Tableting Punch Performance Can Be Improved With Precision Coatings

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High efficiency manufacture of solid dose pharmaceuticals requires the use of high performance tableting presses and precision tableting tooling. Finished tablet quality is determined by the operating parameters of the presses as well as the design and performance of tablet punches and dies. Since punches and dies are in intimate contact with formulation powders during tableting, the properties of the surfaces on the punch tips and in the die bore can have a significant impact on both tablet properties and manufacturing efficiency. Wear and corrosion of the working surfaces of these tools reduces the quality of the tablet surface, and requires more frequent press stoppage due to the need for more frequent punch cleaning and polishing. Coatings, if properly chosen and applied to tableting punches and dies, can dramatically reduce surface wear and corrosion, and significantly improve manufacturing efficiency and tablet quality.

Wear on tooling surfaces affects product quality and manufacturing productivity

Modern tablet tooling is designed and manufactured to uniform, high quality standards. The steels used are chosen specifically for their compatibility with the operating conditions encountered in tableting operations. Tooling manufacturers work closely with their customers to provide punches that will produce tablets with the desired physical characteristics such as shape, embossed features, thickness, weight, hardness, and friability. The finish on the working surfaces of the punches is most often highly polished in order to produce a smooth surface on the tablet, and to help reduce powder pick-up, which necessitates frequent cleaning and polishing of punches during tableting. As delivered, new punches and dies are precision tools designed to produce quality tablets at high levels of manufacturing productivity.

Many of the excipients and active compounds found in pharmaceuticals, nutritional supplements and vitamins, candy, and industrial products are highly abrasive and corrosive. Wear and corrosion of the polished surfaces on punch tips and in the die bore will lead to roughening and degradation of the finish on these critical surfaces. On a microscopic level, worn and corroded surfaces show features including scratches, ruts, and deep pits that can act to trap and hold powder particles. The effects are two-fold; one affecting tablet quality, and the other reducing manufacturing productivity.

Tablet Quality   All mechanical surface features found on the cup and land areas of punch tips will be duplicated on the tablet surface. Roughness, scratches, and pits will be transferred directly thus degrading the surface finish and appearance of the tablet. During compression, as the formulation powders are pressed into the roughened surface structures they can become mechanically attached. Upon ejection and take-off, pieces of compressed tablet material attached to worn or corroded punch faces will be pulled out of the tablet surface (termed picking and capping). The same mechanical attachment of powders in the die bore can result in an increase in the force required to eject the finished tablet (termed sticking). Material can also be removed from the tablet band in this case.

Manufacturing Productivity   The appearance of sticking, picking, and capping requires that the tableting press be stopped and punches and dies removed for cleaning and polishing. Production time is lost and extra costs are incurred for tooling maintenance. Manufacturing productivity is reduced and the cost of production increases.

Thus, to the extent that wear and corrosion cause sticking, picking, and capping, anything that can be done to maintain the original polished finish on the working surfaces of punches and dies will help improve tablet quality and manufacturing productivity.

Coatings Can Reduce Wear and Corrosion

In many other industries coatings are used to improve the operating performance and useful life of tooling and engineered components. Electroplated metal coatings such as nickel and chromium both can provide improved wear- and corrosion-resistance, and both can be applied to the surfaces of most steels including the alloys most popular for tablet punches (D-series, S-series, and stainless steel). Hard refractory nitride compound coatings, such as titanium nitride and chromium nitride, are in widespread use on cutting tools, metal forming tools, and plastic molding tools in order to increase the production performance and wear life of the tooling.

A comparative index of the wear resistance provided by the various coatings can be obtained using a Taber Abraser Test. Performed according to a standard procedure (Society of Automotive Engineers/AMS 2438A), coatings are deposited on four-inch diameter circular disks that are run against resilient rollers impregnated with fifty-micron diameter alpha phase aluminum oxide grits. The coated disks are weighed, run for a fixed number of cycles, and then re-weighed. The thickness of coating material worn away is calculated, the inverse of which is presented as an index of wear resistance. Since standard test parameters are used (grit sizes, wheel RPM, and surface loading), the abrasive wear index numbers calculated are directly comparable as measures of abrasive wear resistance.

