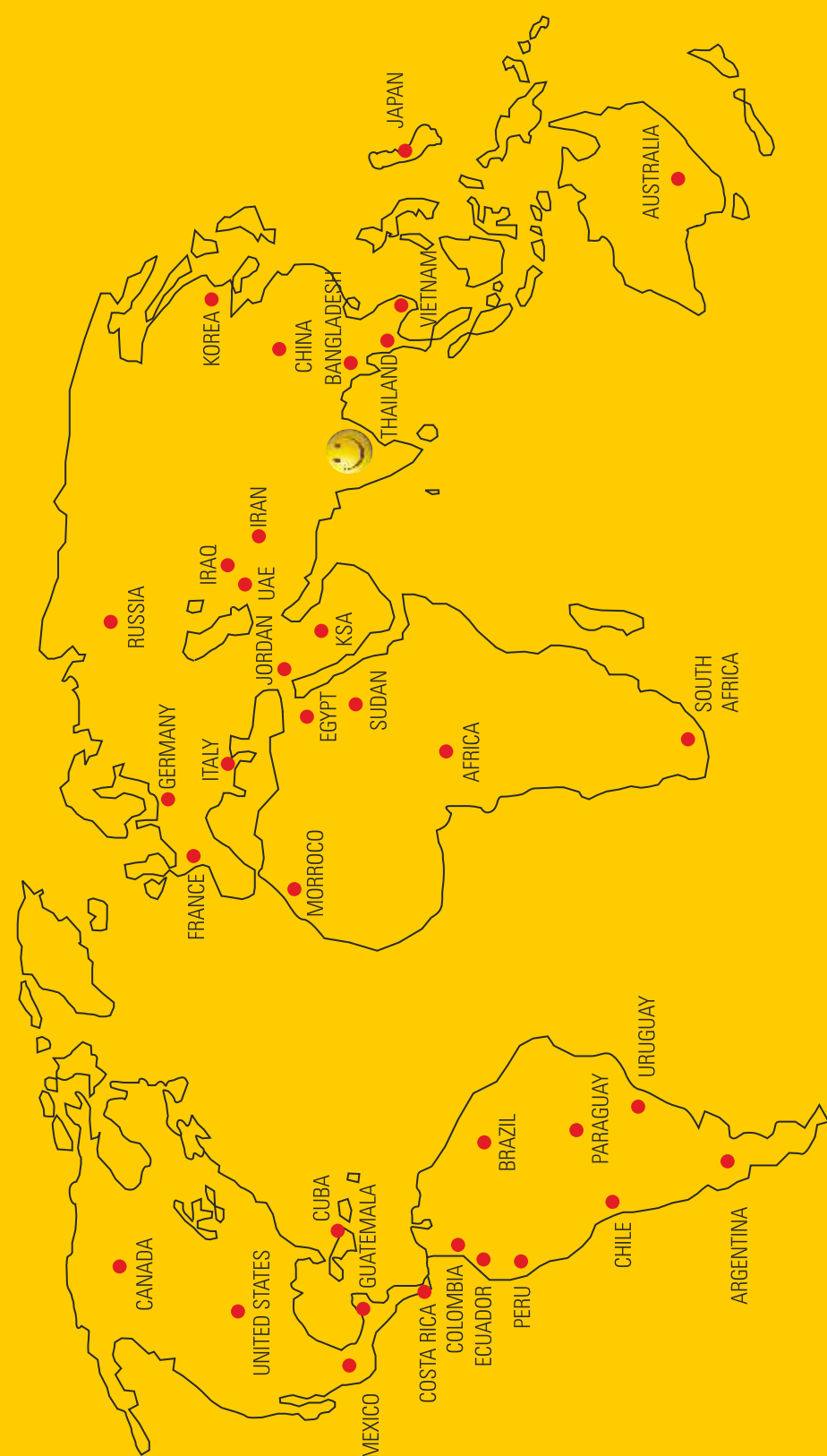


P R E S E N C E



Pioneering Nitrosomine-Safe Excipients

Nitika Pharmaceutical Specialities Pvt. Ltd.

