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NITIKA

Pioneering Nitrosomine-Safe Excipients

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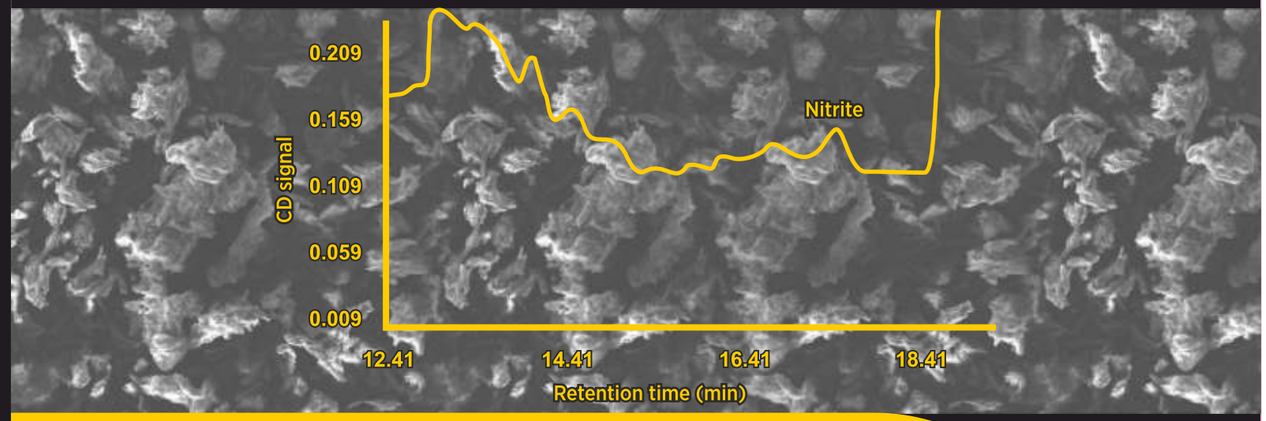

Nitrosamines - Safe Excipients

In-House Tested • Proven • Documented

MCC

LUBRICANTS

DISINTEGRANTS

ANTACID ACTIVES

MINERAL SALTS

- MCC manufacturing capacity 700mt/month expandable to 1200mt/month
- Spray drying technology
- Offering harmonised multicompendial grades

NITIKA

Vision

Impacting human lives positively.

Mission

Our Final Product ...
The Happy Customer.

WHAT SETS US APART

- Nitrosamines -Safe by Design
- Regulatory Ready
- Active US DMF / EU DMF

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SOME OF OUR HAPPY CUSTOMERS

Abbott · NOVARTIS · MERCK · Pfizer
Cipla · teva · HETERO · ik
SUN PHARMA · LUPIN · VIATRIS · gsk
Glenmark (A new way for a new world) · SANOFI · P&G · AUROBINDO

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ESG

- RSPO MB-certified operations ensure responsible, sustainable sourcing.
- 350 kWp solar plant cuts ~400 tons of CO_2 annually.
- Equals planting 18,000+ trees each year.

CERTIFICATIONS

KOSHER · ISO · EU GMP · BSE/TSE · HALAL · DSIR · GMO FREE · EXCiPACT · FDA DMF

NITIKA

1991 — **Started manufacturing fine chemicals**
Foundation year marking our entry into specialty chemistry

2005 — **US DMF #18912 (Magnesium Stearate)**
Enabling supply to regulated U.S. market

2007 — **European DMF #1252 (Magnesium Stearate)**
EU dossier established for broader market access.

2009 — **WHO-GMP certification**
Demonstrated compliance with internationally recognized GMP standards.