Figure 1 shows the abrasive wear-resistance measured for electroplated and refractory nitride coatings compared to the abrasive wear-resistance of uncoated, hardened steels used for tablet punches (D2 & S7). Nickel plating (Teflon impregnated) actually wears much faster than the uncoated, hardened D2 or S7 steels. Hard chromium plating provides a factor of 2X improvement in wear-resistance compared to uncoated D2 or S7 steel. The chromium nitride and titanium nitride hardcoatings provide a 10X and 50X increase respectively in abrasive wear-resistance compared to uncoated D2 or S7 steel. When tableting formulations containing abrasive components, the use of coatings can dramatically reduce tool wear and therefore the need for continuous punch cleaning and re-polishing.

Proper Choice of Coatings and Coating Processes

There are a variety of wear- and corrosion-resistant coatings available for use on pharmaceutical tableting punches (see Table I). Choice of the correct coating, and the correct coating process, are the keys to success in obtaining improved performance for tableting punches and dies. The various coatings available are deposited by either electroplating or by advanced vacuum deposition processes. Metallic coatings such as nickel and chromium are deposited by electroplating. Materials such as Boron (B), and Teflon (PTFE), can be added to enhance plated coating hardness, and coating lubricity, respectively. Processing temperatures during plating are below 200 °F, but the coated tool must be baked post-plating at higher temperatures (375 °F) to prevent hydrogen embrittlement. Hard refractory nitride coatings such as Titanium Nitride and Chromium Nitride are usually deposited by physical vapor deposition (PVD) processes. In order to insure good adhesion and optimum coating properties, the PVD processing temperature must be done at 900 °F or above. At these temperatures the bulk tool material will soften and precision dimensions will distort. These nitride hardcoatings can also be deposited by a low temperature ion beam enhanced deposition (IBED) process. Coating temperature does not exceed 200 °F, which is low enough to eliminate the danger of dimensional distortion or bulk softening of the punch. Coating adhesion is guaranteed by first forming a layer (termed a case layer) in the surface of the punch, and then growing the coating out from the case layer.

Maintenance of the pre-coated surface finish is also an important factor to be considered when choosing a coating and coating process. Electroplated and PVD coatings grow with large crystalline grain structures. This degrades the surface finish originally present on the punch tip, which requires that the surface be re-polished after coating. IBED coatings are amorphous in nature and replicate the surface finish exactly thus eliminating the need for post-coating re-polishing.

FDA Issues

All equipment, including tooling, used in the manufacture of pharmaceutical and nutritional products is regulated by the Food and Drug Administration. FDA regulations specific to equipment used in the manufacture of solid dosage tablets is found in 21CFR211.65 which states, "equipment shall be constructed so that surfaces that contact components, in-process materials, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements." Thus any coating applied to the working surface of punches and dies cannot react with, wear off into, or absorb any ingredient of the formulation being tableted.

Performance of Coated Tableting Punches

A coating was applied to a set of punches used to tablet a particularly abrasive and corrosive product (Calcium Gluconate). Chromium nitride (Cr_2N), which is a chemically inactive ceramic material, was chosen since it is more resistant to abrasive wear than both electroplated nickel and chromium, and its' chemical inertness makes it highly resistant to corrosion. The coating was deposited by the low-temperature IBED process. The appearance of coated and uncoated punch tips both before and after a production run is seen in Figure 2. The chromium nitride coating dramatically reduced the abrasive and corrosive attack on the polished punch tip surface. In addition, the improved abrasion and corrosion resistance of the chromium nitride coating will allow repeated cleaning of the tooling without loss of the enhanced performance properties.