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Email: enquiry@nitikapharma.com

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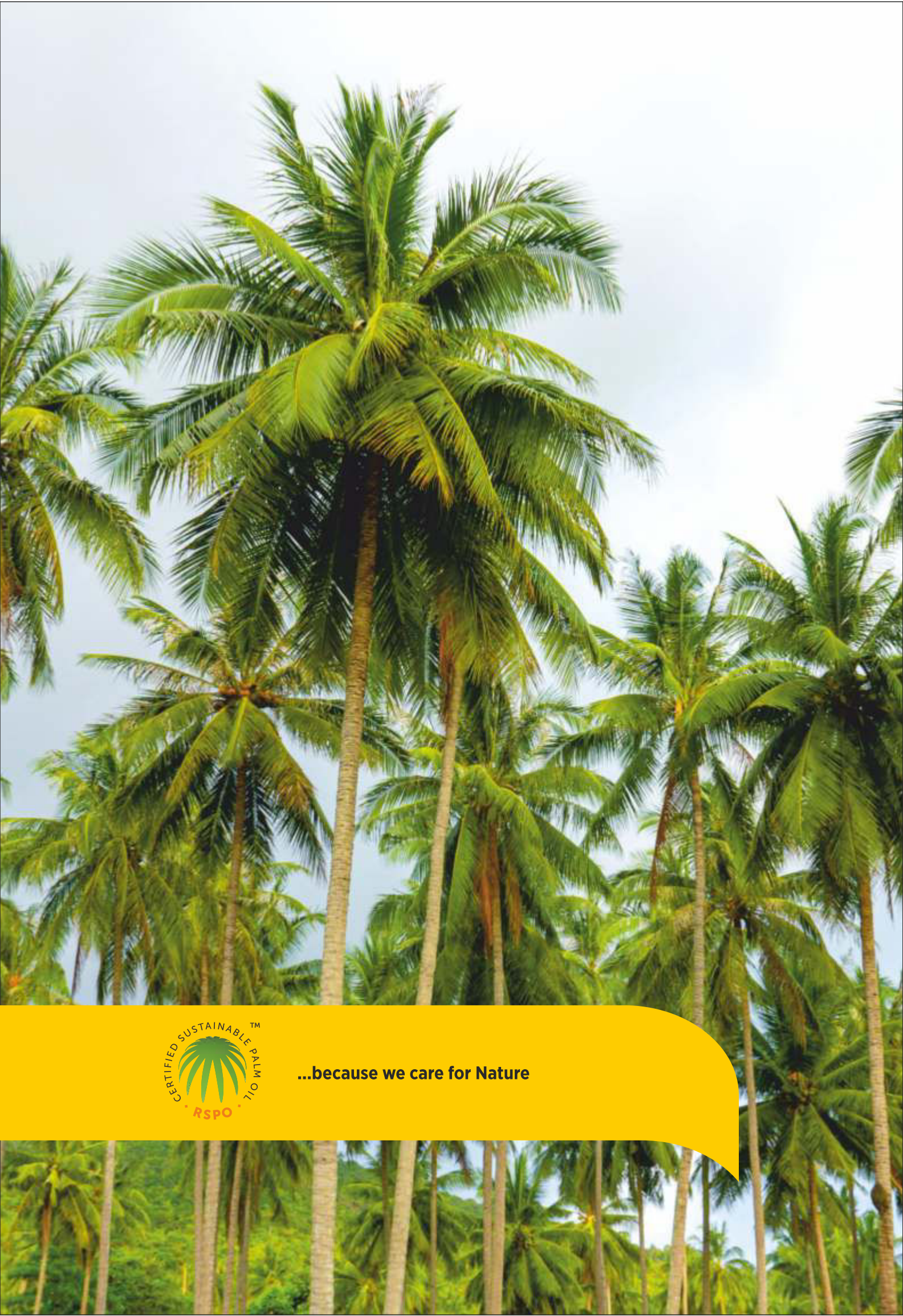


NITIKA

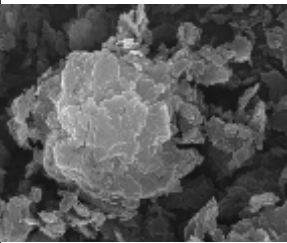
Pioneering Nitrosomine-Safe Excipients



TABLUBĒ[®] Magnesium stearate
....A lubricant with A difference !



