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COATING


Food And Drug Administration (FDA) regulations regarding manufacture of solid dosage form of pharmaceuticals can be found in "Code of Federal Regulations: Title 21: Food and Drugs.

Within these regulations, specific conditions about manufacturing instrumentation of solid dosage tablets are listed in : "Part 211 -- Current Good Manufacturing Practice For Finished Pharmaceuticals, Subpart D: Equipment, Sec. 211.65 Equipment construction." As follows:

- (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.

Moldmate/Toolmate CrN, a CrN based PVD coating produced by  are non-reactive, non-absorptive and non-additive and strictly satisfy the FDA regulations stated in above mentioned **21CFR211.65** guideline set.

MOLDMATE/TOOLMATE ALLIGA PVD COATINGS

MoldMate/ToolMate CrN series of PVD hard coatings produced by  have multilayer structure of CrN layers. They are applied to various industrial tools and molds used for different production applications. Coatings are produced by evaporating pure Chromium and/ or Zirconium metals and reacting with pure nitrogen in a perfectly controlled vacuum PVD coating system. Thickness of the coating varies between 0,5 to 10 µm for different applications, and those thin coatings do not change production tolerances of the tools and molds. **Moldmate/Toolmate CrN** has and hardness of 3100-3500 Hv and has a very dense and compact structure. It has extreme wear resistance and do not leave any wear debris during operation of tools. It is chemically very inert and does not react with drug components, does not absorb any material in liquid or solid form and can be easily cleaned after operation. By having a low friction coefficient of 0,35 and perfect surface quality, CrN prevents sticking and adhesion of drug materials which has tendency to stick over tool

Chemical Properties

Base layer of CrN is Chromium Nitride-CrN (CAS# 24094-93-7) having metallic grey colored and no odor. It is non-volatile non-flammable, insoluble in water and organic solvents and only slightly react with strong inorganic acids and strong oxidizing agents.

Health Effects

Both ZrN and CrN components of **Moldmate/Toolmate CrN** are listed as not having any specific known hazards to health, is not specifically listed as carcinogen and both coatings have application in drug and food industries