Wear and corrosion on tableting tooling can be significantly reduced when the correct coating is chosen, and applied by the correct coating process. Benefits include improved tablet quality and manufacturing productivity, both of which fall right to the bottom line – better profitability.

Figures and Tables:

Figures and tables appear on the following pages.

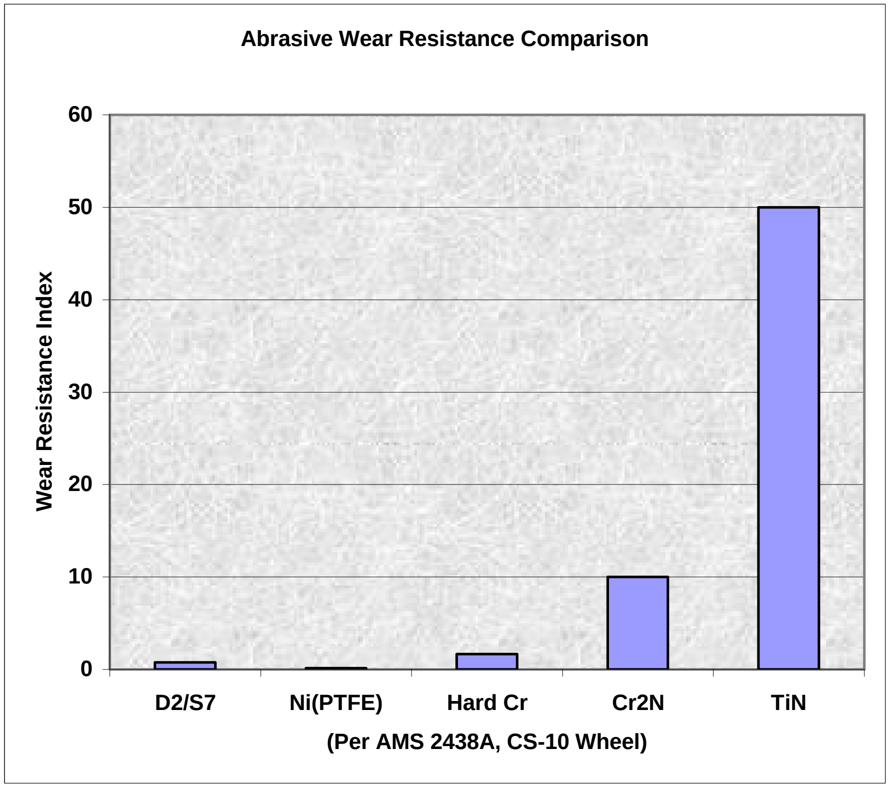
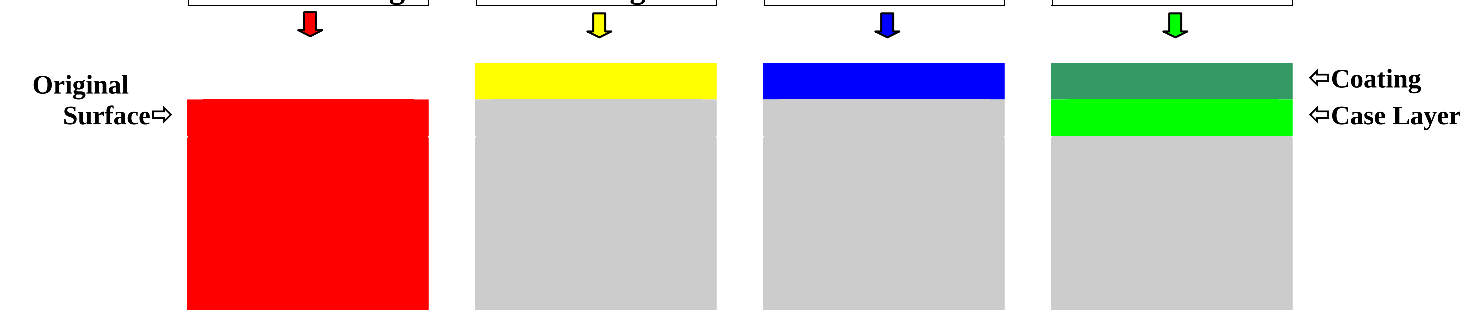


