NITIKA

Pioneering Nitrosomine-Safe Excipients

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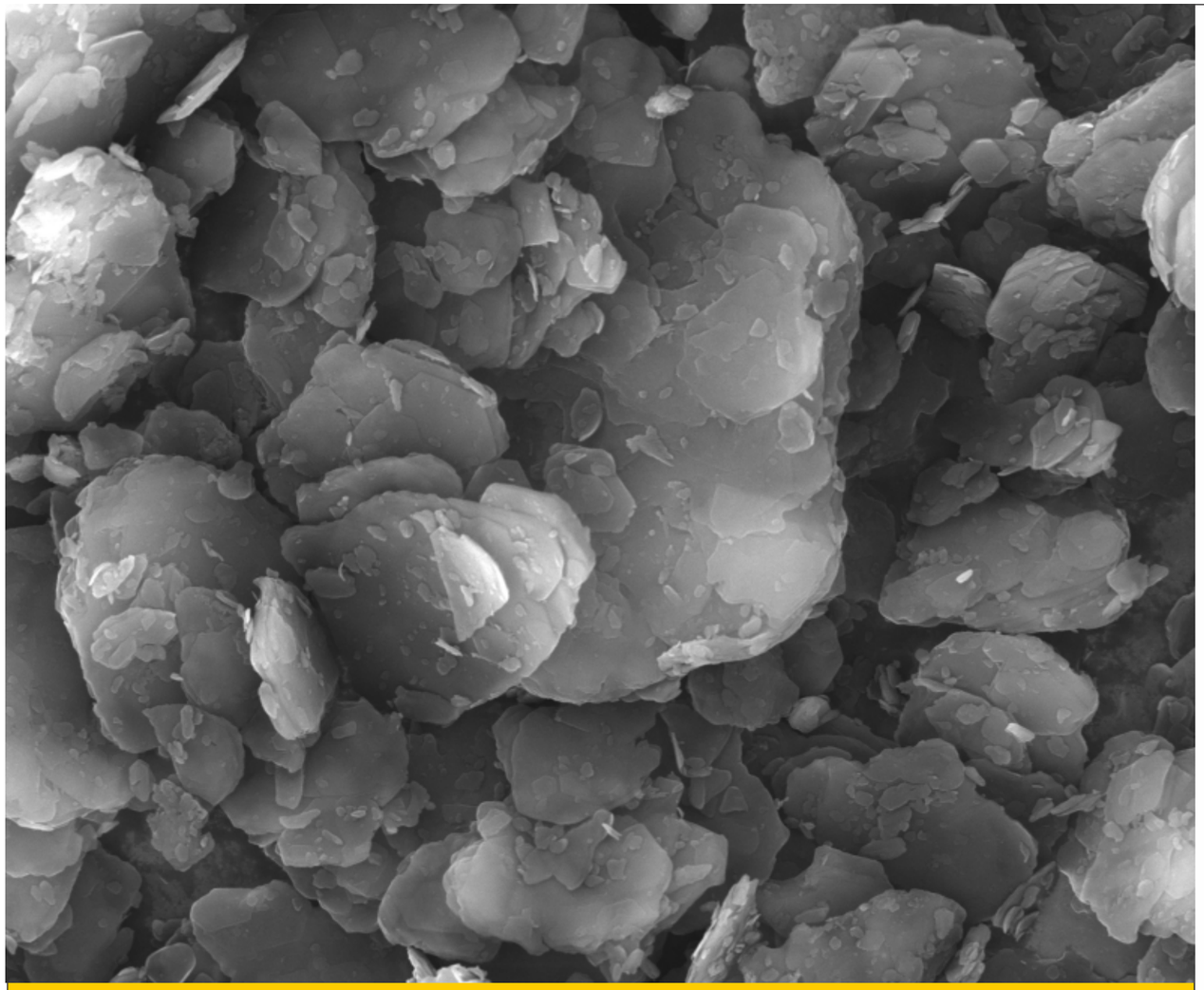
The Next
Generation
Lubricant ...