...because we care for Nature



Magnesium Stearate

Magnesium stearate is the magnesium salt of long-chain fatty acids (predominantly stearic with a small palmitic fraction). It is a hydrophobic, fine powder that is practically insoluble in water and alcohols, physiologically inert.

In tablets and capsules it acts as a boundary lubricant: under shear/compaction it forms a thin film on particle and die-wall surfaces, lowering ejection forces, preventing sticking/picking, and protecting tooling.

Tablube®-Nitika’s Magnesium Stearate for predictable, scalable performance

- Proven platform: 32+ years of manufacture, supplied to 90+ countries/1,000+ customers.
- We meet the standards set by all major pharmacopeias, including Ph.Eur, USP/NF, JP, BP and IP; supported by US DMF No. 033414 and EUDMF No. 1252
- Tight control of CMAs: Grade-specific SSA, PSD, bulk & tapped density for reproducible lubrication across direct compression, roller compaction, and wet granulation
- Low-Nitrite option: Available with nitrite ≤ 0.05 ppm and nitrate < 1 ppm (batchwise ion-chromatography data) to support modern nitrosamine-risk strategies
- Responsible sourcing & quality: Vegetable-origin stearates with RSPO-aligned sourcing, GMP manufacture, full CoA traceability, and technical support on blend end points and scale

TABLUBE® (Magnesium Stearate) Grade Matrix

Characteristics	TABLUBE 0515	TABLUBE 0313	TABLUBE 0510	TABLUBE 1025
Specific Surface area	5-15 m ² /g	3-13 m ² /g	5-10 m ² /g	10-25 m ² /g
Bulk Density	0.10 to 0.30 g/cc	0.15 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):4-9(µm)	D (10):5-10(µm)	D (10):2-7(µm)
	D (50): 9-13(µm)	D (50): 10-14(µm)	D (50): 10-15(µm)	D (50): 8-12(µm)
	D (90):15-35(µm)	D (90):15-50(µm)	D (90):20-50(µm)	D (90):13-30(µm)

RSPO-Certified



Nitika is RSPO-certified, enabling fully vegetable-origin grades of magnesium stearate produced under certified chain-of-custody (SCC) controls. We maintain end-to-end traceability with qualified mills and oleochemical suppliers, verified by third-party audits, and—where available—can supply under RSPO Mass Balance or Segregated claim models with supporting purchase documentation and batch CoAs that note RSPO status. Our program aligns with NDPE principles (no deforestation, no peat, no exploitation), helping customers advance responsible-sourcing and Scope-3 objectives. Crucially, RSPO compliance is layered onto our GMP and pharmacopeial standards, so there is no trade-off in quality, performance, or regulatory readiness for your Tablube® vegetable grades

THE MECHANISM OF TABLUBE® (MAGNESIUM STEARATE)

- Magnesium Stearate exists as “plate-like” crystals, stacked like a deck of cards. As blending progresses, these plates shear off the stack and coat adjacent particles or granules.
- The higher the concentration of Magnesium Stearate used, or the longer the blending continues, the more complete the coating becomes. This characteristic improves lubrication and enhances powder flow during the tableting process.



TABLUBE® LN

Magnesium Stearate Low Nitrite Grade

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

Nitrite Levels in Magnesium Stearate :
Lhasa Limited conducted an evaluation of nitrite levels in Magnesium Stearate samples obtained from nine different suppliers. A total of 44 results were analyzed, showing nitrite concentrations ranging from 0.1 to 6.1 µg/g, with a mean value of 2.6 µg/g.

