NATOLI KNOWLEDGE

A Complete Guide for

NUTRA-TABLETING CHALLENGES

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Introduction

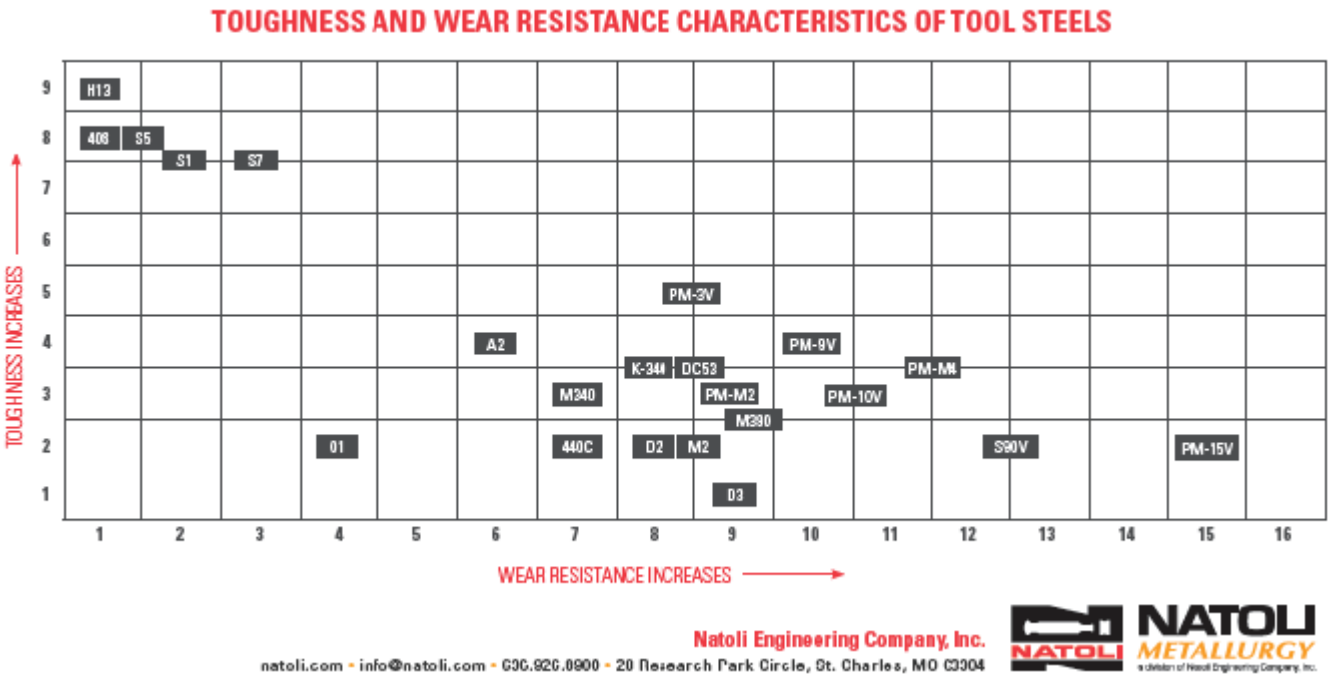
Tablet presses are used to manufacture a variety of products, such as pharmaceuticals, nutraceuticals, veterinarian products, confectionary, and industrial tablets. Each industry faces unique challenges due to the properties inherent to any particular formulation. A variety of steel types/coatings, tool design modifications/options, and tablet design recommendations can work together to increase tool life and improve tablet quality.

Abrasive Wear-Types and Issues

The most common challenge with nutraceutical products is abrasive wear on the tooling, due to the nature of many ingredients in nutraceutical tablets, such as calcium, magnesium and zinc. This abrasion leads to degradation of the cup finish, which may result in potential sticking and poor tablet quality.

Step 1: Use a Wear Resistant Grade Steel

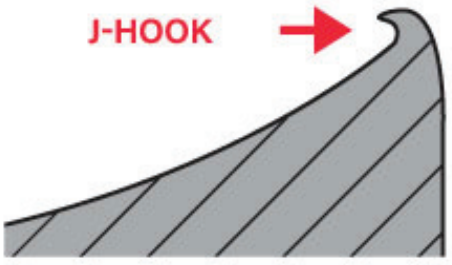
The usual first step to addressing this issue is to use a wear resistant grade tool steel. Common wear resistant steels for punches include D2, K340, DC-53, M2 and for extremely abrasive products, PM-3V, PM-9V and PM-10V. The alloy chemistry and increased hardness of these steels makes them more resistant to abrasion. However, wear resistant grades are unable to support higher compression force due to their lower impact toughness.