Nitika pharmaceutical specialities pvt ltd

NOVALUBE®

SODIUM STEARYL FUMARATE

UV Separation



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NOVALUBE Sodium Stearyl Fumarate (SSF) is a hydrophilic, non-metallic tablet lubricant that delivers efficient die-wall lubrication while preserving dissolution and disintegration-even with poorly water-soluble APIs, high drug loads, and ODT/chewable formats where mouthfeel matters. Unlike traditional metallic stearates, SSF does not introduce divalent metal ions and is less sensitive to blend time and concentration, helping maintain hardness and friability targets across direct compression, roller compaction, and wet granulation. The result is a cleaner, more predictable lubrication profile from development through commercial scale.

What makes Novalube Unique Lubricant

- **Minimal impact on release:** Hydrophilic profile preserves dissolution and disintegration kinetics
- **Robust to over-lubrication:** Lower sensitivity to blend time/use level than metallic stearates
- **Broad API compatibility:** Non-metallic with low reactivity; suitable for poorly water-soluble and taste-sensitive formulations (e.g., ODT/chewables)
- **Manufacturing ease:** Dual lubricant/anti-adherent action lowers ejection force, reduces sticking/picking, improves blend flow, and maintains consistent tabletability
- **Low-Nitrite option:** NOVALUBE® Low-Nitrite with batchwise ion-chromatography data (nitrite ≤ 0.05 ppm; nitrate < 1 ppm) to support nitrosamine-risk programs
- **Process-ready support:** Practical guidance on use levels blending endpoints, and compatibility across DC, RC, WG, and continuous trains

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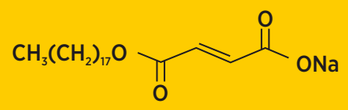
Novalube® Structure



Novalube® sodium stearyl fumarate exhibits lower hydrophobicity compared to magnesium stearate, attributed to the fumarate group at the end of its structure. Beyond enhancing water dispersibility, the inclusion of the fumarate moiety in Novalube ® raises the melting temperature, providing enhanced functionality during high-speed compression. The stearate chain in Novalube ® preserves lubricity, ensuring minimal ejection forces and preventing adhesion issues.

Novalube ® Properties	
Molecular Formula	$C_{22}H_{39}NaO_4$
Molecular weight	390.54
Physical State	Solid
Appearance	White Powder
Reccomended Use Level	0.5-2% of Formulation
Melting Point	220-240 °C
PH	8.04
Saponification value	141.2- 145.0
Specific surface area	1.2 m^2/g- 3m^2/g
CAS No.	4070-80-8

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NOVALUBE® LN

As a hydrophilic, non-metallic lubricant widely chosen for ODT/chewables and poorly water-soluble APIs, SSF must carry a consistently low nitrite/nitrate background to support modern nitrosamine-control strategies and stable long-term performance, results of batches mentioned as below;

Test	Batch No		
	SSFM4M185	SSFM4M186	SSFM4M187
Nitrate	< 1 ppm	< 1 ppm	< 1 ppm
Nitrite	< 0.05 ppm	< 0.05 ppm	< 0.05 ppm

Why Novalube® ?

- Enhances drug stability
- Improves lubrication efficiency
- Exhibits reduced sensitivity to blending time
- Ensures excellent batch-to-batch consistency
- Promotes faster dissolution rates
- Accelerates disintegration times
- Yields harder tablets compared to those produced with magnesium stearate
- Lowers the probability of overblending
- Facilitates faster formulation development and scale-up

