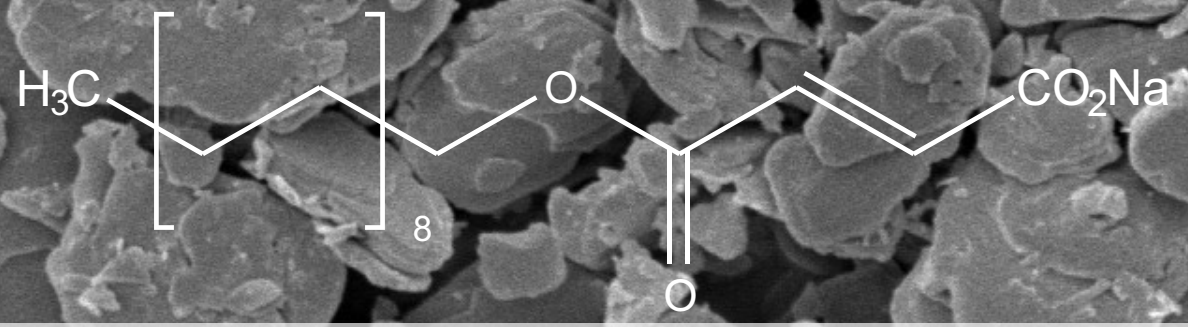
LUBRISTAR™

SODIUM STEARYL FUMARATE

USP/BP/EP/US-DMF No: 037309

Innovation, Quality & Competence in API's & Excipients



GANGWAL

WHO-GMP & ISO Certified

About Us

Gangwal Healthcare is a efficacious solution provider and manufacturer that combines innovative research and smart, seamless technology that can tackle the complex challenges of the healthcare system through novel formulations that enhance the quality of life.

Today, as we see newer health challenges cropping up day after day, at Gangwal Healthcare we strive to resolve these by plugging in our rich knowledge and working alongside industry experts who have a strong foothold in pharmaceuticals and nutraceuticals. To give the optimum solution and produce products of the highest quality begins with understanding your needs and concerns and extracting those insights. Promptly followed by bringing in the raw materials that promise the best outcome and blending them with our latest technologies and processes to manufacture a product that can simplify your complications.

Mission
To become a global healthcare company through Innovation, Quality and Competence.

Vision
To build healthier society - Driven by innovation to serve with quality.

Quality

We keep quality as the highest priority when it comes to the products manufactured at Gangwal along with processes deployed or technologies adapted. We firmly believe that nothing can supersede a product or a service that is backed by excellent quality. As solution providers, we strive to have a global footprint through each phase of our journey.

Innovation

Modern medicine is seeing the traces of ancient sciences blend with it effectively, thanks to technology and innovation. Our highly dedicated task forces keep innovation at the center of their activities so that the world can truly reap the optimum benefits of what we create or source. Innovations aid us to challenge the most complex health concerns, thereby addressing your prominent issues.

Consistency

Nothing can make an impact in its entirety unless it comes with consistency. Be it our top management or other teams within the organization, we thrive on consistency at work, in order to see the bigger reforms in health that we are aiming for. Whether it's our external or internal stakeholders we are strongly driven by persistent efforts towards improving the quality of lives that people lead.

Our Quality Certificates

CDSCO · ISO 9001:2015 · HALAL · fssai · WHO GMP · GOOD MANUFACTURING PRACTICE GMP

Introduction

Description

Sodium Stearyl Fumarate is a fine, white powder with agglomerates of flat, circular-shaped particles.

Empirical Formula

C22H39NaO4

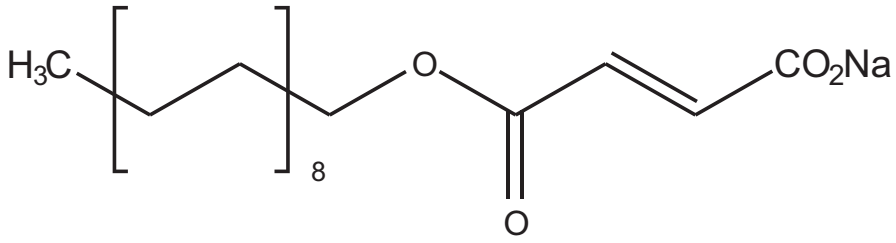
Molecular Weight

390.5

CAS NO

4070-80-8

Structural Formula



Functional Category

- Lubristar™ is an hydrophilic, tablet lubricant, useful in situations where other lubricant (i.e., Magnesium Stearate) fail to provide adequate stability, hardness, uniformity, disintegration and dissolution rate.
- Sodium Stearyl Fumarate is used as a lubricant in tablet and capsule formulations at 0.5–2.0% w/w concentration.

