IBED Titanium Nitride

FDA Regulatory Issues

The Food and Drug Administration (FDA) regulates the pharmaceutical and nutritional products manufacturing industry. Regulations governing the manufacture of pharmaceuticals in solid dosage form are found in the "Code of Federal Regulations: Title 21 – Food and Drugs." The regulations specific to equipment used to manufacture solid dosage tablets is found in Part 211 "Current Good Manufacturing Practice for Finished Pharmaceuticals;" Subpart D "Equipment," Section 211.65 "Equipment Construction." As stated in 21CFR211.65:

"(a) 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."

"(b) Any substances required for operation, such as lubricants or coolants, shall not come into contact with components, drug product containers, closures, in-process materials, or drug products so as to alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements."

Clearly the Beamalloy IBED titanium nitride coatings applied to the working surfaces of tableting punches and dies, since they are non-reactive except with extreme oxidizing agents, non-absorptive, and non-additive, satisfy the FDA regulatory guidelines set forth in 21CFR211.65.

Ion Beam Enhanced Deposited (IBED) Coatings

Beamalloy IBED coating technology allows deposition of precision high quality engineered hardcoatings on virtually any metal and metallic alloy surfaces. Operating at temperatures below 200° F, the process is highly controllable resulting in coatings with precise thickness and repeatable properties. Beamalloy IBED coatings are first formed in the subsurface region of the part to be coated and then grown out to a typical thickness of up to 6 microns. This tight metallurgical bond guarantees excellent coating adhesion and eliminates the possibility of chipping and flaking of the coating during tool operation.

Chemical Properties

Titanium nitride (CAS #25583-20-4) is a metallic nitride compound having a chemical formula of TiN. It is a solid material exhibiting a light metallic gold color and having no odor. In solid form as a thin coating it is non-volatile and non-flammable, and is insoluble in organic solvents. It is only slightly reactive with strong inorganic acids and will react with and dissolve in strong oxidizing agents (hydrogen peroxide and persulfates). It is hard (HKN 2800), highly resistant to abrasive wear and as such does not release wear debris. When deposited as a coating using the IBED process, titanium nitride is fully dense and void-free, and as such will not absorb or trap any powdered or liquid materials that it may come into contact with.

Health Effects

Titanium and titanium compounds including titanium nitride are considered to be physiologically inert. Titanium nitride is not listed as a carcinogen, and neither acute nor chronic exposure induces toxic effects.

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