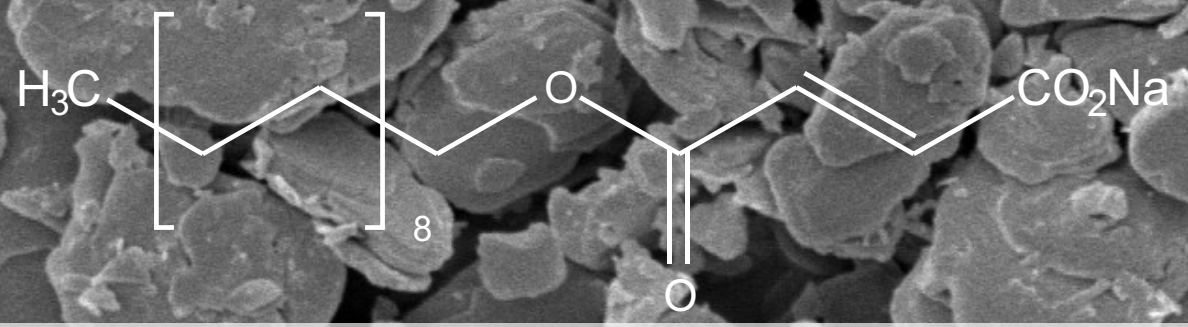
LUBRISTAR™

SODIUM STEARYL FUMARATE

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

Innovation, Quality & Competence in API's & Excipients



GANGWAL

WHO-GMP & ISO Certified

About Us

Driven by innovation, inspiration and competence

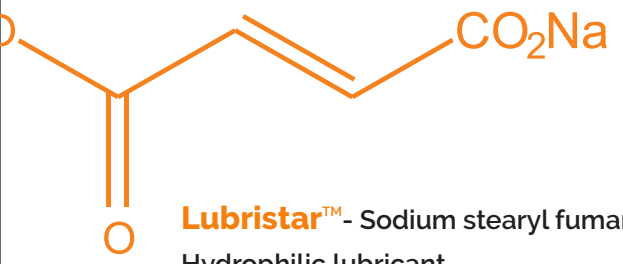
Gangwal Healthcare Pvt. Ltd., part of the prestigious Gangwal Group, has been a pioneer in the Pharmaceutical industry since 1987. Driven by the sense of social wellbeing and the steely determination to make a difference through technology and expertise, Gangwal Healthcare continues to be at the forefront of Pharmaceuticals, Nutraceuticals and Personal Care sectors in India. Nutraceutical industry globally, is a fastest growing market. As per the recent reports, India has remained 2% of the global nutraceutical industry of USD 400 billion and has potential to be a USD 50 billion by 2025 and USD100 billion by 2030. Our people are our core asset. Their vision, their ideas, their formulations, all connected at the core of Gangwal's success. The team turn our formulations into reality. A reality that has made Gangwal's name synonyms with INNOVATION & QUALITY

Mission

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

Vision

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



Lubristar™- Sodium stearyl fumarate (SSF)

Hydrophilic lubricant

Lubristar™ - Sodium stearyl fumarate (SSF) used in the manufacturing of tablets, capsules and other dosage forms. Due to its high hydrophilicity, it is used for high performance formulations, where other lubricant (i.e., magnesium stearate) fail to provide adequate stability, hardness, content uniformity, disintegration and dissolution rate.

Lubristar™ is used similarly as magnesium stearate with a same lubrication efficiency. However, due to less hardness, and insufficient tablets stability provided by conventional lubricating agents, SSF is very effective.

Lubristar™ has good compatibility with APIs and a perfect lubricant for high-performance formulations. It is used in various application such as wet granulation, dry granulation, and direct compression. Some of the properties of Lubristar™include anti-adherent, hydrophilic, control particle size, less sensitivity to blending time, high consistency compared to magnesium stearate.

Marketed formulations with Sodium stearyl fumarate

Almotriptane Malate	Zolpidem	Ibuprofen
Fluroxamine Maleate	Levofloxacin	Salicylic Acid
Nifidipine	Cefaclor	Metoprolol Succinate
Clarithromycin	Sulfasalazine	Vitamin B12
Azathioprine	Isosorbidmononitrate	Trandolapril
Fluvoxamine	Ketorolac	Donepezil-HCL
Metaxalone	Amlodipine	Pravastatin Sodium
Cilazapril	Albuterol Sulphate	Ramipril
Omeprazole	Tramadol	Diclofinac