Figure 1: Comparative Wear Resistance of Various Coatings

Surface Treatment Technologies



	Heat Treating	Plating	PVD	IBED
Process Type	Chemical - Thermal			Physical
Temperature		300 – 500 °F	900 –1200 °F	< 200 °F
Coating		Ni, Cr	TiN, CrN	TiN, Cr_2N
Repolishing		Required	Required	Not Required
Dimensions	Entire Volume Treated	0.1-15 mil Thick Coated Layer	0.04-0.4 mil Thick Coated Layer	0.02 mil Case 0.04-0.4 mil Coat

Table I: Treatment Technologies Available for Tableting Tooling

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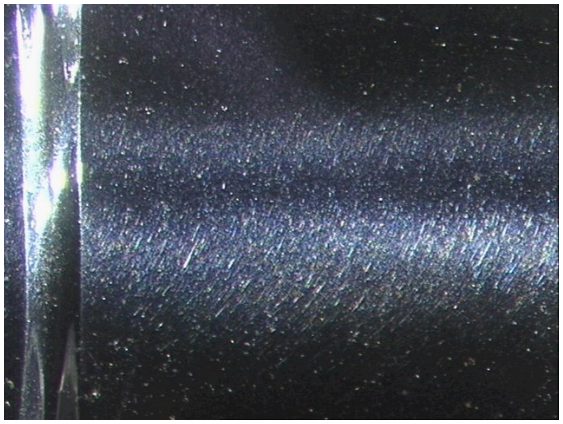
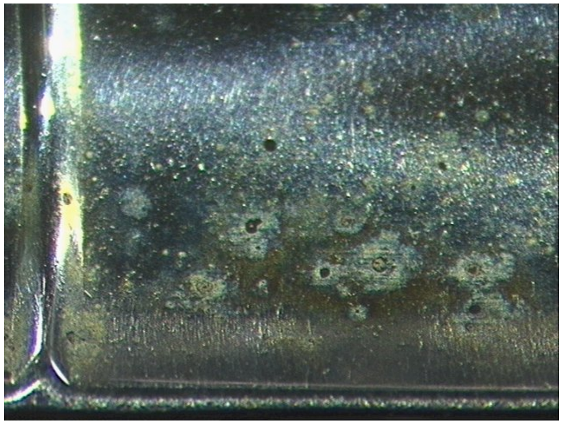
Uncoated Punch Face



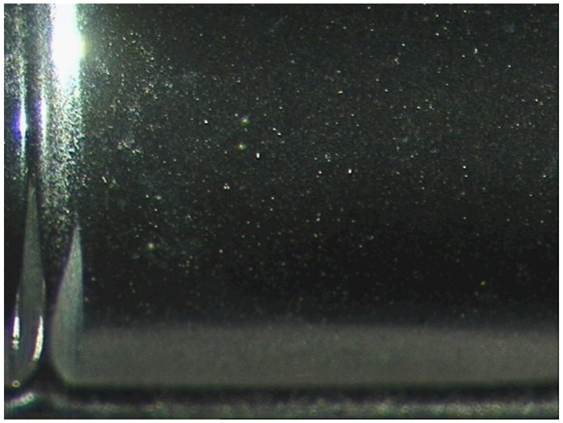
Before Production Cycle



After Production Cycle

Chromium Nitride Coated Punch Face

Before Production Cycle



After Production Cycle

Figure 2: Appearance of Coated and Uncoated Punches, Before and After Use.
(Image taken at 15X magnification. Feature in left of each frame is the tablet bisect.)

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