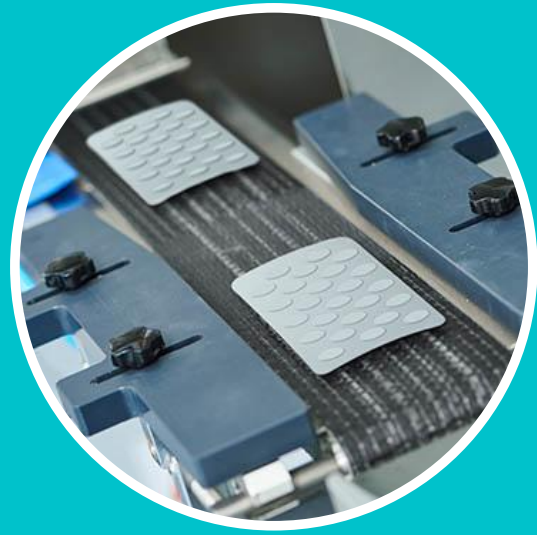


LUBRICANTS FOR PHARMACEUTICAL INDUSTRIES

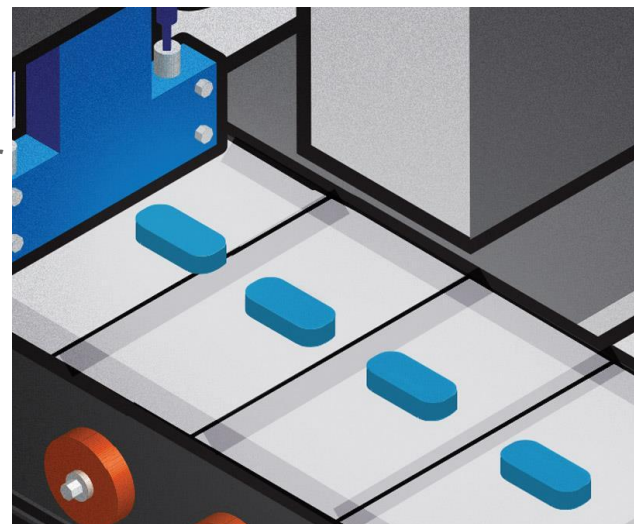
CURRENT SCENARIO

Over few years, increasing interest is seen in the use of food-grade lubricants for the machines operating in the pharmaceutical industry. Modern machineries used in the production of pharmaceutical products generally requires minimal lubrication in the section of the production line. Other machines with the chains or moving with chains or moving components near the production line may need lubrication and lubricants here recommended might not always be classified as H1 food grade or ISO 21469 std. In such cases, it must be well determined whether the machinery should be lubricated with conventional lubricants or if there are specific requirements for selecting Lubricants for Pharmaceutical industries.



Lubrication selection should begin by considering the lubrication need of the equipments in terms of the load, speed, viscosity and also the application method. Once these parameters have been defined, food grade properties must be taken into account. While the use of food-grade lubricants is widely accepted in pharmaceutical facilities, these H1-registered or ISO 21469-certified products are primarily intended for food-processing plants and applications in which there is incidental contact with food. The National Sanitation Foundation (NSF) provides regulations and good practice recommendations regarding pharmaceutical manufacturing equipment and lubricants within the Code of Federal Regulations (CFR). 21 CFR 211.65, states: "Equipment shall be constructed so that surface in contact, will not be reactive so as to alter the safety, strength, quality, and purity of the lubricating product beyond the official requirements."

When a lubricant is needed in an area that is exposed to the drug product, the potential impact should be analyzed to ensure it will not be detrimental to the product's intended fitness for use. This requirement is stricter than the criterion for food-processing machines, which allows a maximum lubricant contamination of 10 parts per million. In general, sealed-for-life or non-lubricated components should be the first choice for machinery components. Food-grade lubricants are a good option for isolated production machine components that need lubrication. Of course, proper cleaning and sanitizing practices will be required after the application of lubricants within the production area.



REQUIREMENTS OF LUBRICATION

In CFR 21.211, the FDA provides guidance regarding lubrication practices and machine maintenance used in the manufacturing, processing and packing of pharmaceuticals. It emphasizes the importance of maintaining clean equipment and establishing written procedures, including lubrication procedures. If a lubricant change or lubrication issue could impact product quality, written records are required to be kept relating to the affected product batch. However, routine maintenance such as lubrication does not have specific record-keeping requirements.



SELECTION OF LUBRICANTS

For effective lubricant selection in pharmaceutical facilities, one of the first steps should be to classify machines by the application. For support services equipment not located in the production area and that have no potential contact with production machinery or the product/packaging, it is possible to use H2 lubricants, which are not intended for food-grade (incidental contact) applications. These types of machines would include pumps, compressors, gearboxes and hydraulic systems involved in the supply of water, compressed gases and energy. Most lubricants (non-H1) in the market fulfill H2 requirements, while only a limited number have a formal H2 registration. If a compressed air line for production machines requires lubrication, an H1 lubricant would be a good choice. Machines or machine components that are situated in the production area but with a physical barrier blocking exposure to the locations where products and packages are processed have no formal requirements for lubricant selection. However, food-grade lubricants may be preferred to maximize safe maintenance practices related to the production machines.



SCOPE FOR MOSIL

MOSIL's product basket has number of lubricating products which meets the food grade standards, NSF approvals for any kind of incidental contact of inprocess products with the lubricants. MOSIL also has products for general lubrication purpose for all type of industries. It also has NSF approved cleaning products which are used for cleaning purpose in food as well as pharmaceutical industries.