Specification

Description

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

Empirical Formula

$C_{22}H_{39}NaO_4$

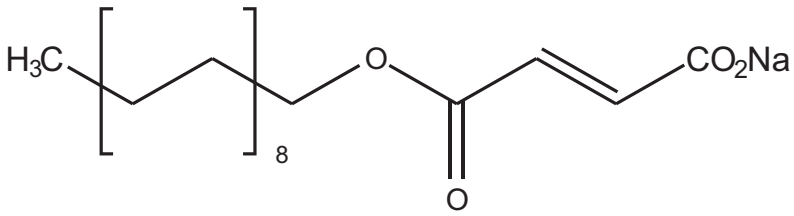
Molecular Weight

390.5

CAS NO

4070-80-8

Structural Formula

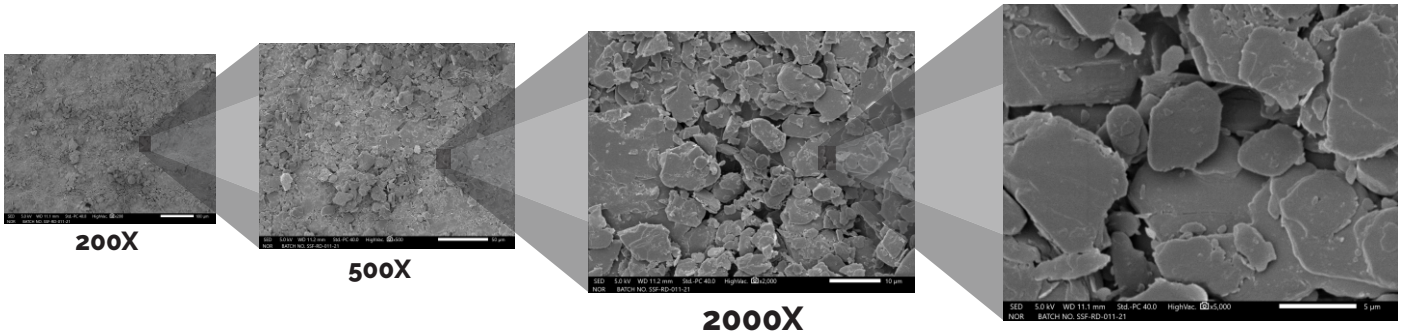


Functional Category

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.

Physical properties of Lubristar

- White fine powder
- Good lubrication properties
- Uniform particle size distribution



SPECIFICATION

Sodium stearyl fumarate is used as a lubricant in tablet and capsule formulations at 0.5–2.0% w/w concentration.

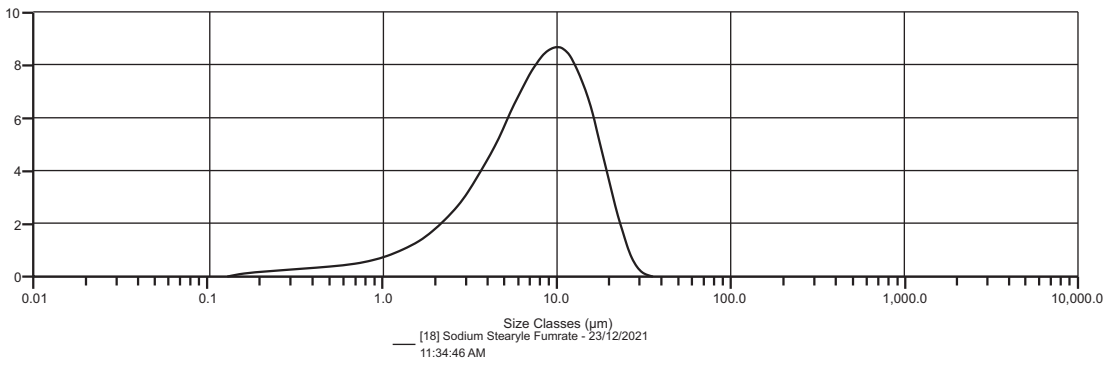
Physical properties:

Physical Properties	Result
Bulk density (g/mL)	0.33
Tapped density (g/mL)	0.45
Surface area	1.20 to 2.00 ms/gm

Particle size (by Malvern):

Particle size distribution of Lubristar™ is a key factor for optimal tableting results. Particle size on disintegration time is very well documented. Reduced particle sizes are directly linked with higher disintegration times.

Parameters	Result
d10	2.12 µ
d50	7.77 µ
d90	16.7 µ



SPECIFICATION

TEST	SPECIFICATION LIMITS
Description	White or almost white, fine powder.
Solubility	Slightly soluble in methanol, Practically insoluble in water, acetone and ethanol.
Identification A. (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.
B. (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
Specific Surface Area	(IH*) Between 1.2 to 2.0 m2/g
Residual Solvent Acetone Toluene	NMT 500 ppm NMT 890 ppm
Particle Size distribution (Laser diffraction)	(IH*) d 10 : Max 2.5µm d 50 : Max 20µm d 90 : Max 45µm

* IR- Infrared Spectroscopy | * IH- In house | * Ref- Reference of USP & EP

Experimental Section

Direct compression study

To provide more flexibility and reduce blending sensitivity associated with lubricants, direct compression study carried out to check the effects of addition of Lubristar™ compared to available marketed SSF in different ratios.

