PEHEL SPECIALITIES

VEGHA

01/03/2024

EQUIVALENCY REPORT OF SODIUM STEARYL FUMARATE

Dear Customer,

In the dynamic realm of pharmaceutical manufacturing, where competition and market uncertainties persistently challenge business norms, the importance of cost reduction has never been more pronounced. As a trusted partner in your journey towards efficiency and excellence, we are committed to providing solutions that not only meet but exceed your expectations.

In this regard, we are thrilled to present a study that addresses a critical aspect of pharmaceutical production: **Lubricant selection**. As you are well aware, the choice of lubricant profoundly influences tablet quality and manufacturing efficiency.

Hence, it is with great pride that we introduce our comprehensive equivalency assessment between VEGHA (Sodium stearyl fumarate manufactured by Pehel Specialties) and Sodium stearyl fumarate manufactured by a leading European Manufacturer.

Our meticulous analysis has yielded compelling results.

VEGHA emerges as a true equivalent to its European counterpart across specifications, physical parameters and performance in tablet formulations. This study not only underscores the efficacy of VEGHA but also empowers you with invaluable insights to make informed decisions in lubricant selection, thereby optimizing your production processes and enhancing tablet quality.

The equivalency assessment comprised three pivotal tests:

Analytical Comparison: Rigorous analysis of various pharmacopoeial standards ensured compliance with regulatory requirements for both VEGHA and European Manufacturer.

Physical Comparison: In-depth examination of crystal shape, particle size distribution and specific surface area revealed the consistency and reliability of VEGHA across multiple batches.

Application Testing: Tablet Formulation: Tablet formulations containing VEGHA and European Manufacturer were meticulously evaluated for dissolution, weight variation, hardness, and other critical parameters, affirming the equivalency of VEGHA in achieving desired tablet properties.

In conclusion, as you navigate through the complexities of the generics pharmaceutical market, rest assured that our commitment to quality, innovation and excellence remains unwavering. We are here to support your endeavors and drive success through superior products and unparalleled expertise.

Thank you for your continued trust and partnership. Together, let us embark on a journey of innovation and excellence.

Yours Sincerely,

Pranav Zota
Head Global Business
Mobile - +91 9892235356
Email - paz@pehelspecialities.com

Scope and Methodology:

The study compares European Manufacturer and VEGHA sodium stearyl fumarate across three key tests: specifications comparison, physical parameters analysis, and application testing involving tablet manufacturing. Physical parameters include shape, particle size distribution (PSD), and specific surface area. Analytical data from specifications comparison evaluates various parameters such as water content, heavy metals, related substances, residual solvents, and assay. Application testing involves the formulation and evaluation of tablets using both lubricants.

1. **Test 1: Specifications Comparison:**

This test evaluates various specifications outlined in pharmacopoeial standards, including identification, water content, heavy metals, related substances, assay. Both VEGHA and European Manufacturer were subjected to rigorous analysis to ensure compliance with regulatory standards.

2. **Test 2: Physical Parameters Analysis:**

In this test, the physical properties of VEGHA and European Manufacturer were compared, focusing on crystal shape, particle size distribution (D10, D50, D90), and specific surface area. Trend data analysis was conducted to assess the consistency of VEGHA across multiple batches.

3. **Test 3: Application Testing: Tablet Formulation:**

Tablet formulations containing VEGHA and European Manufacturer as lubricants were prepared and evaluated for various parameters, including dissolution, weight variation, dimensions, hardness, disintegration time, and assay. The performance of tablets made with VEGHA was compared to those made with European Manufacturer to ascertain equivalency.

