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.

$$H_3C$$
  $O$   $CO_2N_6$ 

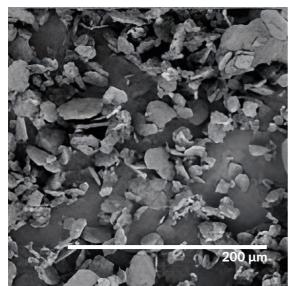
#### Applications of **VEGHA**

- 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 with low toxicity and minimal side effects. It reduces friction during tablet compression by adsorbing onto the surface of powder particles, forming a protective layerthat reduces interparticle friction. Additionally, the polar carboxylate groups on the fumarate moiety interacts with



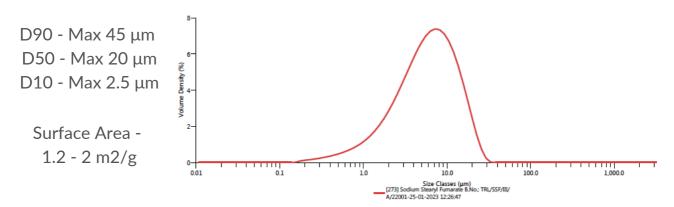
SEM of VEGHA -Sodium stearyl fumarate

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

#### **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**



**VEGHA** - is engineered for the ideal particle size and surface area, **consistently** so that your formulation can have 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
- Almotriptane Malate
- Amlodipine
- Cefaclor
- Cilazapril
- Clarithromycin
- Donepezil-HCL
- Fluroxamine Maleate

- Ibuprofen
- Isosorbid mononitrate
- Ketorolac
- Levofloxacin
- Metoprolol Succinate
- Nifidipine
- Omeprazole
- Pravastatin Sodium

- Ramipril
- Salicylic Acid
- Sitagliptin
- Sulfasalazine
- Tramadol
- Trandolapril
- Vitamin B12
- Zolpidem

#### Properties of VEGHA

| Molecular Weight | 390.5     | Water                   | Max 5.0% w/w   |
|------------------|-----------|-------------------------|----------------|
| CAS#             | 4070-80-8 | Saponification<br>Value | 142.2 - 146    |
| рН               | 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 exterem 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



#### Disclaimer

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# PEHEL SPECIALITIES

You focus on growth - We've got the ingredients

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