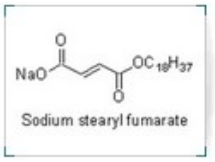
Hydrophilic lubricant- sodium stearyl fumarate S96

Status of Legislation:

U.S.A DMF#18189

Europe CEP: CEP_RZ_PH_2011-269-0598092

China Import Registration Acceptance Form: JXFL1300005



- Sodium Stearyl Fumarate
- 4070-80-8
- USP, EP, JPE

When used as lubricant tablets and capsules, sodium stearyl fumarate's concentration range is 0.5~2.0% w/w. S96 is white fine powder with agglomerate in the form of flat spheric granule which can solve the related problems when sodium stearyl fumarate is used as lubricant. It can improve disintegration and promote dissolution, especially form protective tissue when applied in effervescent tablet. Sodium stearyl fumarate used in oral preparation is usually considered as non-toxic and non-irritating. The metabolism research of sodium stearyl fumarate in rats and dogs indicates that: approximately 80% of it is absorbed, and 35% is rapidly metabolized. The absorbed parts are hydrolyzed to stearyl alcohol and fumaric acid, then stearyl alcohol is oxidized to stearic acid further. In dog, unabsorbed sodium stearyl fumarate will be excreted through feces in the original form within 24 hours. Stearyl alcohol and stearic acid are the natural ingredients in various kinds of foods, and fumaric acid is the normal ingredients for body tissues. There is no need to confirm the daily intake of stearate or fumaric acid. FDA permits it to be directly added as regulator and stabilizer into the following food for people: various kinds of bake goods, flour thickened foods, dried potatoes and processed grains, the dosage can be 0.2~1.0 of the food. It was recorded in Non-active component instruction (oral capsule and tablet) by FDA. Sodium stearyl fumarate's value shows up when encountering impure stearic acid ester lubricant being not applicable due to chemical incompatibility. The product's hydrophobicity is weaker than that of magnesium stearate and stearic acid, and the hysteresis effects of tablet dissolution is less obvious than that of magnesium stearate. Sodium stearyl fumarate is incompatible with chlorhexidine acetate.

Taiwan Standard is one of the top pharmaceutical enterprises who passed U.S.A FDA's factory inspection for 7 times and was approved by Taiwan cGMP. Over the years, their high quality pharmaceutical products not only met the demands of Taiwan, Hongkong, Macao and mainland pharmaceutical market, but were also imported to mainstream pharmaceutical market like Europe, U.S.A and Japan. Moreover, the sodium stearyl fumarate under its brand was the first to be certified by DMF/CEP. Through years of technology

inputs and strict quality control, Taiwan Standard has extremely promoted the quality of sodium stearyl fumarate. High stability among the batches, compliance with the latest international mainstream pharmacopoeia, remarkable black spot control capability endows Standard's sodium stearyl fumarate excellent reputation in various European and American pharmaceutical factory. This product is also the first choice in excipients for hydrophilic lubricant.

Shanghai Chineway Pharmaceutical Technology Co.,Ltd is the general agent for Taiwan Standard Sodium Stearyl Fumarate in China.