Novalube® offers optimised Surface Area

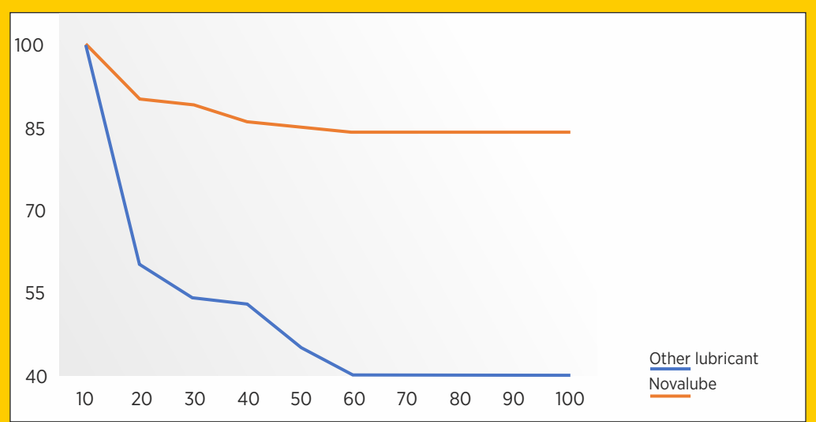
The surface area of the product is crucial for how well the excipient works, affecting its dissolution, disintegration rates, lubrication efficiency, moisture sensitivity and blend uniformity. In line with the Quality by Design (QbD) approach, Nitika Pharmaceuticals provides a variety of customized surface area of Novalube ® formulations. This tailored surface area meets the specific needs of formulators, ensuring compliance with QbD principles and promoting a comprehensive strategy for pharmaceutical quality.

Parameter	Custom 1	Custom 2	Custom 3
PSD (By image	D10: NMT 10 µm	D 10: NMT 2.5 µm	D 10: NMT 2.5 µm
microscopy)	D50: NMT 25 µm	D 50: NMT 20 µm	D 50: NMT 20 µm
	D90: NMT 45 µm	D 90: NMT 45 µm	D 90: NMT 43 µm
SSA (In House)	1.0 m^2/g – 5 m^2/g	1.2 m^2/g – 3 m^2/g	1.2 m^2/g – 2 m^2/g
Formulation type	Tablet Immediate	Capsule (Sustained Release)	Controlled Release (Coating)

Novalube® offers Improved Blending Robustness

The blending duration plays a critical role in the formulation process, and it has been observed that traditional lubricants like Magnesium Stearate, stearic acid are highly sensitive to the blending process. Even a slight over-blending with these lubricants can lead to a significant reduction in the mechanical strength of the final product.

In contrast, Novalube® exhibits a lower susceptibility to over-blending. This unique characteristic enhances the adaptability of process conditions, providing greater flexibility in the manufacturing process. Moreover, the reduced risk of batch failures attributed to over-blending minimizes waste and contributes to a more efficient and reliable production cycle.



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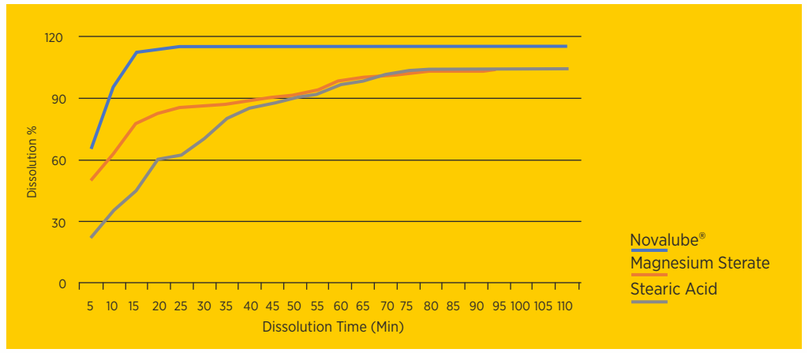
Novalube® offers improved dissolution

An API must dissolve within a fair amount of time to have a satisfactory bioavailability. If a medicine has a low or average solubility, it can cause major problems.

Conventional lubricants like Magnesium Stearate and Stearic Acid, known for their hydrophobic properties, can exacerbate the problem by slowing down the dissolution process. In contrast, Novalube ® , being more hydrophilic, minimizes interference with disintegration and dissolution.

