

The Importance of Tooling Maintenance in the Production of Animal Solid Dose

The global animal medicine market reached a value of nearly \$42,469.3 million in 2019, having grown at a compound annual growth rate (CAGR) of 4.8% since 2015, and is expected to grow at a CAGR of 6.53% to nearly \$54,690.0 million by 2023. The market is expected to increase to \$62,005.7 million in 2025 at a CAGR of 6.48% and to \$85,059.4 million in 2030 at a CAGR of 6.53%.¹

This growing demand for animal medicine, and in particular solid dose form, is putting pressure on the manufacturers as they search for ways to produce tablets in the most productive manner through the use of innovative methods and resources. This can be extremely challenging for those in the manufacture of animal pharmaceuticals and nutraceuticals due to the abrasive nature of the formulations found within the tablets for animals. It is therefore important that the tooling used for production is maintained proficiently to help optimise the manufacturing process.

85% of tablet punch and die problems can be traced back to poor handling and aftercare procedures. This surprising figure highlights the importance of why correctly maintaining tablet tooling and ensuring they are in good working condition will not only reduce tablet press downtime, but also minimise prolific compression problems. Regular maintenance also increases the lifespan of the tooling, therefore, retaining the value and productivity of each set of punches and dies.

Poor Maintenance = Poor Tablets

There are many problems which are a result of badly maintained tooling from poor handling through to insignificant monitoring. One of the most common is sticking and picking. When in an optimum condition the surfaces of a tablet punch face are usually polished to a high mirror finish (the exception to this are textured finishes designed to alleviate specific sticking issues). This finish can deteriorate over a period of time due to the continuous compaction of granules. This deterioration can lead to tableting defects like sticking which occurs from the adhesion of the granule to the worn uneven finish. This degradation in the tool's surface can be identified during proper assessment and rectified by cleaning granule from the surface and through effective polishing. When required light polishing using an automated polishing system is recommended, this should enable a smooth and efficient surface to be maintained thus aiding the reduction of sticking and picking issues.

Another problem which is significantly high within the manufacture of tablets for animal health is wear due to the coarse nature of the formulation being compressed. Some ingredients can cause adverse effects on the punch tips, for example, certain granules are extremely hard and abrasive. These can scratch, wear and impregnate the steel surface. Other granules can contain corrosive elements which react with the steel. Demanding processes are applied throughout the manufacturing process and despite using hardened and tempered tool steel materials, tooling will be affected if not maintained regularly. This deterioration can lead to tableting

defects like sticking causing costly wastage, reduced product quantity and unwanted press downtime. This degradation in the tool's surface can be identified during proper assessment and rectified by cleaning granule from the surface and through polishing.

Handle with Care

Damage through handling, most often accidental, is another familiar problem when it comes to tooling defects and can lead to significant production failings. It is important to understand the delicate nature of the tooling and treat it with care.

There are several stages of the tablet manufacturing process where damage can take place, including unpacking the tooling, loading and unloading the tools in or out of the tablet press, during tool cleaning and maintenance procedures as well as through storage and transportation. If damage occurs it can lead to the production of poor-quality tablets, and even further damage to both the tooling and the tablet press. It is therefore important to implement and operate good tool care, maintenance, storage and handling procedures.

Die Bore Wear

Die bore wear or ringing is another defect that occur if maintenance processes are not put in place as standard procedure. Ringing is caused by abrasive wear and deformation from continuous forces acting on the face of the die bore. It can lead to problems such as tablet capping where the tablet separates horizontally from the main body causing tablet ejection issues resulting in reduced tablet output. This type of wear can be reduced by utilising the zones in the die bore where the tablet is compacted or by the selection of a harder more wear resistant die material. However, unless maintenance procedures are put in place where wear can be monitored and identified through early diagnosis and assessment measures, the negative effect on tablet output will increase.

Making the Match

Incompatibility between punches and the tablet press can often also cause damage to the punch heads. The punch heads are subjected to high cyclic loadings, and if they are running tight there will be resistance between the punch heads and the cams and rollers, increasing the high frictional force. This will lead to premature wearing and eventual fatigue and total breakdown of the tool material. The result is contamination in the tablet press due to metal particles, and expensive damage to tooling, press cams and compression rollers. This type of damage can be avoided by close monitoring of the tooling condition and good tooling and tablet press maintenance procedures.