Nitrite Results (µg/g)						
Excipients	min	Mean	Median	Max	No. of Suppliers	No. of Results
Magnesium Stearate	0.1	2.6	2.4	6.1	9	44

- This study highlights**
- Data demonstrates that the nitrite content in magnesium stearate is among the highest when compared to other excipients studied
 - Nitrite concentrations ranging from 0.1 to 6.1 µg/g, with a mean value of 2.6 µg/g. This study highlights the variability in nitrite content across commercially available sources
 - The nitrite concentration varies even from the same supplier

TABLUBE® LN (Magnesium Stearate)

Keeping in mind the growing concern over nitrosamine impurities the need for low-nitrite (LN) grades of various excipients, Nitika has developed for the first time in the world the low Nitrite grade of Magnesium Stearate. By utilizing LN grade Magnesium Stearate, manufacturers can significantly reduce the risk of nitrosamine formation, ensuring the safety and efficacy of their drug products. Nitika introduces TABLUBE(r)LN, specifically formulated to minimize nitrosamine formation while adhering to industry guidelines. This low-nitrite Magnesium Stearate not only enhances product safety but also ensures regulatory compliance in pharmaceutical applications; Nitrite and Nitrate results for batches as below ;

TEST	BATCH NO		
	MGST9M2310	MGST9M2311	MGST9M2314
Nitrate	<1 ppm	<1 ppm	<1 ppm
Nitrite	<0.05 ppm	<0.05 ppm	<0.05 ppm

Challenges Due to Poor Quality Magnesium Stearate



TECHNICAL ADVANTAGES OF USING TABLU[®]

- Specified Particle size distribution
- Clearly defined Specific surface area
- Desired Functionality
- Specific reproducible bulk density
- Excellent Whiteness Index >90 %
- High batch to batch consistency

In-House laser diffraction technology to measure particle size



FUNCTIONALITY BENEFITS

- Proper hopper flow can be achieved.
- Minimal ejection force required
- Efficiency in production could be achieved.
- Life of Dies and punches improves.
- Avoid picking & sticking
- Increases tablet friability
- Reduces wear & tear
- Smooth & shiny tablets
- Act as Flowability agent

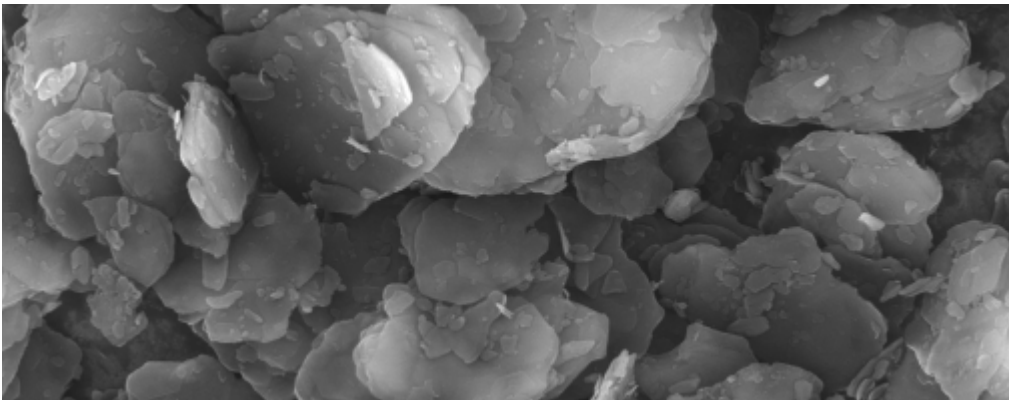
PUBLISHED CASE STUDY – QBd Approach

As per the Research Article published in International Journal of Pharmaceutical Sciences and Research, 2012, Volume 3, this article is giving emphasis on the decisive role of particle size of highly hydrophobic lubricant i.e. Magnesium Stearate, its concentration and lubrication time to establish the desired quality attributes of formulation containing highly soluble model drug Metformin Hydrochloride. Magnesium Stearate from Nitika (F1-F9) and one of the top global manufacturer (F10-F18) with different Particle size distribution (PSD) range was selected.