Results:

Test 1 - Analytical Comparison:

Both VEGHA and European Manufacturer meet the specified requirements for identification, water content, heavy metals, related substances and assay as set out in USP-NF/Ph Eur, JPE, and IP (Draft)

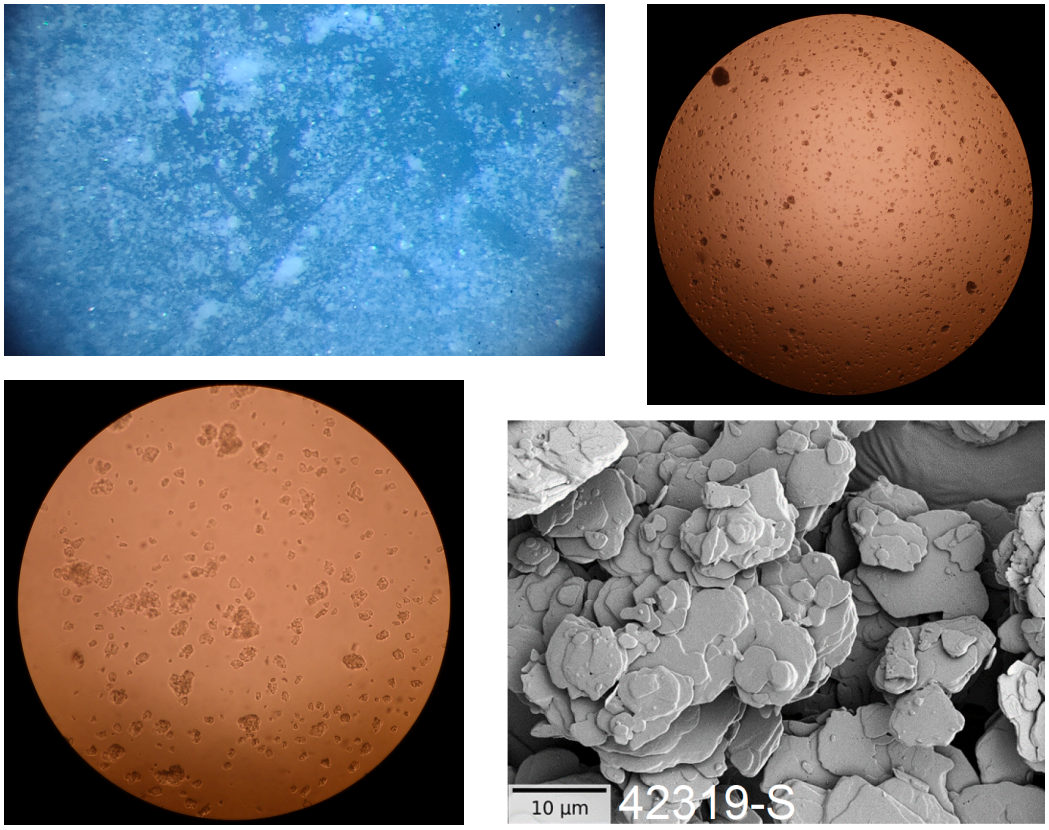
The conformity of VEGHA and European Manufacturer to regulatory standards ensures their suitability for pharmaceutical tablet formulations.

	Reference	VEGHA	European Manufacturer
Appearance	**Ph. Eur / NF / JPE**	**Complies**	**Complies**
Solubility	**Ph. Eur / NF / JPE**	**Complies**	**Complies**
Identification	**Ph. Eur / NF / JPE**	**Complies**	**Complies**
Water	**Ph. Eur / NF / JPE**	**Complies**	**Complies**
Lead	**USP**	**Complies**	**Complies**
Heavy Metals	**USP / JPE**	**Complies**	**Complies**
Arsenic	**JPE**	**Complies**	**Complies**
Related substances by TLC	**NF**	**Complies**	**Complies**
Related Substance by TLC	**JPE**	**Complies**	**Complies**
Related substance by GC	**Ph. Eur**	**Complies**	**Complies**
Fats and fixed oils	**NF / JPE**	**Complies**	**Complies**
Residual Solvents	**Ph. Eur / NF / JPE**	**Complies**	**Complies**
Assay - On anhydrous basis	**Ph. Eur / NF / JPE**	**Complies**	**Complies**

Chart demonstrates Comparison between VEGHA and European Manufacturer and to showcase compliances to various Pharmacopeia

Test 2 - Physical Parameters Analysis:

VEGHA exhibits similar crystal shape, particle size distribution, and specific surface area compared to European Manufacturer.