Caption: This chart is meant to be used as a guide to compare the relative wear resistance and impact toughness of various tool steels. Contact your tool vendor for additional guidance.

Abrasive Wear-Types and Issues (cont.)

Abrasion from the granulate can usually cause the land to erode, compromising the mechanical integrity of the punch tip and making it more susceptible to damage and fracture. This can lead to the formation of J-hook, resulting in capping, which can be addressed by utilizing a premium abrasion resistant grade steel mentioned above. However, this may only delay erosion of the land. There's an easy remedy to restore land with minimal time and equipment. A deburring stone, followed by a quick buffing, can be used to remove any J-hook and restore land, thus reestablishing the mechanical integrity of the tip.



Caption: Punch tip exhibiting J-hook (possible result of land erosion.)

Dies are also subject to abrasion. The abrasive nature of nutra-formulations combined with high compression forces often used for many nutra-products can lead to wear rings in dies. Wear rings can allow powder to extrude between the die wall and punch tips during compression, causing the edges of the punch tips to then become rounded, resulting in tablet flashing. This may also accelerate wear on the perimeter of the punch tip. Die wear rings can also cause excessive ejection forces, leading to pre-mature wear of the lower punch head and may cause accelerated head pitting.

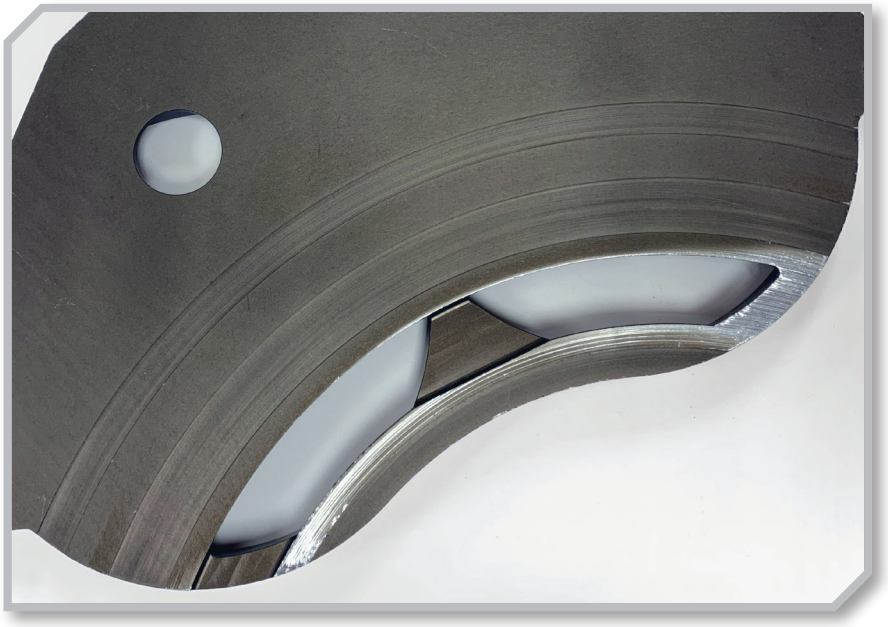
Caption: Sectioned die showing wear ring and associated punch tip wear which can result in tablet flashing.

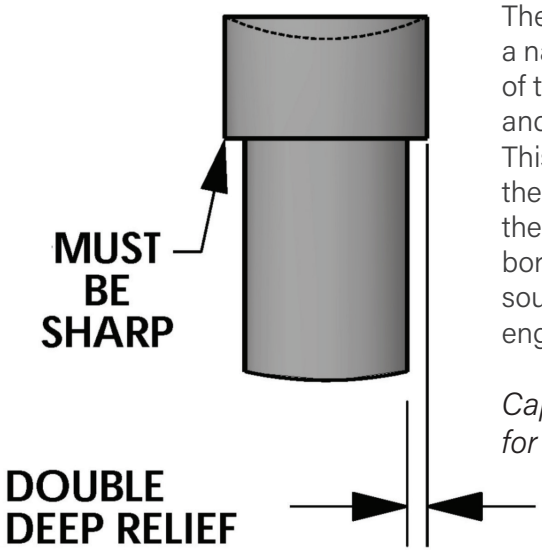
Dark Spots

Dark spots, or dark visual defects, aren't uncommon in tablet compression. However, there's a lot of causes as to why they occur. Dark spots on the faces, or even mixed throughout the tablet, can indicate excessive lubrication. An improperly set feeder pan can also cause dark spots.

