

Advanced Coatings Help Pharmaceutical Machinery Meet FDA Standards



Elizabeth-Hata chooses Nedox® and Tuftram® coatings for its rotary press.

Machine builders have long used engineered coatings to reduce wear. In the pharmaceutical industry, however, picking the right coating can be difficult. FDA regulations rule out many common coatings in product-contact applications. Making matters worse, some of the coatings that do pass muster with the FDA are not widely available globally, which is important as machine builders expand internationally.

Elizabeth-Hata, a leading manufacturer of tablet presses, recently found a couple of coatings that not only comply with FDA requirements but also have global availability. For its rotary tableting machine, the company chose NEDOX and TUFRAM coatings from General Magnaplate Corporation. “Both coatings are FDA compliant, so we were able to use them in product-contact areas that are susceptible to abrasive wear,” says Elizabeth-Hata’s International Operations Manager.



Those product-contact areas include a powder feeder, scrapers and turrets. Left unprotected, all of these components can experience abrasive wear as the machine compresses powdered pharmaceuticals into tablets at pressures up to 20 tons.



Tuftram For Aluminum. For the press's aluminum parts, Calvin selected TUFGRAM HO. These parts include the feeder, scrapers and deck plates. With a hardness of 40 to 50 Rc and a dry-lubricated surface, TUFGRAM gives all these components good release properties relative to the powder. TUFGRAM also protects the aluminum parts from wear, corrosion, sticking and galling.

Before choosing TUFGRAM, the operations manager passed over a variety of industry coatings – including hard anodize, polymer impregnated hard anodize, hard coat anodize and sulfuric anodize. Some of these aren't considered FDA compliant, while others had subpar wear properties and longevity compared to TUFGRAM.

Nedox For Steel. For the press's steel parts, such as the 316 stainless steel turret that holds the die and punches, NEDOX SF-2 was used. With a hardness of Rc 65 and inherent lubricity, NEDOX protects the turret from wear and corrosion. By selecting NEDOX SF-2, the operations manager rejected a number of industry coatings – including nickel-plating, electroless nickel plating, sulfamate nickel, co-deposited electroless nickel and polymer-impregnated electroless nickel.

TUFGRAM PROPERTIES

- Temperature range from -360°F (-218°C) to as 800°F (427°C)
- Good thermal conductivity
- Surface hardness between Rc 40 and Rc 65
- Properties that exceed AMS 2469 and AMS 2482 requirements
- Permanent self-lubricating properties for extended wear
- FDA, USDA compliance
- Abrasive wear and galling prevention
- Simple cleanup and sanitation
- Mold release properties
- Low coefficient of friction
- High dielectric strength
- Resists chipping, peeling and flaking
- Compliance with the End of Life Vehicle initiative for the automotive industry
- Non-wetting surface properties
- Excellent performance in extreme environments



Global Availability. After expanding its manufacturing operations to India, Elizabeth-Hata found that it needed to choose technologies that could be applied consistently regardless of the manufacturing location. That need factored into their coating selections since Magnaplate has licensed its coatings to partners around the world, including in India. “If I have a part made in India, I want it to have the same coating as the parts we make domestically,” the operations manager says. “With TUFRAM and NEDOX, that’s the case every time.”



General Magnaplate’s coatings are available globally through the Magnaplate Worldwide alliance of licensees that extends our industry leading products and applications expertise as far afield as Canada, Europe, Australia, Japan, India, and South Korea.

NEDOX PROPERTIES

- Operating temperatures from -250°F (-157°C) to 550°F (288°C)
- Surface hardnesses up to Rc 68 (940 Vickers)
- Coating thicknesses between 0.0002 to 0.002 inches
- Chemical and acid resistance
- Self-lubricating, non-porous, non-wetting surface characteristics
- Good electrical properties, including:
 - Low dissipation factor
 - Low coefficient of thermal expansion
- Excellent thermal conductivity
- Compliance with industry standards, including:
 - AMS 2404 and ASTM B733
 - USDA and FDA compliance
 - NASA material #20386 in the MSFC Handbook 527F, Johnson Space Flight Center #D9604F