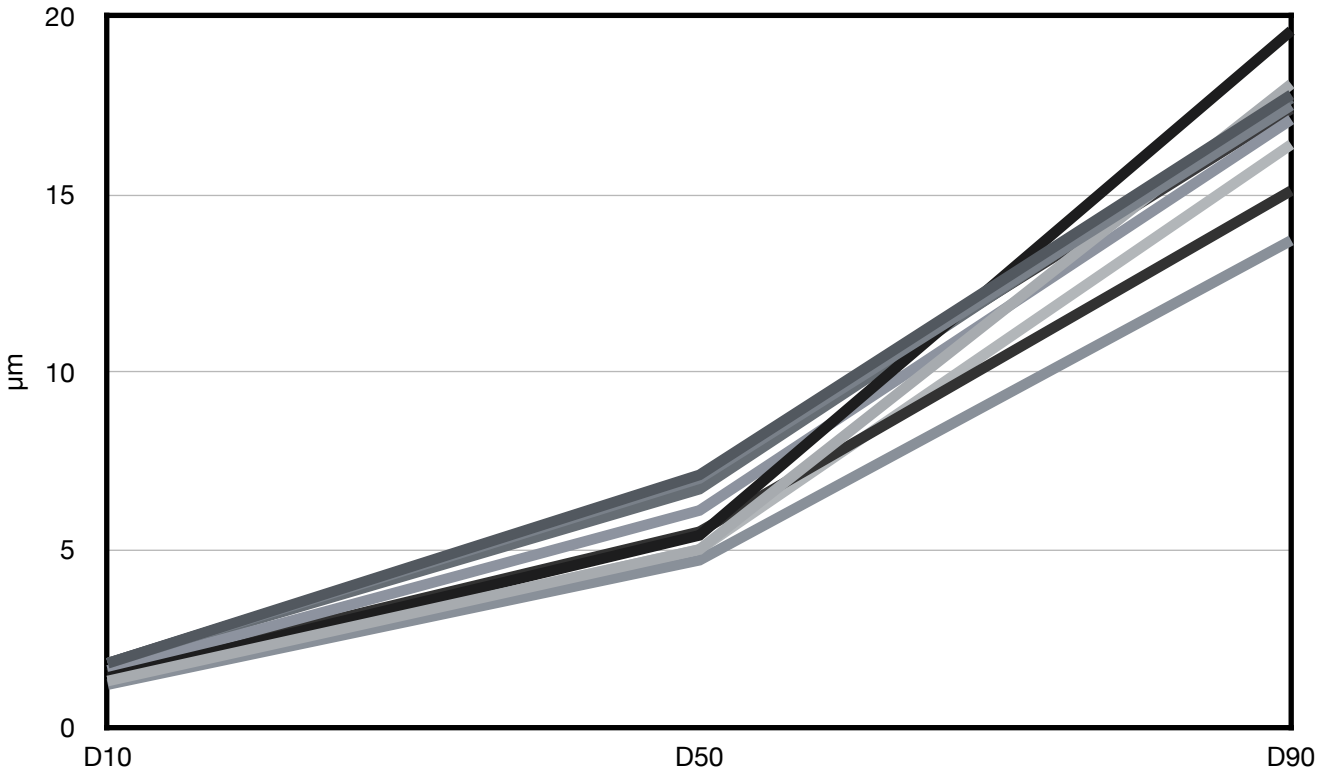


Images above are of VEGHA at different levels of magnification

Particle Size distribution

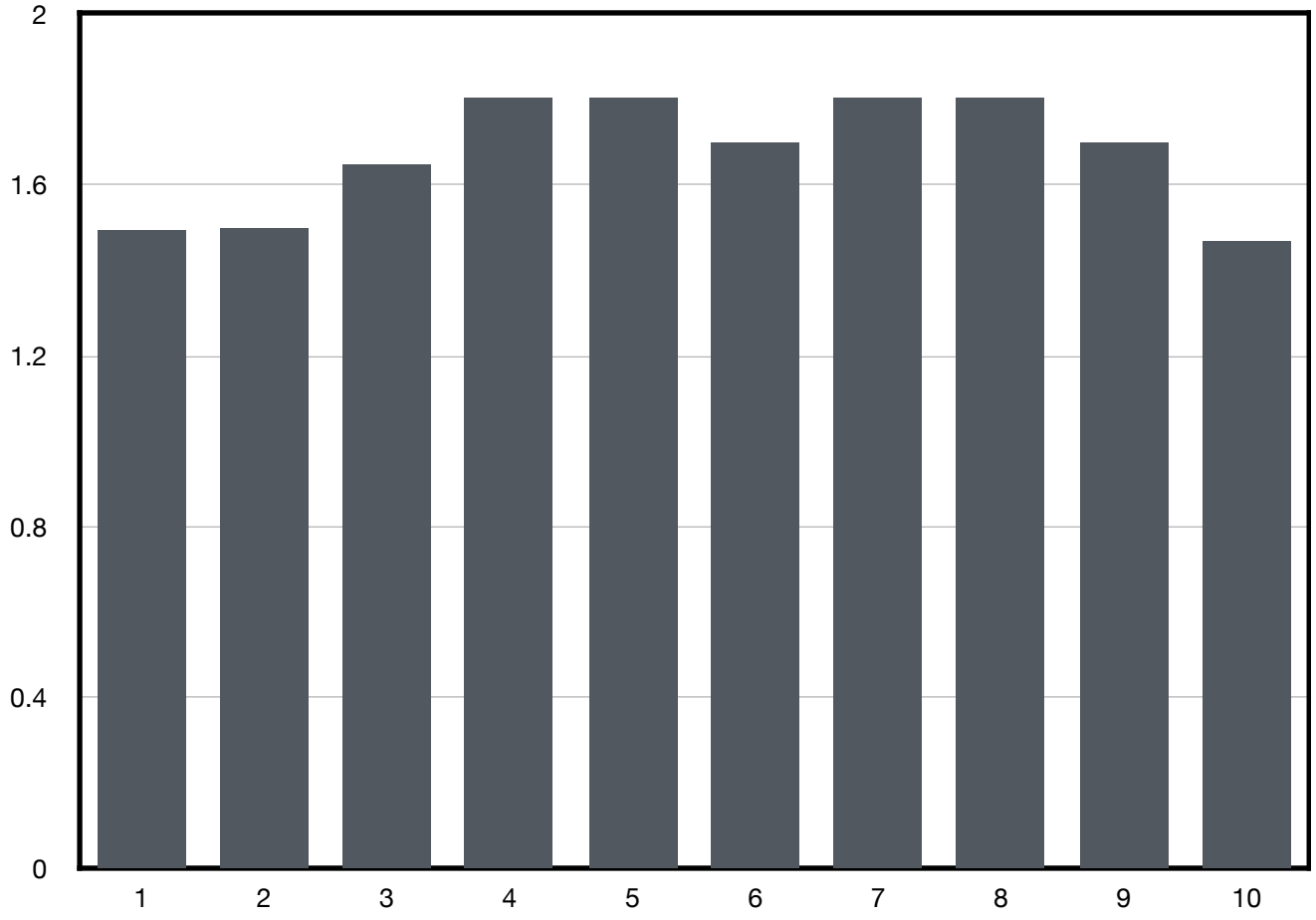
Trend data analysis confirms the consistency of VEGHA across multiple batches, indicating reproducible physical properties (in µm).

	1	2	3	4	5	6	7	8	9	10
D10 µm	1.8	1.8	1.3	1.4	1.6	1.5	1.8	1.2	1.3	1.8
D50 µm	7.1	7	5	5.4	6.1	5.5	6.7	4.7	5	7
D90 µm	17.8	17.5	18.1	19.6	17.1	15.1	17.7	13.7	16.4	17.4



Specific Surface Area

	1	2	3	4	5	6	7	8	9	10
m^2/g	1.49	1.5	1.65	1.8	1.8	1.7	1.8	1.8	1.7	1.47



Carried out using Blaine Apparatus method, as specified in our Test procedure.

