Don’t Forget Your Coat
How the Correct Tablet Tool Treatment Can Help to Increase Production

There are several methods to administer medication to animals, with the oral route of delivery often used in livestock, cattle and companion animals. The popularity of solid dosage forms and its associated high production volumes brings with it manufacturing problems. Here we look at how selecting the correct tablet tool coating can have a huge impact on efficient tablet manufacture.

Tablets used in animal health ‘consist of one or more active ingredients and numerous excipients which can be a conventional tablet that is swallowed whole, a chewable tablet, or a modified-release tablet or bolus. Conventional and chewable tablets are used to administer drugs to dogs and cats, whereas modified-release boluses are administered to cattle, sheep, and goats. The physical and chemical stability of tablets is generally better than that of liquid dosage forms making them a popular choice.

Solid dose manufacturers are under pressure to make production more cost-effective. It needs to be quicker, more effective and able to keep in line with competition from developing markets, and for these reasons it is important to have the right ‘tools’ for the job.

Specialised punch and die coatings can have a huge impact on the efficiency of tablet manufacture. With the correct coating or treatment in place, some of the biggest challenges that can delay production like corrosion, wear and sticking issues can be prevented.

Coating technology has advanced significantly over the years, and when used in conjunction with high quality tooling steel, tool coatings are increasingly seen as an acceptable means of solving production problems. They allow for better tabletting efficiency and output by reducing the requirement for tools to be taken out of production for additional cleaning and maintenance work to remove problematic residue which, if left untreated, may cause potential production issues.

Making the Right Choice
When choosing a tool coating, it is important to understand the product being compressed and the formulation’s characteristics. Some formulations can be exceptionally abrasive. This can be a major problem in tabletting operations, particularly when compressing ingredients containing high quantities of hard, abrasive, sharp-edged elements that can scrape away or penetrate the surface of the tool when repeatedly compressed. That abrasion can erode the punch tip’s detail, such as logo embossing and other identification. Eventually, the wear can lead to tablet weight variation, sticking, and other issues, prompting scrappage of the punch and die set.

When producing solid dose formulations containing abrasive components, the use of coatings can significantly cut tool wear, resulting in less punch cleaning and repolishing and therefore lowering down-time. There is a tool coating to suit every requirement, whether that is reducing wear and corrosion or preventing sticking.

Tablet tooling experts can offer advice on the best tool coating to overcome specific production challenges with the application of researched and practised models. These calculate what tool coating is required for a formulation. An example of this is the I Holland TSAR Predict (Tabletting Science Anti-stick Research) model. By combining and contrasting data on a range of parameters including surface chemistry, temperature and humidity, it calculates what tool coating is necessary to stop the ‘sticking’ issue. Applying the model stops the need to carry out expensive and time-consuming production trials with a variety of coated punches to find the correct fit.

Traditional vs Modern Coating
The most common coating for tablet tooling is hard chromium, primarily because it is an inexpensive treatment which can have satisfactory resistance to corrosion and wear. This traditional coating is recently being questioned as it has been proved to have numerous disadvantages when compared to more advanced solutions.

The main problem with hard chromium coating is microcracking. This arises during the plating process when the internal stress exceeds the tensile strength of the chromium, which is hard but brittle. Micro-cracks provide a porous route to the substrate that will, over time, allow aggressive tablet formulas or cleaning solutions to damage the steel beneath the coating, decreasing the tool’s strength.

Just applying a hard chromium coating can reduce tooling strength as it can cause hydrogen-embrittlement. This is where hydrogen atoms diffuse into the microstructure of a metal, causing it to become brittle, resulting in sudden and unpredictable fracture. When it is applied to tooling, a proportion of hydrogen penetrates the substrate, which can decrease the steel’s working load by up to 20%, making it weak and prone to unpredictable fracture. To counter this effect, the plated tools undergo a baking process known as de-embrittlement that reduces, but does not totally eradicate, this unwanted characteristic.

Another drawback is its hardness rating. When comparing hard chromium to more advanced coatings like
chromium nitride (CrN) it has a very low hardness rating when measured on the Vickers scale. Hard chromium measures just 900 Hv compared to CrN, which doubles this number with a hardness rating of up to 2000 Hv.