2023 — **MCC plant commissioned**
700 MT/month, expandable to 1200 MT/month

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Regulators now expect: assess → test → maintain controls, with explicit focus on excipient nitrite.A large cross-industry dataset (2,500+ tests, 130+ excipients) shows wide variability; so choose low-nitrite grades with validated ion chromatography

Partnering for Nitrosamine Control

- **Documentation on demand:** In-house validated IC method available
- **LN-grade excipients:** First in the world to offer low nitrite Magnesium Stearate and Sodium Stearyl Fumarate with 50 ppb nitrite level.
- **Batch proof on CoA:** Every lot released with nitrite/nitrate results
- **Regulatory mapping:** Aligned with FDA/EMA expectations for assess → test → results

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Pioneering Nitrosomine-Safe Excipients

LOW NITRITE EXCIPIENTS

≤50 ppb

Backed by IN-HOUSE Validated IC Method

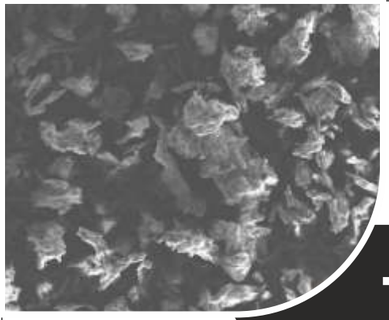
Comprehensive COA With Nitrite Result

Strict regulatory compliance

Supports with IC method validated documents

Every LN shipment includes ion-chromatography Results for nitrite & nitrate on the COA

1	2	3
Microcrystalline Cellulose LN grade	Magnesium Stearate LN grade	Sodium Stearyl Fumarate LN grade
Tabcell LN	**Tablube LN**	**Novalube LN**



TABCELL® Microcrystalline Cellulose

Tabcell Microcrystalline Cellulose is available with USDMF number 040341, tabcell complies with USP/NF/EP/BP/JP/IP.

TABCELL® (Microcrystalline Cellulose) Grade Selection Guide

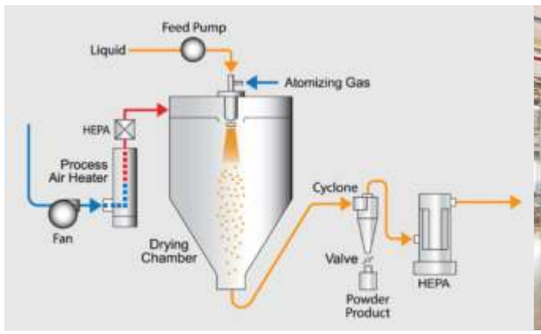
Type	LOD	Bulk Density	Particle Size		Distribution	
			D 10(µm)	D 50(µm)	D 90(µm)	
101	NMT 6.0	0.24-0.36	<30	45-75	>110	High shear wet granulation, Extrusion Spheronization
102	NMT 6.0	0.28-0.35	<50	90-140	>170	Direct Compression, Dry granulation
105	NMT 5.0	0.35-0.44	<15	17-27	>35	Direct Compression
112	NMT 1.5	0.28-0.34	<50	90-140	>170	Low Moisture Grade for Direct Compression, Dry Granulation
200	NMT 6.0	0.29-0.39	<85	150-280	>310	Direct Compression, Dry Granulation
302	NMT 6.0	0.35-0.46	<50	90-140	>170	Direct Compression

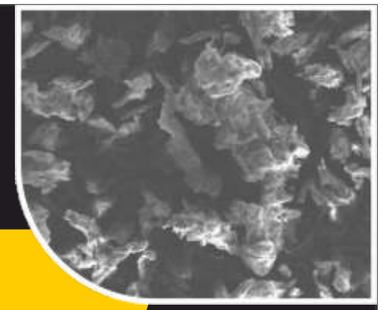
MCC manufactured using spray drying technology , advantages:

PROPERTY	SPRAY DRIED
Particle Size	Consistent & uniform
Flowability	Excellent Flowability
Compressibility	Excellent Compressibility
Appearance	Spherical Smooth Particle

Black particles control :

Nitika's 33 ft × 90 ft spray dryer ensures uniform drying with minimal product contact on hot surfaces, effectively reducing black particle formation. The fully enclosed stainless-steel system, HEPA-filtered air, and automated CIP cleaning further prevent contamination. With strict raw material selection and continuous in-process monitoring, Nitika delivers MCC with exceptional whiteness and visual purity