Asp = Kna •√t

Where Asp = specific surface area
Kna = apparatus constant for sodium stearyl fumarate
t = flow time#

Test 3 - Application Testing: Tablet Formulation:

1) Preparation of Ciprofloxacin Tablets

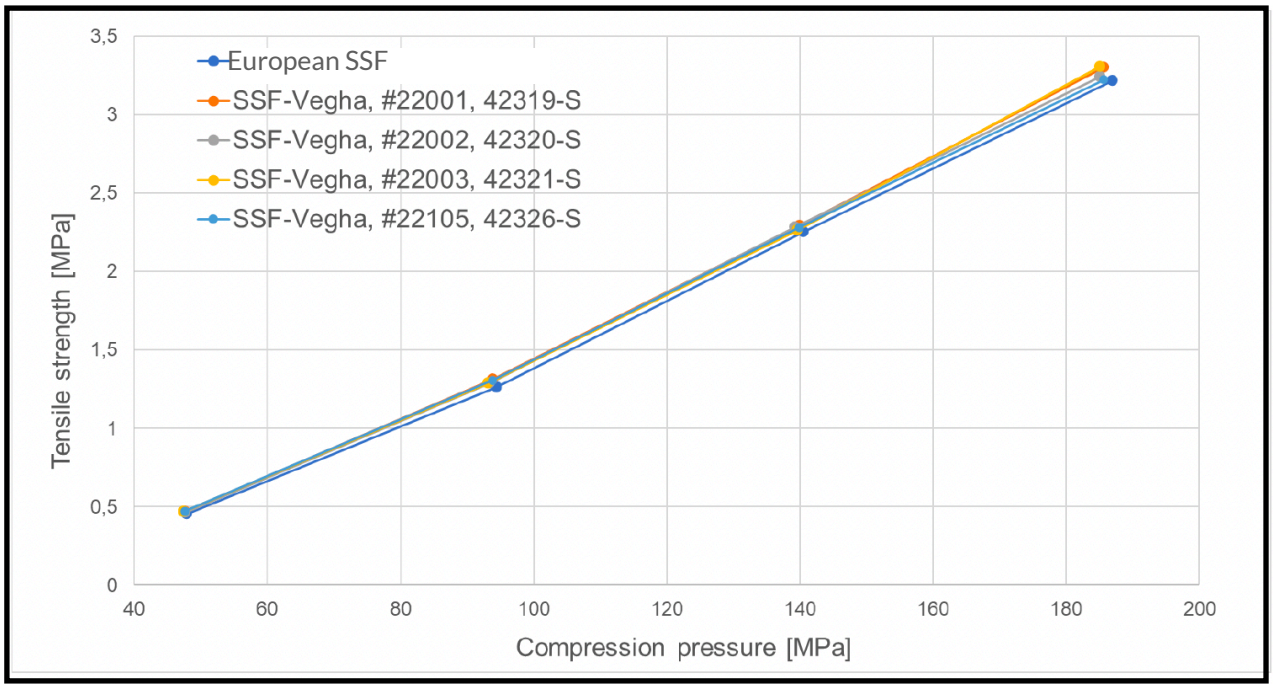
Ingredients used
- Ciprofloxacin
- Lactose
- Povidone K30
- Sodium Stearyl Fumarate

Test Specification	Results with European Manufacturer	Results with VEGHA	Individual Remarks	Implications
Dissolution: NLT 80% (Q)	103.8%	104.3%	Both formulations exceed the minimum dissolution requirement, indicating high drug release efficiency.	VEGHA and European Manufacturer demonstrate equivalent performance in drug release.
Weight of 20 Tablets: 14.00g	14.115g	14.074g	Both formulations meet the target weight, ensuring uniformity in dosage.	Consistency in tablet weight ensures uniform drug content.
Average Weight per Tablet: 700mg	708.71mg	702.70mg	Results fall within the acceptable range, indicating uniformity in tablet composition.	VEGHA and European Manufacturer formulations offer consistent drug content per tablet.
Thickness: 4.80mm	5.09mm	5.10mm	Slight variations observed, but within acceptable limits.	Comparable compression behavior of tablets made with VEGHA and European Manufacturer.
Length: 19.1mm	19.06mm	19.05mm	Minimal variation observed, indicating consistent tablet dimensions.	Tablets exhibit uniform size, facilitating handling and packaging.
Width: 8.10mm	8.06mm	8.07mm	Negligible difference observed, ensuring consistent tablet width.	Uniform tablet dimensions enhance uniformity in manufacturing processes.