Code of Magnesium stearate	Particle size distribution (PSD)	Specific surface area
A (Nitika F1-F9)	D(50) = 40.8 Microns	4.15 m²/gm
	D(90) = 71.3 microns	
B (Global mfg. F10 -F18)	D(50) = 12.7 Microns	6.4 m²/gm
	D (90) = 23 microns	

COMPOSITIONS OF THE STUDIED FORMULATIONS AND THE MEASURED RESPONSES

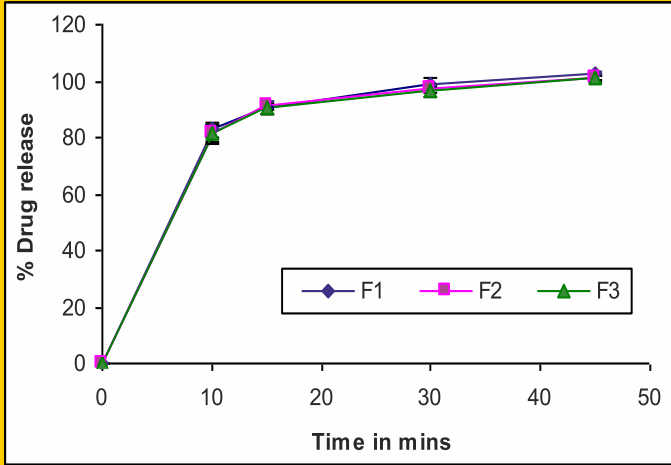
Independent Factors							Dependent Factors					
Code	Particle size	Lubrication conc.	Mixing time	CI	HR	FRI	HD	DT	Dissolution (Min.Sec)			
									10 min	15 min	30 min	45 min
F1	A	0.75%	5	13.8±1.2	1.12±0.21	0.242±0.025	14.3±1.5	8.52±0.24	82.8±2.5	90.3±1.8	99.1±1.8	102.4±0.75
F2	A	0.75%	10	14.2±1.7	1.16±0.34	0.257±0.018	12.8±1.8	8.47±0.33	81.5±3.1	91.2±1.5	97.2±1.0	100.8±0.8
F3	A	0.75%	15	13.3±1.1	1.14±0.15	0.254±0.023	13.6±2.1	9.12±0.28	81.2±3.2	90.7±2.4	96.7±2.1	101.3±1.2
F4	A	1.00%	5	15.1±0.8	1.23±0.18	0.219±0.037	14.1±1.9	9.54±1.06	76.5±3.5	88.4±2.7	94.5±1.6	99.4±0.58
F5	A	1.00%	10	14.6±1.6	1.19±0.27	0.388±0.041	12.6±1.5	8.46±0.47	74.8±4.1	85.5±2.8	93.9±1.7	100.5±1.1
F6	A	1.00%	15	15.4±1.2	1.24±0.21	0.345±0.028	12.3±1.4	10.15±0.25	73.1±3.4	82.5±2.3	92.7±1.9	98.8±0.9
F7	A	1.25%	5	16.0±1.4	1.21±0.28	0.347±0.038	14.3±1.3	9.30±0.49	67.5±2.7	80.1±1.8	91.4±1.3	99.9±0.7
F8	A	1.25%	10	16.1±1.2	1.11±0.19	0.339±0.042	14.7±1.6	10.58±1.02	67.1±4.6	78.5±2.7	90.4±2.0	102.1±1.8
F9	A	1.25%	15	16.8±1.5	1.13±0.22	0.319±0.026	13.2±2.1	11.12±0.36	64.5±5.6	77.8±3.2	89.8±2.4	99.4±1.5
F10	B	0.75%	5	14.5±1.2	1.26±0.31	0.473±0.035	13.8±1.1	13.39±0.46	58.8±5.2	67.9±3.6	90.1±2.4	98.9±2.2
F11	B	0.75%	10	16.8±1.1	1.22±0.15	0.436±0.027	13.5±1.5	13.15±0.54	46.7±4.7	59.5±3.8	87.4±2.6	97.2±1.1
F12	B	0.75%	15	15.9±1.2	1.13±0.11	0.318±0.031	13.8±1.2	13.54±0.55	38.0±3.7	51.9±2.2	81.6±1.3	95.8±0.7
F13	B	1.00%	5	16.8±1.5	1.20±0.33	0.331±0.021	14.1±1.7	13.48±0.38	48.2±4.2	66.4±2.9	91.7±1.8	100.5±0.8
F14	B	1.00%	10	16.5±0.8	1.31±0.31	0.419±0.019	13.2±1.4	14.56±1.24	38.6±5.1	51.6±3.2	80.5±2.6	94.4±1.8
F15	B	1.00%	15	17.6±0.6	1.25±0.24	0.404±0.042	13.6±1.1	14.38±1.07	35.6±4.2	48.3±2.4	77.2±2.1	96.5±2.2
F16	B	1.25%	5	19.4±1.1	1.30±0.23	0.458±0.033	11.4±1.8	16.45±0.58	39.8±4.8	52.4±3.6	83.1±2.6	97.4±2.7
F17	B	1.25%	10	20.1±0.8	1.37±0.21	0.563±0.047	10.7±2.2	18.11±1.22	33.1±3.7	44.9±2.5	70.6±1.8	85.8±1.5
F18	B	1.25%	15	19.7±1.3	1.29±0.15	0.584±0.040	10.5±1.3	18.5±1.04	29.8±5.6	41.4±3.7	68.0±2.5	84.7±2.1