TABCELL LOW NITRITE GRADE

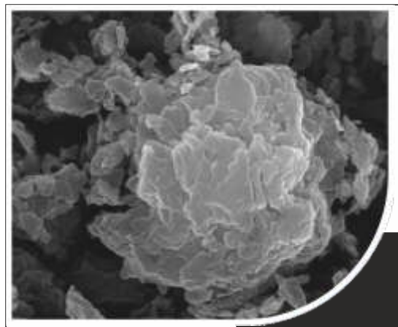
Tabcell® LN is your reliable solution for minimizing nitrosamine risk, delivering consistently low nitrite levels of less than 50 ppb in every batch with validated in- house ion chromatography method

Grade	Nitrite	Nitrate
Tabcell PH 101 LN	<0.05 ppm	<1 ppm
Tabcell PH 102 LN	<0.05 ppm	<1 ppm
Tabcell PH 112 LN	<0.05 ppm	<1 ppm
Tabcell PH 200 LN	<0.05 ppm	<1 ppm

CO-TABCELL Co-Processed Microcrystalline Celluloses

The table showcases various co-processed excipients with Microcrystalline Cellulose (MCC), highlighting their specific applications in pharmaceutical formulations. These co-processed excipients offer improved formulation efficiency, enabling better performance in solid dosage forms and dietary supplements.

Co-processed Excipient	Utilization
MCC+Sod.CMC(RC-591)	Thickner, stabilizer & emulsifier
MCC+Sod.CMC(RC-581)	Improve stability & texture
MCC+Sod.CMC(CL-611)	Food additive & pharmaceutical excipient
MCC+Silicon dioxide (SMCC)	Binder, disintegrant, diluent



TABLUBE® Magnesium Stearate

Tablube® is engineered for precise, reproducible lubrication across today's solid-dosage workflows. Whether your process is direct compression, wet granulation, or roller (dry) compaction, Tablube® forms an efficient boundary film-delivering smooth ejection, tooling protection, and stable tablet attributes.

With tightly controlled specific surface area, particle-size distribution, bulk and tapped density.

Tablube Magnesium stearate is available with USDMF No. 033414 and EUDMF No. 1252.

TABLUBE® (Magnesium Stearate) Grade Matrix

Characteristics	PREMIUM I	PREMIUM II	PREMIUM III	PREMIUM IV
Specific Surface Area	5-15 m^2/g	6-10 m^2/g	5-10 m^2/g	10-25 m^2/g
Bulk Density	0.10 to 0.30 g/cc	0.10 to 0.30 g/cc	0.15 to 0.35 g/cc	0.10 to 0.30 g/cc
Particle Size	D(10):3-8 µm	D(10):NMT 5 µm	D (10):5-10 µm	D(10):2-7 µm
	D(50):9-13 µm	D(50):7-11 µm	D (50):10-15 µm	D(50):8-12 µm
	D(90):15-35 µm	D(90):NMT50 µm	D (90):20-50 µm	D(90):13-30 µm

We offer customized surface area and particle size to meet specific formulation and performance requirements.

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TABLUBE® LN (Magnesium Stearate)

Magnesium stearate is present in most OSD formulas; without tight control it can be a persistent source of excipient-side nitrite/nitrate across lots and a driver of upward nitrosamine drift during stability. Choosing a low-nitrite grade lowers this baseline, stabilizes CQAs (Critical Quality Attributes) and lubrication performance, and simplifies nitrosamine risk justifications.

