

Overcoming Problematic Production Issues in the Manufacture of Animal Nutraceuticals

The importance of wellness has been brought to the forefront during the coronavirus pandemic and nutraceuticals have played an important role in this. Nutraceuticals have taken even more of a centre stage as consumers consider ways to stay healthy turning to supplements with natural health benefits. Animal supplements are also seeing ongoing growth as owners look to treat pets as part of the family. This mindset has not wavered during the onslaught of COVID-19 with reports showing that animal nutraceutical supplements are as important as ever.

According to the research study by Facts and Factors, the global pet supplements market was estimated at USD 637.6 million in 2019 and is expected to reach USD 1023.8 million by 2026. The global pet supplements market is expected to grow at a compound annual growth rate of 7% from 2020 to 2027¹.

To meet this demand, developing solid-dose veterinary nutraceuticals and pet supplements into a formulation that can be successfully compressed in a modern tablet press at high speed can be challenging, time-consuming and expensive. It differs from producing veterinary pharmaceutical tablets simply because of the formulas used in vitamin, mineral and food supplement (VMS) production.

In the pharmaceutical industry, one of the main difficulties most tablet producers experience is sticking of granule to the punch tip face. The ingredients in these formulations are very often synthetic and are formulated to aid compression, containing ingredients that help bind the tablet, having little impact on the tooling. VMS, however, in their natural state, can be difficult to compress as they can contain many high percentages of active ingredients which make production problematic.

Multivitamin formulas can contain up to 50 active ingredients and two to eight excipients including coating ingredients. Pharmaceutical formulations usually contain one to four active ingredients and five to six excipients. Due to the high number of active ingredients in nutraceutical formulations, more consideration is required because of the characteristics of the formula. Problems related to particle size, flow, compressibility, moisture sensitivity, ingredient interaction, content uniformity and quality control testing can occur.

Some active ingredients may be available in granular form, and others only in fine powder form. Some may be hydrophilic and others hydrophobic. Because of this, the ingredient blend may have many different particle sizes with a variety of features, including being extremely abrasive and corrosive, resulting in damage to the tooling used during manufacture.

Ingredient blends can also have separation and flow issues. Tablet production from these blends can result in capping, sticking and different patterns on the faces of tablets during compression, as well as basic content uniformity problems.

Tablet punches and dies are the main components that interface with the powders and granules, so have to be robust both metallurgically and in terms of design to withstand the rigours of compacting nutraceuticals. VMS tablets for animals tend to be quite large and bulky when compared with pharmaceutical tablets. They often require high compaction forces to bond the ingredients into a robust tablet, and the tableting equipment is usually run at high speeds for long periods of time to satisfy the industry's requirement for high output and low cost.

Choosing the Correct Tool Steel to Withstand the Demand

Nutraceutical formulations are well known for their coarse granule. This brings with it wear and degradation of the tooling, which leads to other tableting problems; for example, adherence of the granules due to pitted and worn surfaces of the punches, and also capping or lamination of the tablets, all of which will prove costly for the manufacturer.

The answer is to ensure the correct tool selection is made. This means the appropriate tool steel and the right coating for the aggressive formulation which requires compression. Choosing the correct tool material will help to reduce the probability of damage to the punches and dies.

Because of the aggressive nature of the ingredients, the properties of materials are extremely important, and must be balanced to give optimum tooling performance and durability. Tooling needs to be anti-abrasive and wear- and corrosion-resistant, and include compressive strength and resistance to chipping and cracking.

There are many tool steels available, some of which have been specifically designed for nutraceutical compression, and include high carbon, high chrome, cold work tool steels. A common choice when it comes to nutraceutical production is tungsten carbide. This material has high hardness values and specific structures which abrade at a much lower rate, making it extremely wear-resistant. This helps to reduce die bore wear and ringing, and extend the life of tablet compression tooling.