Compairison to Magnessium Stearate

- Reported API incompatibilities with Magnesium Stearate include: Fosinopril, Dextromethorphen HBr, Cefaclor, Diclofenac, Fosinopril, Ibuprofen, Ketorolac, Levofloxacin, Nifedipine, Omeprazole, Ramipril, and Trandolapril.
- Helps to avoid API Incompatibilities and enhances API stability

Applications

Sodium Stearyl Fumarate is used as Lubricant in

- Wet Granulation
- Dry Granulation
- Direct Compression
- Capsules
- Effervescent Tablets
- Buccal Tablets
- Orally Disintegrated Tablets
- Chewable

Benefits

- Improved drug stability
- High degree of API compatibility
- Faster dissolution rate
- Protecting from over blending (robustness to over lubrication) No metallic after tastes
- Improved appearance of effervescent solution
- Low Impurity profile
- Better hardness and low friability

Physical Properties

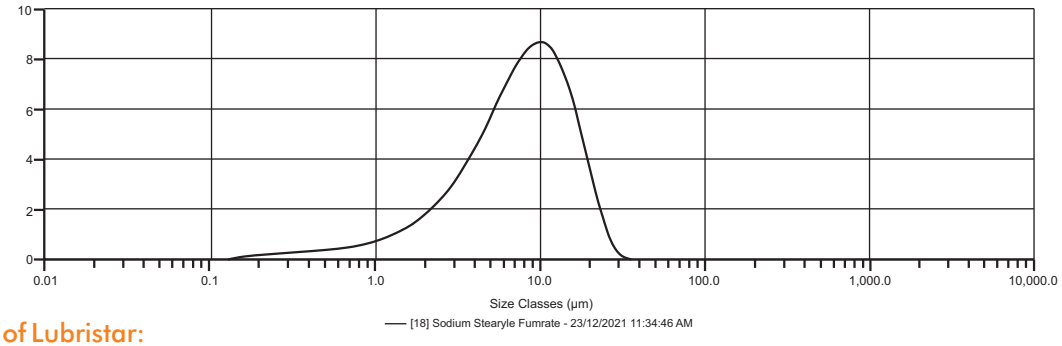
Physical Properties	Result
Bulk density (g/mL)	0.33
Tapped density (g/mL)	0.45

Surface Area	
Medium	1.20 to 2.00 ms/gm
High	2.00 to 4.00 ms/gm

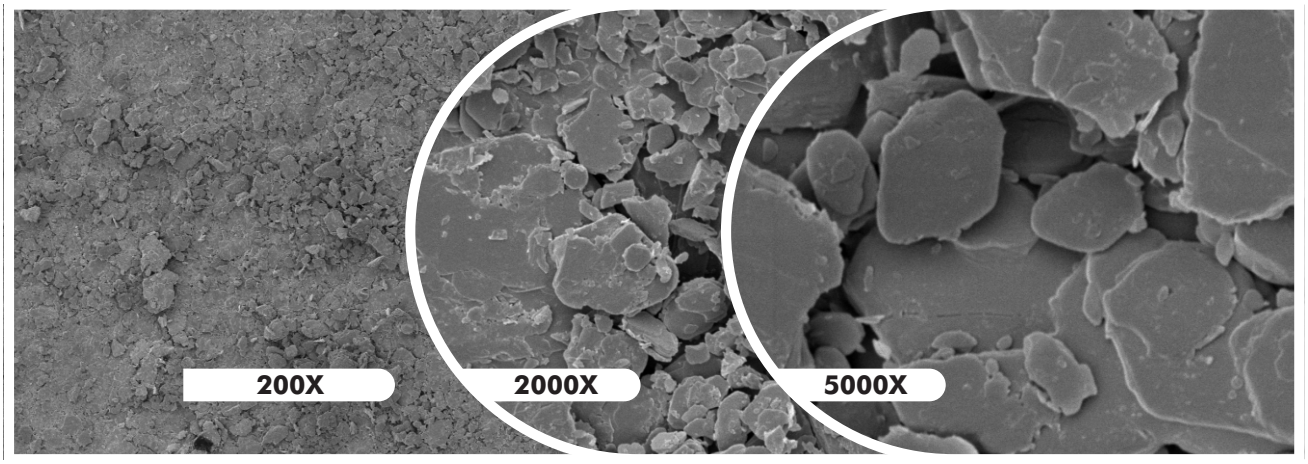
Particle size (by Malvern):

Particle size distribution of Lubristar™ is a key factor for optimal tableting results.