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). 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.

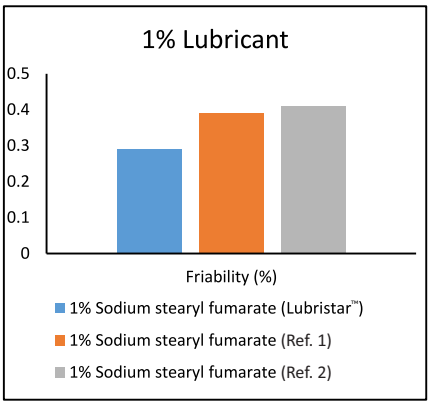
Tableting:

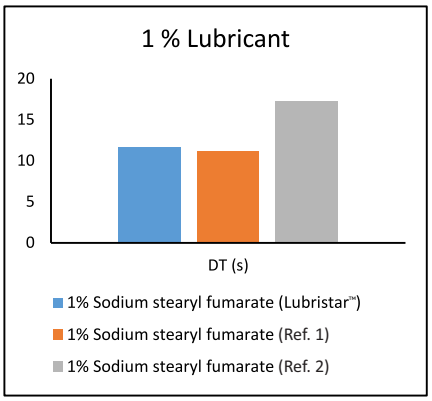
- Tablets were compressed by direct compression method using an automated rotary tablet press using 12 mm round flat punch.
- Tablet hardness kept at 80 – 100N. Main compression force required to achieve the desired hardness was measured.
- Tablet hardness was analysed using automated digital hardness tester. Disintegration time was analysed (n=6) using USP disintegration test apparatus.
- More robust tablets in terms of tablet hardness achieved using Lubristar in comparison to magnesium stearate.
- Sodium stearyl fumarate 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.
- Sodium stearyl fumarate appears to be a good alternative to conventional lubricant.

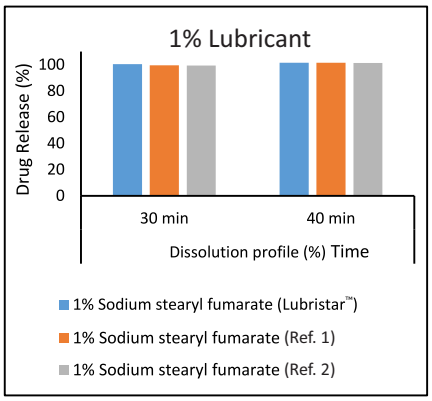
Experimental Section

Results shown in below table:

Parameters	Paracetamol granules with 1% Lubristar - SSF	Paracetamol granules with 1% SSF (Ref. 1)	Paracetamol granules with 1% MS (Ref. 2)
Friability (%)	0.29	0.39	0.41
D.T. (s)	12 to 16	10 to 14	15 to 20
Main Comp Force (tones)	4.1	4.3	5.4
"Dissolution profile (%)" 30 min	99	99	98
"Dissolution profile (%)" 40 min	100	100	99
Thickness (mm)	5.31 - 5.38	5.32 - 5.38	5.32 - 5.38
Hardness (kgf)	8 to 10	8 to 10	8 to 10
Average wt (mg)	800	800	800





