

VEGHA

by
Pehel Specialities

Sodium Stearyl Fumarate
Ph. Eur / USP - NF / JPE

About Pehel Specialities

"पहल" - or Pehel, is a Sanskrit word which means "To begin", These words have as much meaning today as they did when we started. In an ever changing global environment we are always beginning.

Pehel Specialities is family owned and managed - where we value long lasting relationships. The roots of Pehel can be traced to 1984 where we made our first foray into the domestic pharmaceutical market of India.

Guided by the Zota family values of persistence, dedication and resourcefulness, Pehel has reached the pinnacle of the Indian excipient industry and this for us - **is just the beginning**

A key factor to our success is the high caliber of our personnel which have ensured that we lead the excipient industry in India and abroad.

"**Quality is mindset**" - These words embody the company wide ethos of every team member in Pehel, which ensures that you get the not only the highest quality material, but the highest quality relationships and problem solving ability.

In all we welcome you to the Pehel family and look forward to an exciting journey ahead.

*At Pehel, we understand that the quality of our products directly correlates to the success of our business. That's why we make it our mission to **consistently deliver the highest quality products to our customers***

Our Values



Team Work

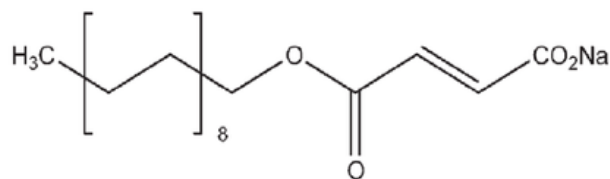


Relationships



Quality

VEGHA - Sodium Stearyl Fumarate is a hydrophillic lubricant which is used in formulations where other traditional lubricants are incompatible or either have manufacturing or process challenges.



Applications of **VEGHA**

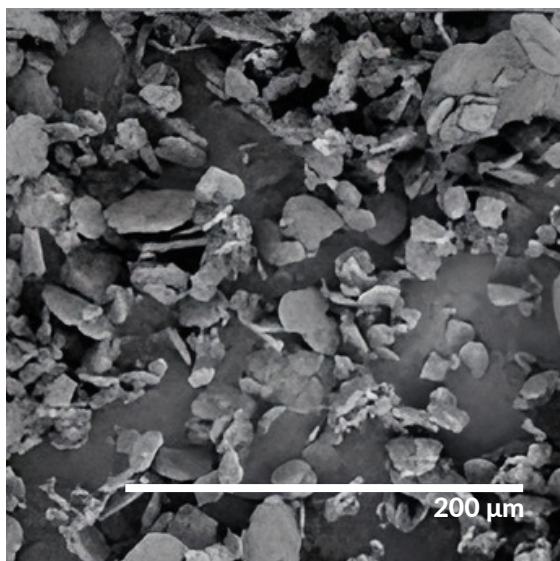
- Tablets
- Continuous manufacturing
- Direct compression
- Dry granulation
- Hot melt extrusion
- Wet granulation

Benefits of **VEGHA**

- Enhanced lubrication efficiency
- Faster dissolution rates
- Faster formulation development
- Harder tablets
- Improved drug stability
- Protection from over-blending

VEGHA - is a white crystalline powder and is valued for its excellent flowability, compressibility, and ability to reduce friction between particles. It is also considered to be a safe and effective ingredient and Generally Recognised As Safe. It reduces friction during tablet compression by adsorbing onto the surface of powder particles, forming a protective layer that reduces interparticle friction. Additionally, the polar carboxylate groups on the fumarate moiety interacts with the surface of

manufacturing equipment, reducing the adhesion between the powder and the equipment surface.