Applying Consistent and Structured Maintenance Procedures

There are tried and tested processes that all tablet manufacturers should implement as a standard operating procedure (SOP) to ensure productivity per punch can be maximised more effectively to meet high-capacity manufacturing requirements and to help to alleviate production problems.

The '7 Step Process' is a logical, planned and professional approach to tooling maintenance and storage. This process has been adopted by many companies around the world and is used consistently to ensure punches and dies are clean, undamaged, within specification and ready for use at all times. The 7 steps include – clean, assess, repair, measure, polish, lubricate and store. These are designed to provide a consistent approach to tooling maintenance and aids production at all times.

Step 1 – Clean

The first and most critical stage in the 7-step maintenance process is to clean the tooling. Punch and die cleaning is essential for the removal of residue and to avoid product contamination. It also reduces potential production issues such as sticking. Cleaning also allows for an accurate assessment of tooling condition during further processes within any maintenance schedule. If the procedure is not carried out effectively it will have a negative impact on the subsequent steps in the maintenance process. For example, if punches are not adequately clean, visual assessment of the punch tips and die bores for signs of wear, damage or corrosion will be difficult. This can then lead to problems like die bore ringing.

Cleaning also helps to highlight damage to the delicate punch tip edges which are seen in the form of nicks and bruises which can cause burrs and occasionally chipping. These defects can eventually lead to more serious failures such as punch tip breakage.

When tooling is removed from the tablet press, it must be thoroughly cleaned to remove any oil or product residue, particularly from difficult to reach areas such as embossing and keyways. One of the most reliable cleaning methods to remove all deposits from the tablet tooling is through ultrasonic cleaning. Ultrasonic baths allow for consistent cleaning results, reduced processing and operator time and reduced risk of tablet contamination. Importantly, ultrasonic cleaning allows for the whole punch to be cleaned including in and around the embossing. It is essential, however, that the process does not cause corrosion of the tooling material therefore a corrosion inhibitor should be used during the process.

Step 2 – Assess

Punches and dies should be visually inspected to establish if the tablet production process is running well and to identify whether any tooling maintenance is required. Assessment



can be carried out visually using an eye glass or a high magnification camera/lens. Close up inspection of the punch tips and cups, die bores, embossing and land will help to identify defects and wear.

One typical problem that can be identified through this step is head wear. This is when areas of a punch that are in contact with other parts of the tablet press and are subjected to high speed frictional and compaction forces resulting in excessive wear. It can derive through a number of causes, but more commonly it is due to punch tightness and/or poor lubrication.

It is important to remember that identifying damage off the tablet press is by far a more efficient method when it comes to time and capital than running tablet production with faulty tooling, hence, step 2 – assess is crucial.

Step 3 – Repair

Step 3 is the repair stage. This allows the user to rectify minor damage to the tooling. Tooling that has experienced light surface wear, corrosion, and minor damage, can be manipulated and repaired back to a useable condition. Equipment such as a motorized chuck and double ended polishing motor are used together with abrasive polishing accessories. However, it is vital that the repair is accurately and extensively completed by skilled technicians to ensure that the tooling does not exceed tolerance limits. Importantly, repair should not be carried out on coated tooling as this may remove the surface treatment from the punch.

Step 4 – Measure

This step is essential after any repair. Critical tooling dimensions must be maintained within an acceptable working tolerance range to ensure accuracy and quality throughout the manufacturing process.

The equipment for measuring tablet tooling can range from simple handheld micrometers, vernier callipers and height gauges, to semi-automatic, computerised digital gauging systems. The use of digital measurement systems allows for dimensions to be taken consistently, reducing the risk of manual data entry errors.



Even if a repair has not been necessary, measuring should be carried out at regular intervals, to check for natural wear during the compaction process. The essential measurement is the critical working length of the punch, as this controls tablet thickness, weight and ultimately dosage. Importantly, as the punches are already clean and assessed, outside influences to measurement such as oil or compacted granule will not interfere with measurement data.

Step 5 – Polish

Good cleaning is essential to maintain good tooling, but so too is the implementation of an effective polishing regime. It is cleaning and polishing that delivers the most noticeable benefit in production, reducing tablet press down time and helping to increase productivity.