Parameters	Result
D10	NMT 2.5 µm
D50	NMT 20 µm
D90	NMT 45 µm



SEM images of Lubristar:



SPECIFICATION

TEST	SPECIFICATION LIMITS
Description	White or almost white, fine powder.
Solubility	Slightly soluble in methanol, Practically insoluble in water, acetone and ethanol.
Identification by IR*	To comply by IR. Compare the spectrum with that obtained with the test solution corresponds to the peak in the chromatogram obtained with reference solution.
Identification by HPLC	In the assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.
Water content	NMT 5.0%
Lead	NMT 10 ppm
Heavy Metals	NMT 20 ppm
Saponification Value	Between 142.2 – 146.0
Limit of sodium stearyl maleate	NMT 0.25%
Limit of stearyl alcohol	NMT 0.5%
Assay	Between 99.0% to 101.5%
Related Substances Largest single imp Total impurities	NMT 0.5 % NMT 5.0 %
Arsenic	NMT 2 ppm
Residual Solvent Acetone Toluene	NMT 500 ppm NMT 890 ppm

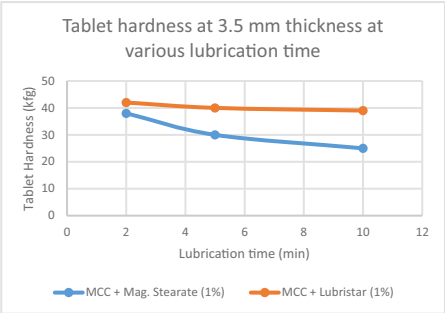
* IR- Infrared Spectroscopy

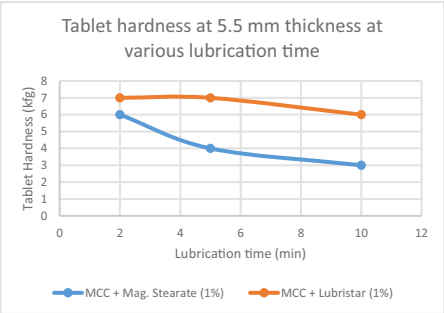
Experimental Section

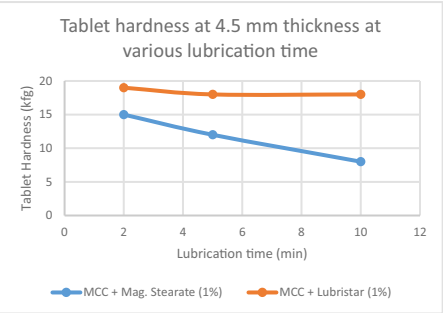
Case study: Reduced overblending sensitivity.

Challenge: Lubrication with lipophilic lubricants like Magnesium Stearate, overblending and underblending of lubricant may lead to reduce in tablet strength. Lubrication is a scale dependent unit operation, which needs to be optimized carefully at the time of scale up / technology transfer. In this study, comparative data of compression of MCC 102 with 1% Lubristar and Magnesium Stearate separately at different blending time is generated to evaluate two different lubricants.

Hardness achieved at different lubrication time with 1% Lubristar & Magnesium Stearate



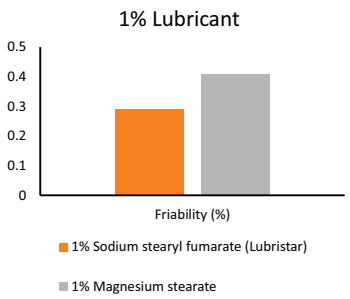


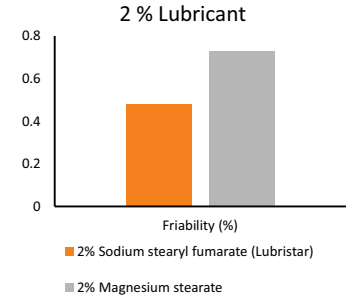


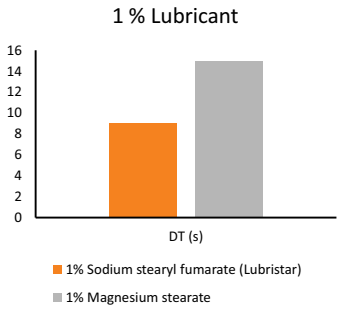
Conclusion: Lubristar do not have any adverse effect on tablet strength upon overblending, hence it makes scale up / technology transfer process easy and more reproducibility.