If that is not enough of a disadvantage to push manufacturers to using a newer alternative, then the environmental implications may do. Although hard chrome in itself is not an eco-hazard, there are environmental problems associated with the plating procedure. The main cause of concern is the chromic acid solution used during the process. This generates a carcinogenic waste product containing hexavalent chromium. This has significant implications on worker safety and is strictly controlled by regulators like the European REACH (Registration, Evaluation, Authorisation and restriction of Chemicals) control.

Waste produced from the hexavalent chromium bath is hazardous and must be treated prior to disposal. Regulators like REACH have strict rules on how such a substance is handled. Chromic acid has been added as a substance of very high concern, which requires authorisation in order to continue its supply and use for specific applications. Restrictions like this will only become more stringent with time as regulatory bodies tighten their policies, making the process even more difficult.

With so many disadvantages surrounding hard chromium, tool manufacturers have developed innovative alternatives which address the issues of tooling strength, hardness rating and safety and environmental implications.

**How Does the Coat Get Applied?**

Apart from electro-plating, there are two physical vapour deposition (PVD) processes used to apply coatings to tooling, including ion beam deposition (E Beam) and arc physical vapour deposition (aPVD).

PVD is a method in which a metal vapour is created that can be reacted with different gases forming a thin film coating. The most common process in PVD is ARC deposition (aPVD). Traditionally, an advanced coating like chromium nitride (CrN) is applied using the ARC method. During this process, droplets are created while vapourising the target material with an ARC (target is pure chromium in the case of CrN). These droplets, together with the particles of chromium, are attracted towards the punch and deposited onto the surface. The droplets are then removed from the punch face either during polishing or production, which leaves holes in the surface and can cause sticking and reduce the punch’s corrosion resistance. Because of its unreliability, leading tooling manufacturers are leaning toward the E Beam technique.

E Beam Deposition is when atomised material is evaporated by an Ion Beam instead of an ARC like standard PVD. When applying a coating like chromium nitride, the technology uses a high energy E Beam to vapourise the target material and deposit it on to the tablet tooling without the troublesome droplets being formed and deposited.

Some PVD processes can be performed at lower temperatures, therefore not affecting the tooling material, unlike aPVD. These improved methods give a smoother finish than the ARC process and do not cause droplets to form on the surface of the tablet tooling, improving its anti-stick performance. Coating that can be applied through this technique includes chrome, chromium nitride, and titanium nitride.

**Moisture and its Influence on Coatings**

Unless the process of tablet production takes place in a controlled environment, influences like humidity have a huge impact. It is therefore important to choose the correct tool coating and steel type to combat any varying circumstances.

One of the main root causes of sticking is capillary bridges forming on the surface of the punch tip. This can be created by high relative humidity or high moisture content in the formulation itself.

Every formulation has different characteristics with variable moisture content. This is often needed to help the binding, or compaction effect, but too much fluid within the tablet can be one of the causes of a rise in adhesive forces and thus sticking. Moisture can enter the production process either in wet granulation, or due to excess humidity in the compression chamber and formulation preparation and storage areas if they are not temperature- and humidity-controlled.

Applying an anti-stick coating which attracts less moisture will help in this instance. It is important to also consider coatings and steels that offer good corrosion resistance to alleviate the effect of excess moisture.

Certain constituents of the formulation can contain corrosive elements such as chlorine, salts and acids which will react with the tooling surfaces and result in oxidation. In addition, wash in place systems fitted to some modern tablet presses expose tooling to water and cleaning solutions therefore they require tooling to have good corrosion-resistant properties.

Post-compression cleaning procedures can also cause corrosion if not controlled sufficiently. Corrosion can appear as discolouration, etching or common red rust. To combat this issue, a corrosion-resistant material can be selected; however, standard stainless-steel types are not suitable due to the lack of hardness and wear resistance. Therefore, specialised Martensitic stainless steels with high chromium content should be used. Applying hard coatings with corrosion-resistant properties such as chromium nitride will also help in this instance.

**Make Sure the Coat Fits**

Manufacturing solid-dose animal medication in a timely, economical and efficient manner can be a complex and problematic procedure. There are many considerations and measures that must be put in place for it to be achieved successfully. To deliver the correct quantity of
MANUFACTURING

Issues You Might Encounter

Every ingredient, in each tablet, to the animal requires the assurance that the final product is one which is of a high standard. This is where choosing the correct tooling comes into its own. By selecting the right quality punches and dies, problems during manufacture can be prevented. Tool coating is just one part of the puzzle to successful tablet manufacture, although it is a significant one.

