Sodium Stearyl Fumarate (micronized)

Compliant to EP, USP/NF, JPE

Advantages:

Sodium Stearyl Fumarate is a lubricant used in the manufacturing of tablets, capsules and other dosage forms. Due to its high hydrophilicity, it is especially designed for robust and high performance formulations, where the commonly used lubricating agents fail to provide tablets of adequate hardness, stability, content uniformity, disintegration and dissolution rate.

Particle size distribution of the used Sodium Stearyl Fumarate is a key factor for optimum tableting results. Especially the influence of particle size on disintegration time is very well documented. Reduced particle sizes are directly linked with higher disintegration times combined with small effects on tablet hardness only.

VIO Chemicals can offer micronized Sodium Stearyl Fumarate with controlled D_{50} particle sizes of 10 µm and below

Features:

- Hydrophilic
- Highly soluble
- Highly stabilizing
- Flexible but controlled particle size
- High degree of API compatibility

Benefits:

- Improved drug stability
- Faster dissolution rates
- Harder tablets
- Shorter disintegration times
- Fast formulation development

Applications:

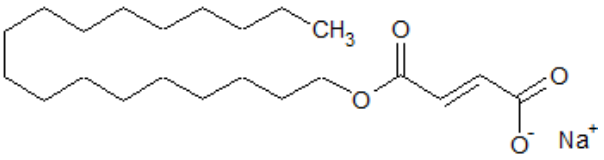
Sodium Stearyl Fumarate has already been used in formulations of a great number of APIs, including:

Omeprazole, Ramipril, Diclofenac, Esomeprazole, Ibuprofen, Irbesartan, Lamotrigin, Levetiratecam, Levofloxazin, Metoprolol, Ritonavir, Pravastatin, Sildenafil, Tamiflu, Telmisartan, Valsartan or Sitagliptin

Technical profile:

- Technical name: Sodium Stearyl Fumarate
- CAS No: 4070-80-8
- Empirical formula: $C_{22}H_{39}NaO_4$
- Molecular weight: 390.53

Chemical structure:



Test	Specification
Identification	IR has to confirm with CRM
Appearance	White or almost white fine powder
Solubility	Practically insoluble in water and acetone, slightly soluble in methanol
Assay	99.0-101.5%
Water content	max. 5.0 %
Saponification value	142.2-146.0
Heavy metals	max. 20 ppm
Lead	max. 10 ppm
Arsenic	max. 2.0 ppm
Related substances	Largest single impurity max. 0.5%
	Total impurities max 5.0%
Sodium Stearyl maleate	max. 0.25 %
Stearyl alcohol	max. 0.5 %
Particle size distribution	Can be adjusted within certain limits, like:
	D_{10}: max. 2.5µm
	D_{50}: max. 10 µm
	D_{90}: max. 30 µm

Compliance: EP, USP/NF, JPE

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