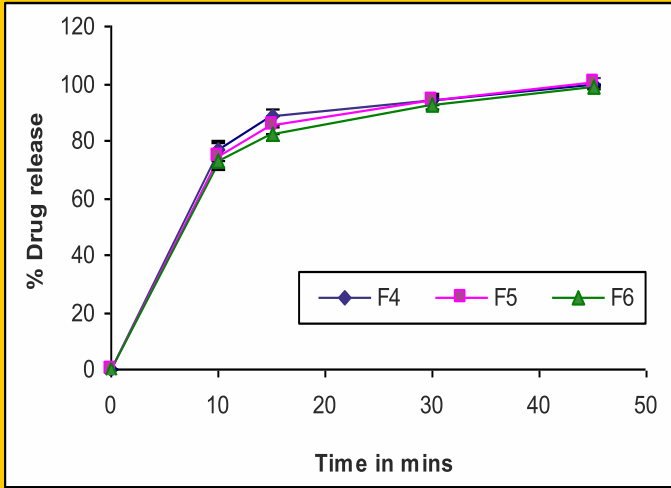
This study shows impact on release profile of Metformin HCl tablet by using magnesium stearate manufactured by Nitika and one of the top global manufacturer. Study includes magnesium stearate with different particle size , concentration and mixing time.