Another option is to use specialised powder metallurgy grade steels. These offer uniform carbide distribution and small carbide size, making them particularly resistant to high wear. Although wear-resistance has to be the number one consideration due to the characteristics of natural formulations, it is also important that steel can withstand an applied stress without failure. Also think about its hardness; does it have enough resistance to impregnation from hard, sharp granules? Is it corrosion-resistant to lessen the chance of oxidising, staining and discoloration, common effects of nutraceutical formulations? Is it tough enough to stop chipping, cracking and punch tip breakage? These are all questions that need to be answered. The best way to find the solution is with the help of an experienced tablet tooling manufacturer who understands the issues and has a comprehensive offering of materials to eliminate common problems.

Improve Wear with Tool Coatings

If the selection of a more wear-resistant steel alone is not sufficient for the rigours of nutraceutical tablet production, then

an enhanced wear-resistant coating should be applied to the tooling. Coating that will improve the hardness of the tooling is extremely important in nutraceutical manufacture. The ingredients used have such high quantities of hard, abrasive, sharp-edged minerals that when repeatedly compressed can scrape away or penetrate the surface of the tool. The abrasion can lead to the erosion of punch tip detail such as logo embossing and other identification specifications. Eventually this wear can lead to weight variation, sticking and other issues, resulting in the scrapping of the punch.

Traditionally, electro-plated hard chromium was the most popular coating used within the tablet tooling industry, but it has many disadvantages. When hard chromium is applied to tooling, a certain amount of hydrogen penetrates the substrate, which can decrease the steel's working load by up to 20%. To counter this effect, the plated tools undergo a baking process known as de-embrittlement that reduces, but does not totally eliminate, the unwanted characteristic. It is also subject to micro-cracks which can develop during the plating process when the internal stress exceeds the tensile strength of the chromium. These micro-cracks are problematic because they provide a porous route to the substrate that will allow tablet formulas or cleaning solutions to attack the steel beneath.

Specialised coatings have been developed which are chromium-rich and applied via an advanced physical vapour deposition (PVD) process. This advanced PVD process creates a very smooth dense anti-stick coating. This process incurs none of the drawbacks associated with applying hard chrome.

Another benefit of using an enhanced coating is its corrosion-resistance. Some formulations can contain a high number of corrosive elements, for example, salts and acids, which react with the steel and eventually result in oxidation and other forms of decay. Corrosion can also present through wash treatments. Some modern tablet presses are fitted with wash in place systems, exposing tooling to water and cleaning solutions, causing corrosion. In these instances, an appropriate coating should be selected; for example, those containing chromium or titanium nitride, both of which contain corrosion-resistant properties.

Finding a coating that will enhance a tablet tool's ability to be highly wear-resistant and strong, and withstand corrosive elements, is crucial. The tool coating should match the characteristics of the formulation to ensure the correct treatment is used for tool longevity and to lessen production problems.

Design Your Tablet to Meet Requirements

Design is another extremely important consideration in the manufacture of nutraceuticals, just as it is in pharmaceutical production. Correctly designed tablets can impact upon anti-counterfeiting, tooling strength, coating of tablets, durability and functionality. It also helps avoid tablet sticking, picking, lamination, capping or premature tooling failures. Ensuring design is correct early in the production process will help in producing a quality problem-free end product.

The tablet design can help in minimising the susceptibility to tablet tooling wear. Tablet designs where the tool profile requires a deep concave can often cause wear around the steepest areas of the concave when compressing abrasive formulations. During the compression stage, the granule has to travel laterally across this area to form the tablet. This will cause friction, which abrades the punch tip face, removing material over time. This can often lead to tableting issues such as capping and delamination, as the tip design's integrity

in this area is compromised and 'crowning' can occur. To reduce this effect, a flatter tablet profile, or one that has been specially designed to reduce the effects of abrasive wear, should be used.

The process is something that should not be rushed; it needs to be well thought out and considered, as good tablet design is essential to prevent downstream problems, produce high quality tablets and maximise the efficiency of the tableting process, a necessity when looking to mass-produce animal nutraceuticals.

Put a Plan in Place

A big obstacle when it comes to insufficient production, and one that should be overcome early, is poor planning.

It is all very well having production goals but how do you manage your tooling to ensure it is available when required and they work seamlessly? The answer is through the implementation of a planned and professional maintenance process to manage tablet punches and dies.