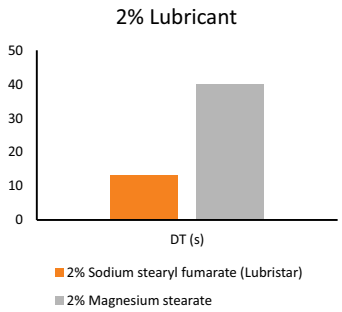
Case Study: Lubristar for faster disintegration and low friability.

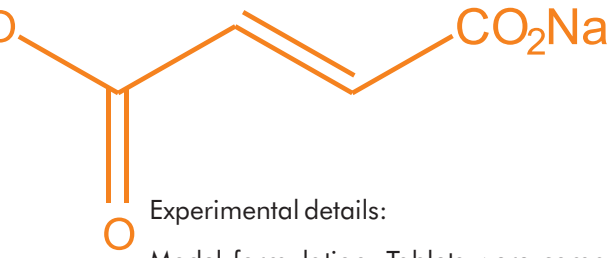
Challenge : During lubrication process Magnesium Stearate has capability to form a hydrophobic film on the other excipients surfaces leading to higher disintegration time of compact because of a delay / hindrance in wetting of particles as of hydrophobic film created by Magnesium Stearate . This hydrophoblic film also reduces adhesive & cohesion of particles in compact which leads to higher friability too. Study conducted on paracetamol as model drug.











Experimental Section

Experimental details:

Model formulation: Tablets were composed of 650 mg Paracetamol, 2% of binder, 2% of disintegrant and variable contents (1 or 2% w/w) of lubricant (SSF or MgSt). Microcrystalline cellulose used as filler.

Blending: 2-step addition method was followed: The components (except the lubricant) were blended for 10 min., followed by addition of lubricant and further 2 min. of blending.

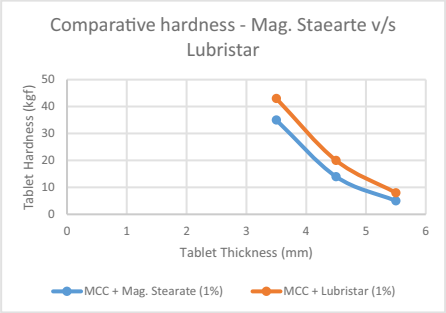
Tableting: Tablets were compressed by direct compression method using an automated rotary tablet press using 12 mm round flat punch. Tablet hardness kept at 80 – 100N. Main compression force required to achieve the desired hardness was measured. Tablet hardness was analysed using automated digital hardness tester. Disintegration time was analysed (n=6) using USP disintegration test apparatus.

Conclusion: More robust tablets in terms of tablet hardness achieved using Lubristar in comparison to Magnesium Stearate. Lubristar reduced the friction and the adhesion to about the same degree as Magnesium Stearate and had also about the same influence on tablet strength and disintegration. Prolonged mixing improved its lubricating effect and had no effect on the tablet hardness and disintegration time.

Lubristar appears to be a good alternative Magnesium Stearate

Case Study : Better tablet strength with lubristar.

Challenge : Lipophillic lubricants especially Magnesium Stearate is an additive that is most frequently used lubricant in tablets. It is capable of forming a hydrophobic film on other excipients during blending, and adversely affects adhesive and cohesive forces to form a compact from lubricated powder blend. This study details about comparative data of effect of Magnesium Stearate & Lubristar on tablet strength.



Tablet weight 500mg , 12mm round table with flat punch lubrication blending time 3 min.

Conclusion : Hardness of compact manufactured using lubristar is better and higher compared to the hardness of compact manufactured using Magnesium Stearate

Lubristar™ is compatible with a wide range of APIs

Magnesium Stearate has compatibility issues with many APIs. It is well known that some widely used APIs, like aspirin, are not compatible with Magnesium Stearate

Magnesium Stearate is incompatible with several API's

Antidiabetic	Anti-inflammatory	Antihypertensive	Antibiotic	Antiviral	Antiamoebic
Chlorpropamide	Ketoprofen	Captopril	Nalidixic Acid	Acyclovir	Albendazole
Glipizide	Aspirin	Oxprenolol	Cephalexin	**Antimalarial**	**Anticancer**
Glibenclamide	Indomethacin	Quinapril	Erythromycin	Primaquine	ß-lapachone
Glimepiride	Ibuproxam	Fosinopril	Oxacillin	**Antiemetic**	**Hypnotic**
Anticoagulant	**Antihistaminic**	Moexipril	Penicillin G	Promethazine	Temazepam
Clopidogrel	Doxylamine				

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GANGWAL

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