SEM of VEGHA -Sodium stearyl fumarate

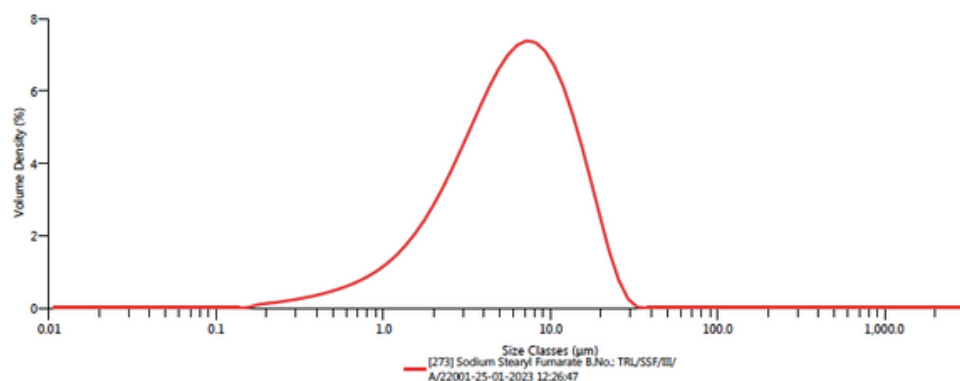
VEGHA

- is produced under IPEC-PQG-GMP conditions
- shows outstanding lubricating properties
- Consistent controls throughout the production process provide a high level of batch to batch consistency
- is of the highest quality

Controlled Particle Size

D90 - Max 45 μm
D50 - Max 20 μm
D10 - Max 2.5 μm

Surface Area -
1.2 - 2 m^2/g



VEGHA - is engineered for the ideal particle size and surface area, consistently so that your formulation can have the the desired hardness, dissolution and lubrication.

VEGHA vs Magnesium Stearate

VEGHA - offers several advantages over magnesium stearate as an excipient in pharmaceutical formulations.

- **Hardness** - It results in better tablet compression leading to higher tablet hardness.
- **Dissolution** - It doesn't form a coating around the drug particles and unlikely to interfere with dissolution
- **Disintegration** - It has better disintegration properties as compared to magnesium stearate and helps in faster drug release.
- **Over blending** - It has better flow properties which improves blend uniformity and reduces the likelihood of segregation during formulation

A few formulations, which use **VEGHA**

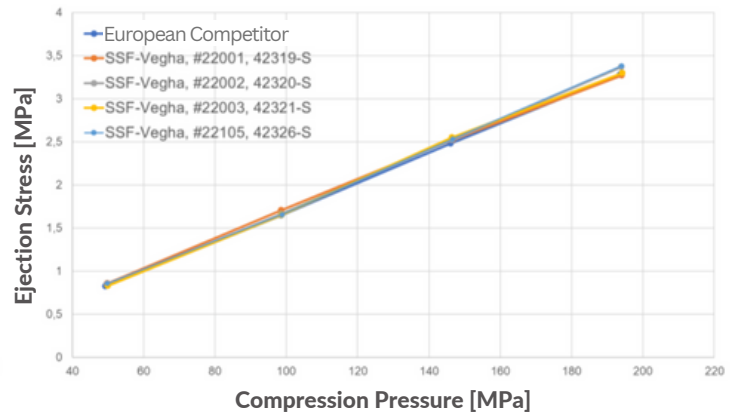
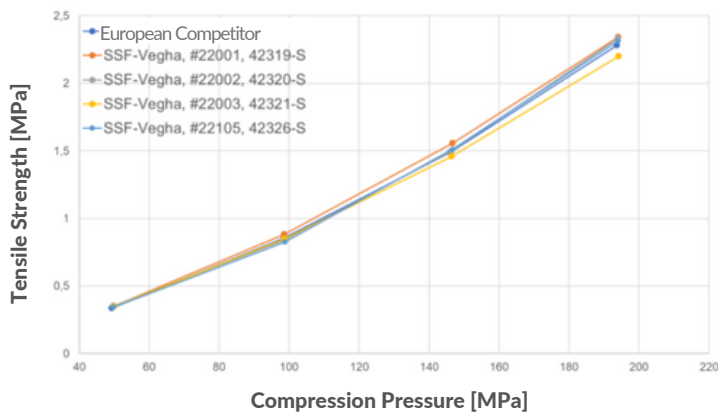
- | | | |
|-----------------------|--------------------------|------------------|
| • Albuterol Sulphate | • Ibuprofen | • Ramipril |
| • Almotriptane Malate | • Isosorbide mononitrate | • Salicylic Acid |
| • Amlodipine | • Ketorolac | • Sitagliptin |
| • Cefaclor | • Levofloxacin | • Sulfasalazine |
| • Cilazapril | • Metoprolol Succinate | • Tramadol |
| • Clarithromycin | • Nifedipine | • Trandolapril |
| • Donepezil-HCL | • Omeprazole | • Vitamin B12 |
| • Fluroxamine Maleate | • Pravastatin Sodium | • Zolpidem |