**DISSOLUTION PROFILE OF FORMULATIONS
MADE WITH NITIKA MAGNESIUM SEARATE**

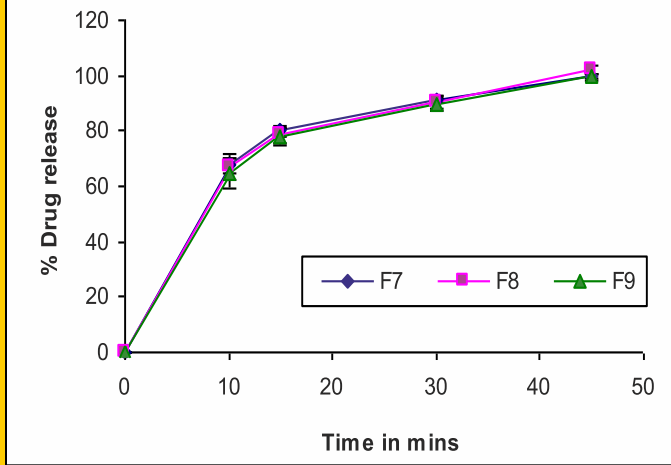
Magnesium Searate 0.75%



Magnesium Searate 1.0%

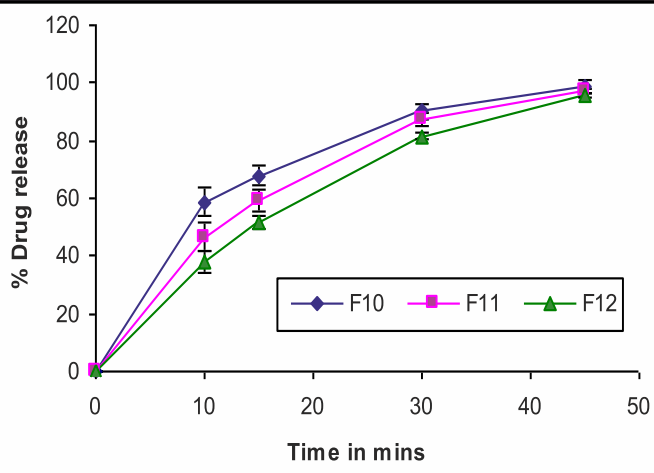


Magnesium Searate 1.25%

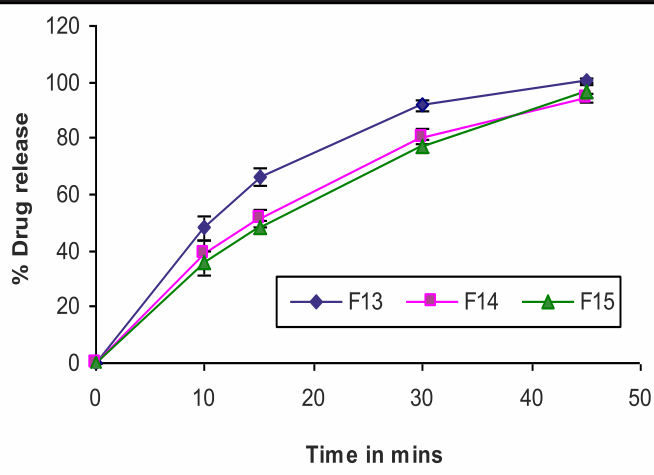


**DISSOLUTION PROFILE OF FORMULATIONS
MADE WITH OTHER MAGNESIUM SEARATE**

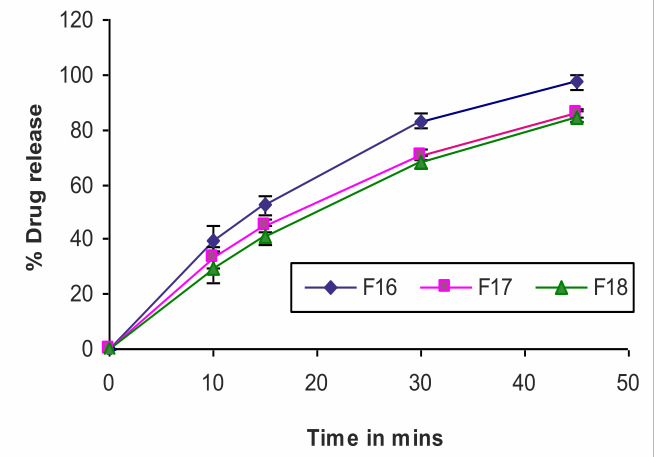
Magnesium Searate 0.75%



Magnesium Searate 1.0%



Magnesium Searate 1.25%



CASE STUDY - CONCLUSION

This study concluded that the change in particle size hence surface area of Magnesium Stearate, along with concentration and lubrication time, can affect the properties of a blend or tablets significantly, such as disintegration time, hardness and most importantly dissolution.

The tablets, containing Magnesium Stearate of larger particle size, have shown the highest percentage of drug release at initial time points as a consequence of poor hydrophobic coating on granules of highly soluble drug. However, tablets contain Magnesium Stearate with smaller particle size and larger surface area had shown a slower drug release profile.

The study investigated that by selecting appropriate particle size of Magnesium Stearate along with some other factors like lubrication concentration and blending time, we can achieve the desired release profile and a very high quality, cost effective formulation.



REGULATORY SUPPORT

- USDMF available
- EXIPACT certified
- Non animal Origin
- TSE-BSE free
- GMO Free
- Elemental impurity statement
- WHO-GMP
- HALAL certified
- Kosher certified
- Organic volatile impurity free declaration
- QBD support for formulation development

SOME OF OUR HAPPY CUSTOMERS



CERTIFICATIONS