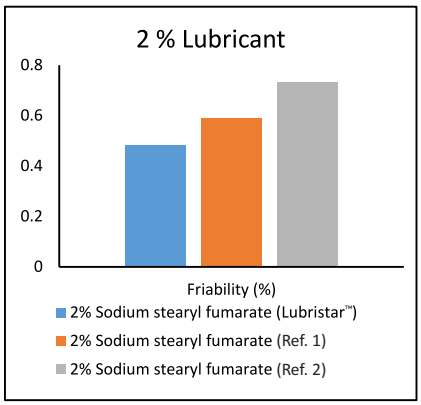


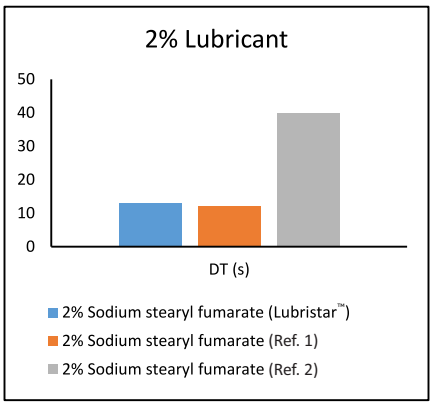
* Ref - Reference Product

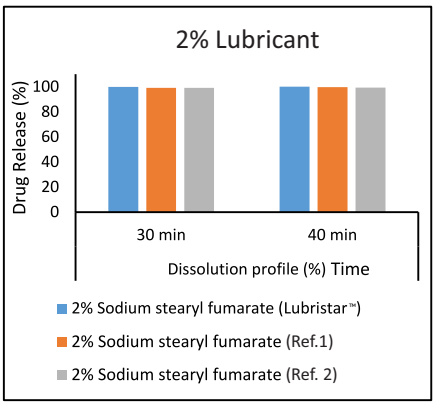
Experimental Section

Results shown in below table:

Parameters	Paracetamol granules with 2% Lubristar™	Paracetamol granules with 2% SSF (Ref. 1)	Paracetamol granules with 2% MS (Ref. 2)
Friability (%)	0.48	0.59	0.73
D.T. (s)	12 to 14	10 to 14	35 to 45
Main Comp Force (tones)	5.8	6	6.4
"Dissolution profile (%)" 30 min	99	99	98
"Dissolution profile (%)" 40 min	100	100	99
Thickness (mm)	5.30 - 5.37	5.32 - 5.37	5.30 - 5.36
Hardness (kgf)	8 to 10	8 to 10	4 to 6
Average wt (mg)	800	800	800







* Ref - Reference Product

SAMPLING & HANDLING

STANDARD PACKING	25Kg material packed in double food grade, virgin, LDPE bags kept in Fiber Board Drum.
STORAGE REQUIREMENT	Preserve in a closed container, store in a dry place, and avoid exposure to excessive heat, store protected from moisture.
EXPIRY DATE / RETEST DATE	Retest date - 3 Years from the date of manufacturing.
SAFETY PRECAUTIONS	Use hand gloves, goggles and nose mask for handling/sampling the product.

ACCREDITATION & USP

Regulatory compliance

Lubristar™ is manufactured at WHO-GMP and ISO certified facility.

Pharmacopoeia conformity: Lubristar™ available in USP, BP, JP and Ph. Eur.

Ready tech pack in line with regulatory requirement.

Regulatory Approvals

Sodium Stearyl Fumarate is also included in Inactive Ingredient database (IIG) of USFDA for Tablet, Capsule, Pellets, Suspension formulations.

Our manufacturing unit is approved by WHO-GMP, Written confirmation (WC) and ISO 9001 : 2008

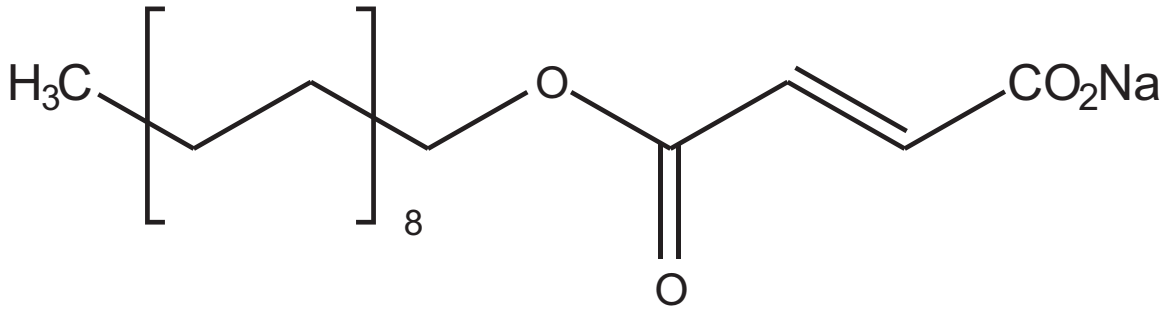
Lubristar™is having registered Type IV US-DMF No- 037309

Advantages of Lubristar

Formulation stability improvement	Less chances of over-lubrication
Reduced disintegration time	Improved compressibility
Better dissolution profile	Batch to batch consistency
Improved lubrication	Avoid incompatibility in comparison to MGST
Less sensitive to blending time	Less friability & capping
Customized particle size,	Custimized bulk density & surface area

Applications in Pharmaceutical Formulations

- Wet Granulation
- Dry Granulation
- Direct Compression



LUBRISTAR

GANGWAL

Contact for more information

Gangwal Healthcare Pvt. Ltd. :

705, Quantum Tower, Rambagh Lane, Behind State Bank Of India, Malad (west), Mumbai, Maharashtra 400064

CIN : U85300MH2021PTC359879, Tel.: 022 2888 8567, Whatsapp: +91 88792 21351 Email: info@gangwalhealthcare.com