



LubriSanaq®

Sodium Stearyl Fumarate

(Ph. Eur / USP-NF)

***The Lubricant
for Tablet
and
Capsule Formulations***



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Sodium Stearyl Fumarate (Ph. Eur/USP-NF)

LubriSanaq[®] Sodium Stearyl Fumarate is an inert, hydrophilic, tablet lubricant.

LubriSanaq[®] is a problem solver when other lubricating agents fail to provide tablets of adequate stability, hardness, content uniformity and show difficulties with disintegration and dissolution rates.

LubriSanaq[®] is used as a lubricant in capsule and tablet formulations at 0.25 – 3.0% w/w concentrations.

Advantages in comparison with Magnesium Stearate

- Superior tablet hardness at equivalent compression force
- Lower ejection force at equivalent compression force
- Less impact on disintegration times
- Performance varies less with blending time or lubricant level
- Solves incompatibilities with Magnesium Stearate

Production Yield

Sodium Stearyl Fumarate has a high melting point and is therefore the preferred lubricant for high-speed direct compression.

Melting point

Sodium Stearyl Fumarate	224 - 245°C
Magnesium Stearate	120 - 150°C
Stearic Acid	55 - 70°C
Calciumstearate	150 - 160°C



Specification

Item	Specification
Description	White powder.
Infrared absorption	The IR spectrum matches with spectrum of LubriSanaq RS or working standard.
Water	Not more than 5.0%
Saponification value	142.2 ~ 146.0, calculated on the dried basis.
Limit of sodium stearyl maleate and stearyl alcohol	
Limit of sodium stearyl maleate	Not more than 0.25 %
Limit of stearyl alcohol	Not more than 0.5 %
Lead	Not more than 0.001 %
Heavy metals	Not more than 0.002 %
Assay	99.0 % ~ 101.5 %, calculated on the anhydrous basis.
Additional Specification (In-House Standard)	
Residual solvents	
Acetone	Not more than 300ppm
Ethyl acetate	Not more than 300ppm
Methanol	Not more than 300ppm
Toluene	Not more than 300ppm

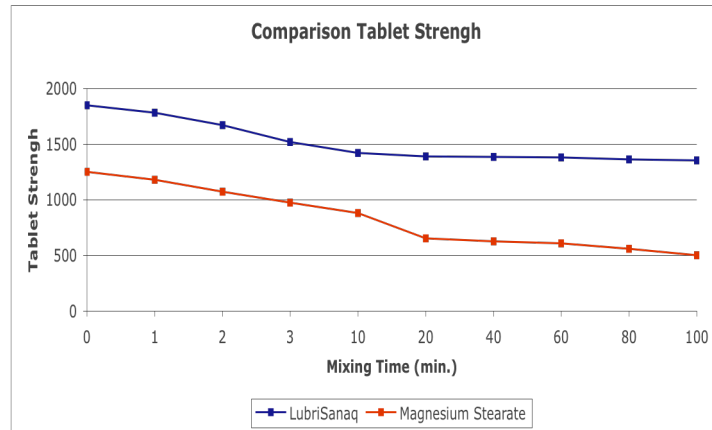
General Information

Packing	25 kg net fiber drum / D 37cm x H 73cm
Storage	Store in well-closed containers
Shelf life	3 Years

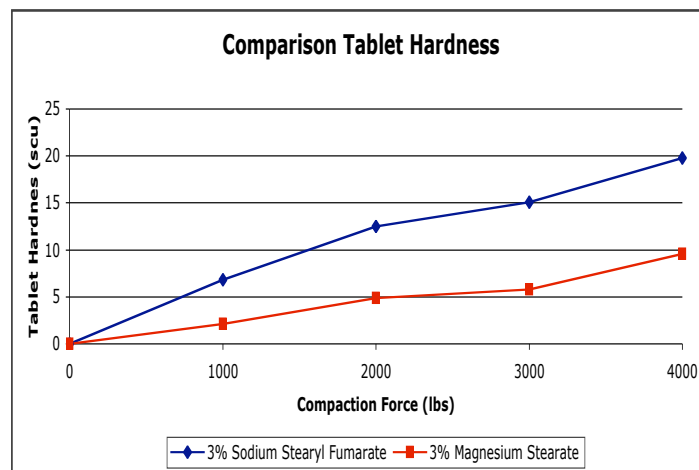


Dissolution Rate

Sodium Stearyl Fumarate is less hydrophilic than Magnesium Stearate, therefore it accelerates the disintegration and shows less retardant effect on the dissolution rate.



Tablet Hardness



Improved Drug Stability

Sodium Stearyl Fumarate is relatively inert. **LubriSanaq[®]** therefore avoids incompatibilities with many API's which results in a better API stability.

Use of LubriSanaq[®]

- to avoid metallic taste of Magnesium Stearate
- in combination with organic salts
- for API's with Carbonyl-Carboxylgroups
- for API's with Sulfogroups
- for high-speed direct compression



Binders, Disintegrants, Glidant, Films

MCC SANAQ®

Microcrystalline Cellulose

OROCCELL

Spherical mannitol compound for ODT formulations in direct compression

SSG SANAQ®

Sodium Starch Glycolate

LUBRISANAQ®

Sodium Stearyl Fumarate

SANAQ® PEG_{series}

Polyethylene Glycol

Neutral Pellets, Granulation aids

CELLETS®

Microcrystalline Cellulose Pellets

SUGAR SPHERES SANAQ®

Sugar non-pareils

MCELL

Mannitol Pellets

TAP

Tartaric Acid Pellets

CARNAUBA WAX PELLETS

C-Wax

LOCAL PARTNERS in ...

AUSTRIA

BELGIUM

CHINA

FRANCE

GERMANY

GREECE

INDIA

ITALY

JAPAN

JORDANIA

NETHERLAND

POLAND

SCANDINAVIA

SPAIN

SOUTH KOREA

TAIWAN

VIETNAM

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