Polishing tooling is extremely important and should not be underestimated. Automated polishing is crucial to ensure punches are evenly polished to a consistent finish. This stage also helps to produce the optimum and consistent tooling condition. By following this step, costly tablet press downtime caused through poorly maintained tool surfaces will be reduced.

Polishing can be achieved through manual or automated methods but due to the controlled and repeatable process, adoption of an automated polishing regime would always be preferable as all punches are polished to a uniform finish. Manual polishing can be unevenly abrasive and extra care must be taken not to deform the tip profile and embossing causing a deviation from the tablet specification. Extensive



polishing of die bores is not recommended as this can easily alter the size and geometry of the bore leading to ejection problems and incorrect tablet size, weight and dosage. Only light polishing or cleaning should be undertaken, with the end result should be a mirror finish and smooth tooling surface.

Step 6 – Lubrication

Lubrication is necessary as it serves to protect, preserve and support continuous press tooling operations. For lubrication purposes, a non-toxic, FDA-compliant oil or grease is recommended. Choose a product that offers machine component protection and lubrication performance with a wide temperature range, to ensure it can be used in all machines.

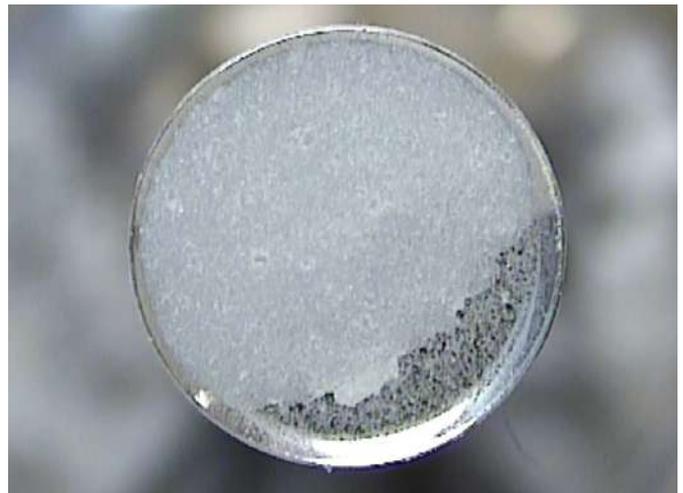
Step 7 – Store

The final step and one not to be underestimated in its importance is storage. Tooling storage and transportation should be specifically designed and developed with high security and safety handling considerations a priority as this reduces the probability of damage and deterioration.

There are many methods for storing punches and dies, from specially designed plastic storage boxes to custom designed and built storage cabinets all of which provide high levels of protection.

The tooling itself must be separated to ensure it avoids contacts with other punches and so that the tooling condition does not deteriorate during storage. Due to the nature and weight of tablet tooling, storage should also ensure safe handling for operators, and so tools should only be moved when necessary.

It is important to maintain longevity and extract the maximum life from tablet tooling. Following a consistent 7 step process will aid in this ideal to ensure punches and dies are always ready for production. This will have a direct impact on the reduction of many common tablet and tooling problems, resulting in a better quality end product and direct time and cost savings for the tablet manufacturer.



Tool Management

To establish compliant, efficient and accurate maintenance of punches and dies, it is important to also implement an in-depth computer-based monitoring system. This will ensure quality specifications are met and regulatory standards are adhered to. Crucially, manufacturers should have a complete audit trail covering tooling usage and maintenance which a tool management system can fulfil. This is not only good practice but an important regulatory requirement in the majority of pharmaceutical environments.

A tool management system is not just important for maintenance history as it keeps track of tooling inventory, but it also supports regulatory procedures and complies with legal requirements in tablet production. The data can also provide information to effectively measure areas of performance by way of showing what and how many products have been produced and a summary of any production issues experienced. Overall it ensures that tooling is never a cause for delay in the production schedule.

Keeping tooling in check is essential to efficient, cost-effective tablet production. Through a logical planned 7-step maintenance process, and the incorporation of an advanced tooling management system, tablet production will be optimised and regulatory and quality standards will be met. This will help manufacturers to meet the growing demand for solid dose forms within animal health.

REFERENCE

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