*list is not exhaustive or comprehensive

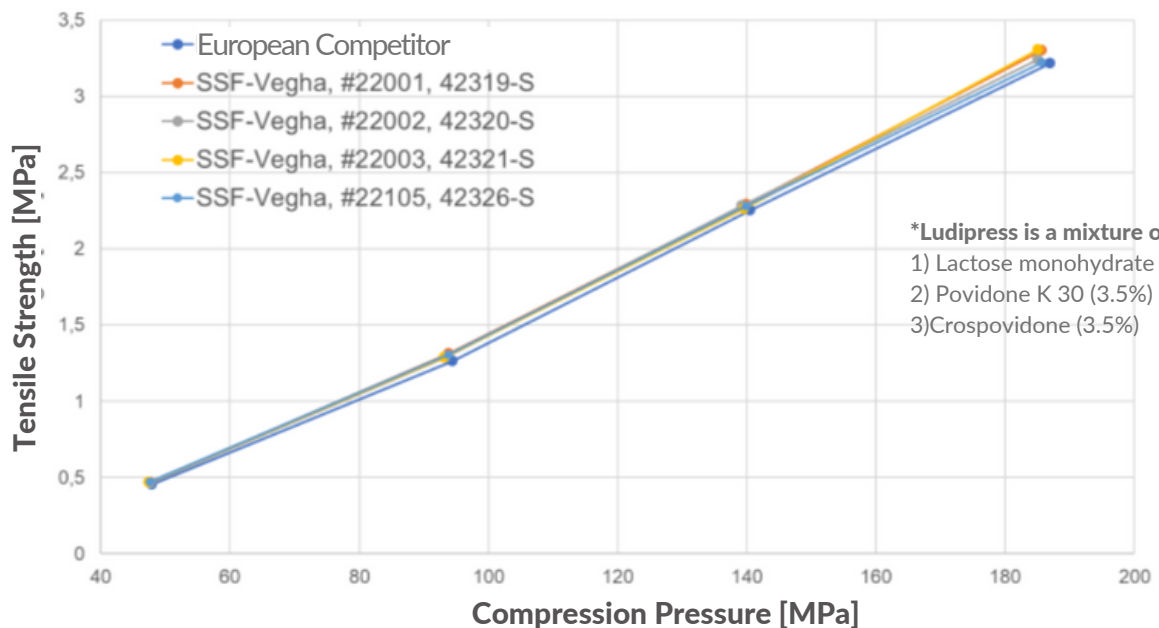
Application Test

Preliminary application studies show that **VEGHA** is comparable to European competitor. Detailed studies are ongoing.

500 mg Tablets of 2% SSF and 98% Di-CAFOS



500 mg Tablets of 1% SSF and 99% Ludipress*[®]



*Ludipress is a mixture of
1) Lactose monohydrate (93%),
2) Povidone K 30 (3.5%)
3) Croscopovidone (3.5%)

Ask your local sales representative for detailed studies and information.

VEGHA

gives consistent performance across multiple batches and similar to European competitor

Properties of VEGHA

Molecular Weight	390.5	Water	Max 5.0% w/w
CAS#	4070-80-8	Saponification Value	142.2 - 146
pH	About 8.5	Assay	99.0% - 101.5%
Recommended Use	0.5% - 2%	Melting point	224 - 245 C



Available Packing

5 Kgs Drum

25 Kgs Drum

Storage conditions

Store at ambient temperature
away from extremem conditions



Regulatory information

- Ph. Eur / USP - NF / JPE
- Synthetic origin
- BSE / TSE
- Halal / Kosher
- GRAS
- Nitrosamines Risk Evaluation
- Elemental Impurities based on ICH Q3D Guideline
- Residual Solvents as per USP/NF, European Pharmacopeia and ICH-Q3C
- ISO 9001-2015, GMP

*Ask your sales representative for detailed information



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VEGHA

PEHEL SPECIALITIES

You focus on growth - We've got the ingredients

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