Certain ingredients, such as magnesium, magnesium oxide and talc, have a propensity to scorch and turn dark when they reach a given temperature. Granules migrate between punch tips and dies, causing friction which generates heat. This turns the granules that are adhered to the die bore walls dark. Excessive heat can scorch the formulation, causing discoloration.

Caption: An improperly set feeder pan can also cause dark spots.





There are a few modifications to the tooling that can help. First, adding a narrow tip width on the lower punch. This decreases the surface area of the tip that is in contact with the die bore, therefore reducing friction and heat generation. The second option is adding a double depth relief. This provides a better "scraping" action for the lower punch to clean the die bore. This also provides more clearance for this material to exit the bottom of the die. Another modification to consider is tapered die bores. Tapered bores help reduce ejection forces, which are another source of friction and heat. However, the depth of the taper should be engineered to be 20-30% greater than upper punch penetration.

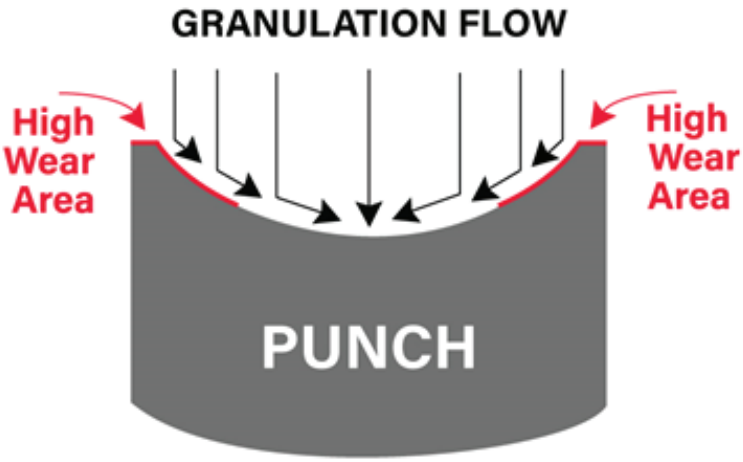
Caption: Adding a double depth relief to the lower punch allows for a better "scraping" action in order to clean the die bore.

Design Optimization

Generally, nutra tablets contain multiple "active" ingredients that are a significantly higher percentage of their total weight with a lower percentage of excipients compared to pharma tablets. They also tend to be larger and often more challenging to compress. These unique properties can be addressed at the tablet design stage with some forethought and communication between the tablet manufacturer and tooling vendor.

The large size of many nutra tablets can be intimidating to some customers. Larger tablets give the impression that they are more difficult to swallow. A tablet design with areas that appear "sharp" will only reinforce this idea. For large high-weight products, tablet designs such as a modified oval should be considered. The rounded edges and cup configuration make even large tablets appear easier to swallow and more appealing.

Nutra tablets often require higher compression forces compared to pharma tablets. Therefore, nutra-tablets should be designed to support high compression forces. Tablet design features, such as excessively deep cups and minimal land, decrease the force rating of the tooling. Keeping cup depths moderate and applying sufficient land ensures the tooling will have a higher compression force rating. Additionally, wider land also increases the abrasive wear life of the tooling. Moderate cup depths also help ensure a more uniform density distribution throughout the tablet compared to the density gradients, or "soft spots," than can occur when compressing deep cups. A shallow curve of the punch cup equates to reduced velocity of the powder as it flows over the punches faces during the filling and compression stages. A lower powder flow velocity equates to less abrasion on the punch face and land.



Granulation flow diagram

KNOWLEDGE IS POWER

Conclusion

Nutraceutical tableting presents a unique set of challenges. However, with some foresight and communication with your tooling vendor, many potential issues can be addressed before the first tablet is ever compressed.

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