Tablet tooling must combine intricate design and functional requirements to ensure productivity and durability are at their maximum in manufacture. To follow this important process, tool coatings offer a solution to tablet punch and die wear and solve sticking issues. It is important to remember that punches and dies are the most critical interface with the tablet, so using the correct material and coating is crucial. Working closely with a tablet tooling expert will help you to determine what coating you should be using for a particular formulation and guarantee there are no production problems.

Adoption of the 7 Step Process Helps to Maintain Tablet Tooling

Although incorrect tool coating has a huge impact on the efficiency of tablet manufacture, there are many other factors which can contribute. Tablet tooling failures are generally the result of one or a combination of issues, which can include:

- Difficult product/granule
- Inappropriate tablet design
- Incorrect tablet press set up and operation
- Inadequate tablet press maintenance
- Poor condition of tablet tooling

The I Holland PharmaCare® 7 Step process is a logical, planned, and professional approach to tooling maintenance, measuring and storage that has been adopted by many companies around the world as a standard operating procedure (SOP). The process includes seven steps; Clean, Assess, Repair, Measure, Polish, Lubricate and Store; designed to help users extract the maximum life from tablet tooling. Having a coordinated
tooling SOP ensures punches and dies are ready for production, with the assurance that they are clean, undamaged and within specification.

Step 1
CLEAN:
Step 1, Clean is the most critical part of the process. Punch and die cleaning is essential for the removal of residue and to avoid product contamination and potential production issues such as sticking and picking. If cleaning is not carried out effectively then it will have a knock-on effect on the other steps in the process.

When tooling is removed from the tablet press, it should be thoroughly cleaned to remove any oil or product residue, especially from difficult to reach areas such as embossing and keyways etc. Equipment used for this process would include ultrasonic cleaning and automated washing processes; however, it is essential that the process does not cause corrosion of the tooling material and to that end, a corrosion inhibitor should be used.

Step 2
ASSESS:
Punches and dies should be visually inspected to establish if the tablet production process is running well and identify whether any tooling maintenance is required. This assessment should also be carried out under magnification for any signs of damage, wear or corrosion, and to validate the cleaning process.

Typical equipment that should be used during assessment includes high magnification lenses and microscopes. Due to the high mirror finish of tablet tooling, it has been especially developed for the close inspection of punch tips and tablets. Any system that is used should be precise and give a clear high-quality image that can be used to identify any problems.

Step 3
REPAIR:
Light surface wear, corrosion and minor damage on tooling can be repaired and re-worked to a useable condition. Equipment such as a motorised chuck and double-ended polishing motors are used in conjunction with abrasive polishing accessories. Repair should be carried out by well-trained and experienced maintenance technicians in order to ensure that the tooling does not exceed tolerance limits. Repair should not be carried out on any coated tooling as this may remove the coating from the punch.

Step 4
MEASURE:
Measuring is essential after repair to ensure that critical tooling dimensions have been maintained within an acceptable working tolerance. The equipment for measuring can range from simple hand-held micrometers, to computerised digital gauging systems. These can inspect the condition of die bores, ensuring that optimum life is achieved from the dies to prevent the production of damaged tablets.

Measuring should be carried out at regular intervals even if repair has not been necessary, 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.

Step 5
POLISH:
Automated polishing is an integral part of this 7 Step Process and will maximise trouble-free tablet production by helping to keep tooling in optimum condition.

With today’s modern tooling often being supplied with coatings, automated polishing is essential to ensure punches are evenly polished to a consistent finish, so these coatings are not removed prematurely. Automated polishing ensures optimum and consistent tooling condition for maximum productivity, reduced sticking, and saved labour costs in terms of time spent on polishing. Manual polishing using polishing pastes with a motorised chuck or double-ended motor may be considered as remedial action.

Step 6
LUBRICATE:
Lubrication is important to protect, preserve and aid smooth operation of the tooling. A range of oils and greases can be recommended for different applications such as preservatives or for lubrication purposes.

Step 7
STORE:
Tooling storage and transportation should be specifically designed to maximise security and safe handling to minimise damage and deterioration. There are different means of safely and securely storing tablet tooling. Whichever system is adopted, it is important that the tooling is separated to avoid contact and so that the tooling condition will not deteriorate during storage.

REFERENCES

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