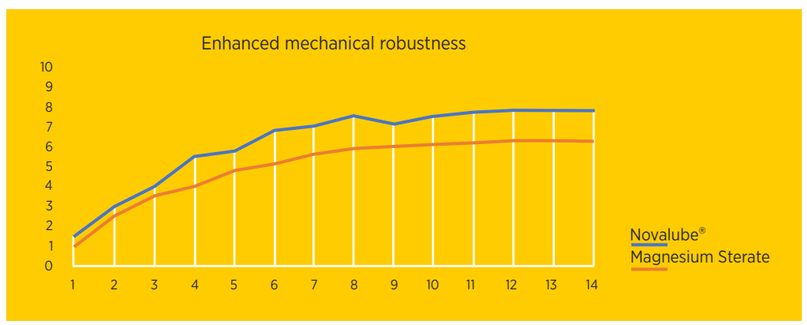
Comparative graphs highlight that, formulations with Novalube ® achieve significantly higher dissolution rates compared to those traditional lubricants, making it a more effective choice.



Novalube® offers ease of manufacturing

Novalube® Sodium Stearyl Fumarate exhibits superior temperature tolerance, accelerates tableting speed, improves production yield, and shortens formulation and scale-up times. It gives exceptional tablet hardness throughout the compression profile.

Graphical representations illustrate that tablets formulated with Novalube ® are mechanically more robust when compared to those utilizing alternative lubricants.



Novalube® offers increased lubrication efficacy

Reducing ejection force is crucial for a lubricant to prevent tablet attrition during the ejection process, which if left unaddressed, could lead to the destruction of tablet bonding, resulting in issues like tablet capping and lamination. Novalube ® demonstrates a significant reduction in tablet attrition, effectively mitigating the risk of tablet capping and contributing to improved overall tablet integrity.

Novalube® offers compatibility with a diverse range of APIs

Novalube® demonstrates compatibility with a broad spectrum of APIs, addressing concerns associated with traditional lubricants such as Magnesium stearate, stearic acid, and calcium stearate. For instance, widely used APIs like aspirin exhibit known incompatibility with Magnesium salts.

Novalube® enhances tablet stability and effectively mitigates API incompatibilities. It proves versatile in lubricating formulations, with few exceptions, where other excipients may demonstrate compatibility issues.

Antidepressant/Antipycotic Drug	Anticancer drug
• Lorazepam • Olanzapine	• Ondansetron Hydrochloride • Venclexta • Valsartan • Sitagliptin
Antihypertensive Drug	**Proton Pump Inhibitors (PPIs)**
• Trandolapril • Plendil • Cilazapril • Ramipril	• Omeprazole • Esomeprazole
Opioid antagonists	**Antithrombotic Agent**
• Buprenorphine-naloxone	• Clopidogrel
Lipid Lowering Agent	**Appetite Suppressant**
• Pravastatin Sodium	• Phentermine
Immunosupressant	**Antibiotics**
• Azathioprine	• Levofloxacin • Clarithromycin • Cefaclor
Calcium channel blocker	**Bronchodilators**
• Amlodipine	• Albuterol
NSAID's	**Keratolytic agents**
• Ketorolac • Ibuprofen • Diclofenac	• Salicylic Acid
Statins	**Serotonin Reuptake inhibitor**
• Pravastatin	• Fluvoxamine • Fluvoxamine Maleate

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Novalube® is available in compliance with IP/BP/USP-NF/JP /EP

Novalube® Complies with all major pharmacopoeias

IP	BP
USP	Ph. Eur

Commercial packaging
- 1 KG drum
- 5 KG drum
- 25 KG fiber drum

Available supporting documentation for Novalube ®

- BP/USP-NF/Ph.Eur. GRAS status
- DMF/USDMF
- BSE/TSE Statement
- Residual Solvent Statement (as per USP Chapter 467)
- Non-Animal Origin Statement
- Allergen-Free Statement
- Material Safety Data Sheet
- Specification sheet
- Elemental impurities sheet

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CERTIFICATIONs:

WHO GMP

Kosher

Excipact

Halal

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NITIKA PRESENCE

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