A maintenance process will help to extract the maximum life from tablet tooling through a consistent and accurate approach. Using a clear, comprehensive and effective strategy helps to reduce many of the common tablet and tooling problems that can occur when manufacturing nutraceuticals. This results in better quality tableting, and reduced tablet press downtime, improving profitability through planned professional maintenance processes.

Modern tablet production requires increased capacity, flexibility, speed of response and robust traceability, with the core objective of maximised press uptime. What was once monitored through simple manual methods is not enough in the current culture of 'high volume' tightly controlled and audited tablet production.

Many nutraceutical tablet manufacturers have the philosophy that tooling should be treated as a consumable item to be written off and thrown away. However, through the development of computer-based monitoring systems, this way of thinking is changing and productivity per punch can be maximised far more effectively to meet high-capacity manufacturing requirements.

Knowing where tools are, and what condition they are in, should be a priority. Without this information, either unnecessary tooling replacements are made, reducing productivity, or punches are deployed when they should be in maintenance or replaced. The latter scenario produces problems with the end tablet when it is found that the tooling being used does not meet the highly demanding process of nutraceutical tablet manufacture. Rejected tablets, wasted formulation, very expensive press damage and press downtime are the usual results. In addition to this, not having a clear picture of tooling availability may lead to the loss of opportunities in a fast-moving and competitive nutraceutical environment.

Any problems within tool inventory management can have serious implications on the bottom line and manufacturers should have a complete audit trail covering tooling usage and maintenance. Without a robust management system that controls the procedure efficiently, the consequences will be costly.

Make the Right Choice

The development of animal nutraceutical products into a formulation that can be compressed in a modern tablet



Abraded punch tip



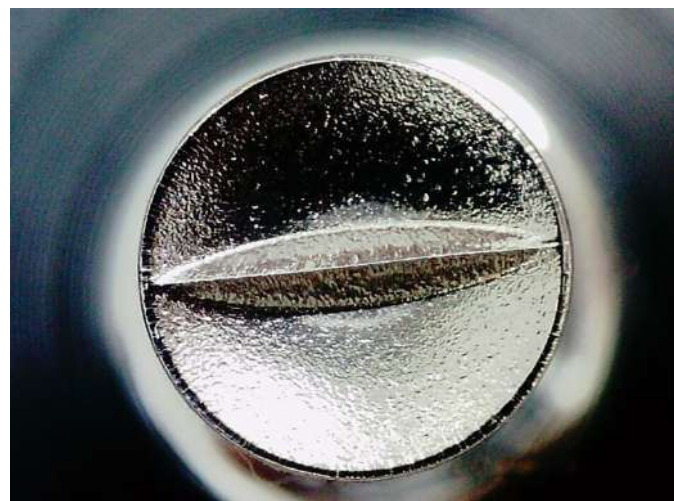
Supplements



Tip wear



Coatings



Punch tip face showing high level of abrasion

press to a tablet form, with both speed and quantity, can be a complex and problematic procedure. With certain considerations and measures in place, however, it can be achieved successfully.

As nutraceutical formulations nearly always have more actives present in a higher weight than pharmaceutical formulas, the room for excipients is restricted, making it harder to formulate. The formulations used within nutraceuticals are also usually coarse and corrosive in nature, another challenge to conquer. By choosing the right quality punches and dies using the correct metallurgy and coating, problems during manufacture can be prevented.

Detailed design of nutraceutical tablets is essential in order to produce robust tablets with tailor-made properties. Manufacturers of animal nutraceuticals should not overlook tablet design, because it is key to the quality of the end product. Let's also not forget to plan your tooling and ensure it is all present and correct and in the best possible shape

to ensure it can successfully produce the challenging formulation found within nutraceuticals. Don't let it be an afterthought.

It is important to consult with an expert tablet designer as early on in the process as possible, who can ensure that tablet designs are not only unique and visually appealing, but are also robust and producible in a rigorous tablet manufacturing environment. Specialist advice on tool materials and coating that match with the nutraceutical formulations being compressed is also extremely important and will save not just time, but also money, as production efficiency is increased and failures are reduced.

REFERENCES

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