concurrently.

An objective assessment of any tablet press' production efficiency will, in most cases, identify opportunities for improvement and focus on the fundamentals of maximizing output, minimizing product losses, and streamlining changeover times. For most, transitioning to a semi-attended capability is a secondary consideration, once the foundation for high operational efficiency has been established. In cases where existing tablet press technology is especially old, the analysis may conclude that a single, advanced tablet press — one in which output and uptime may be maximized through the active use of multiple turrets and that offers the inherent flexibility to produce single- and multi-layer tablets — can replace multiple older machines that lack sufficient flexibility or fast-change design.