Tablube® Low-Nitrite is released with batch-wise ion-chromatography data, recent results are shown below;

Test	Batch No		
	MGST9M2310	MGST9M2311	MGST9M2314
Nitrate	< 1 ppm	< 1 ppm	< 1 ppm
Nitrite	< 0.05 ppm	< 0.05 ppm	< 0.05 ppm

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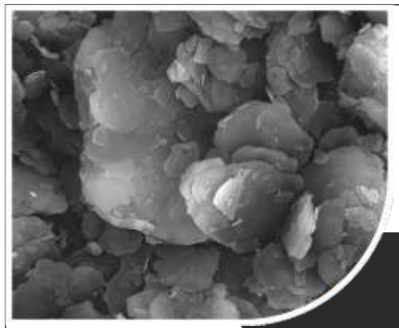

NOVALÜBE® Sodium Stearyl Fumarate

NOVALUBE Sodium Stearyl Fumarate is a hydrophilic lubricant, ideal for API's with poor water solubility and incompatibility with other lubricants.

It's a preferred choice for ODT tablets. Unlike traditional metallic stearates, it provides better mouthfeel, making it suitable for Melt-in-Mouth tablets. It minimally affects tablet dissolution, benefiting poorly soluble drug formulations, and requires lower concentrations, enabling use in situations with limitations on lubricant concentration.

NOVALÜBE® (Sodium Stearyl Fumarate)

PARAMETERS	CUSTOM 1	CUSTOM 2	CUSTOM 3
Particle size distribution	D10 :NMT 10 (µm) D50 :NMT 25 (µm) D90 :NMT 45 (µm)	D 10: NMT 2.5(µm) D 50: NMT 20 (µm) D 90: NMT 45 (µm)	D 10: NMT 2.5 (µm) D 50: NMT 20 (µm) D 90: NMT 45 (µm)
Specific surface area (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

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NOVALÜBE® LN (Sodium Stearyl Fumarate)

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 few 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

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OSD LUBRICANTS

ACILUBE® Stearic Acid Powder

TABLUBE C ® Calcium stearate

PHARMAPEG ® Polyethylene glycol Powder (400/600/6000/4000/3350)

NATLUBE® Clean label Lubricant for Nutraceutical Tablets

EFFERLUBE® Lubricant for Effervescent Tablet

OTHER STEARATES
Sodium / Zinc / Aluminium Monostearate / Distearate / Tristearate

NITIKA

SUPER DISINTEGRANTS/ BINDERS

PHARMELLOSE® Croscarmellose Sodium

TABSOL™ Sodium Starch Glycolate Maize / Potato

STANPURE ® Carboxymethyl Cellulose Sodium

TABSTAR® Pregelatinized Starch

GLIDANTS

TABGLIDE® Purified Talc

COATING MATERIALS

HYPROMALATE® Hypromellose Phthalate

TABELLOSE® (HPMC- E5, E15, E-6, K 100 M, K-4000)

PHARMAPEG ® Polyethylene Glycol Powder (400/600/6000/4000/3350)

COLNAT® Ferric Oxide (Red/Yellow/Brown /Black)

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DILUENTS

TABFIL -DD® Dibasic Calcium Phosphate Dihydrate

TABFIL – DA® Dibasic Calcium Phosphate Anhydrous

TABFILL - T ® Tribasic Calcium Phosphate

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ANTACID ACTIVES & PREMIXES

NEUTRA®
FOR NEUTRALIZING THE HYPERACIDITY

NEUTRA® SIMETHICONE RANGE OF PRODUCTS

Simethicone Powder (30%, 50%, 60%, 65%, 70%)
Simethicone Emulsion (30%)
Simethicone (100%)

NEUTRA® ALUMINIUM HYDROXIDE

Dried Aluminium Hydroxide Gel
Aluminium Hydroxide Gel

NEUTRA® MAGNESIUM ANTACIDS

Magnesium Hydroxide
Magnesium Oxide

NEUTRA® MIXTURES & CO-BLENDS

Magaldrate

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STANPURE® PURIFIED MINERAL SALTS

STANPURE The standerdised pure mineral Salts

Ferrous Fumarate	Calcium Carbonate
Ferrous Sulphate	Sodium Chloride
Calcium Citrate	Potassium Sulphate
Magnesium Sulphate	Sodium Bicarbonate
Sodium Carbonate	Magnesium Citrate
Titanium Dioxide	Zinc Sulphate
Magnesium Lactate	Zinc Chloride

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