Hardness: 60 to 100kg/ cm²	7.0kg/cm²	6.5kg/cm²	Both formulations meet specified hardness range, ensuring tablet integrity.	Tablets exhibit adequate mechanical strength for handling and packaging.
Disintegration Test: NMT 15 Minutes	7.56 minutes	7:22 minutes	Disintegration time meets criteria for both formulations.	Rapid disintegration ensures timely drug release and absorption.
Assay by UV (95% to 105%)	102.8%	103.2%	Both formulations meet assay requirements, ensuring adequate drug potency.	Consistent drug content guarantees therapeutic

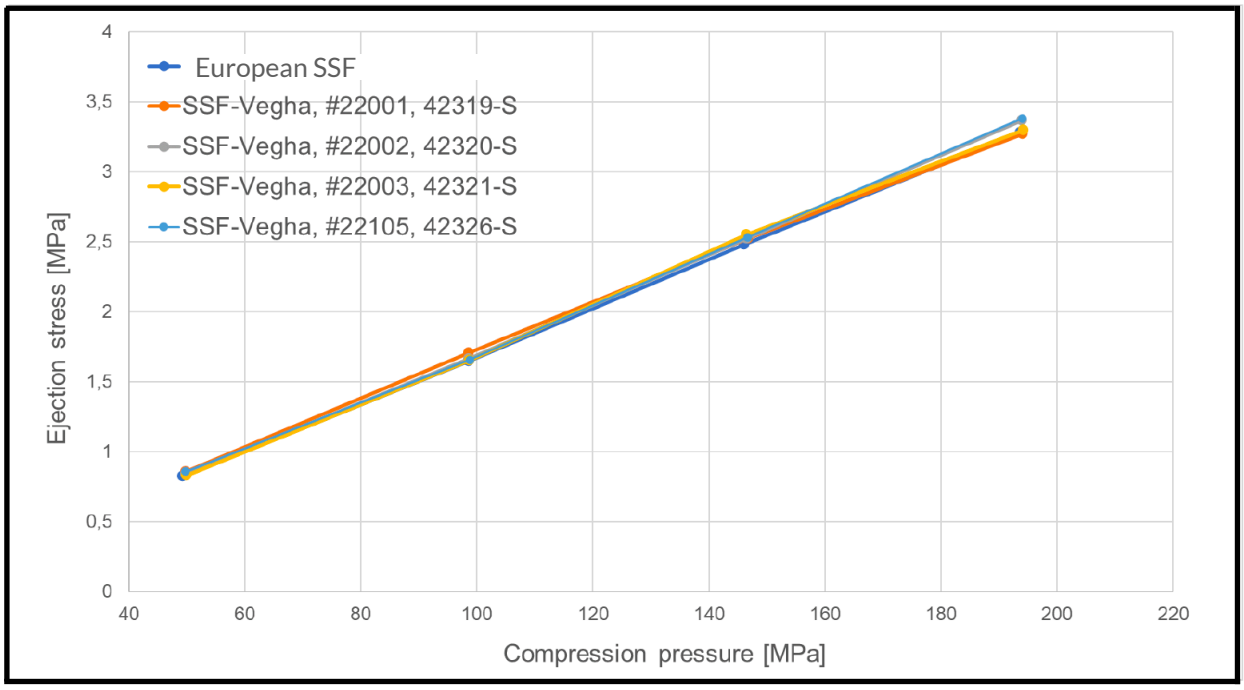
2) Preparation of Ludipress Tablets

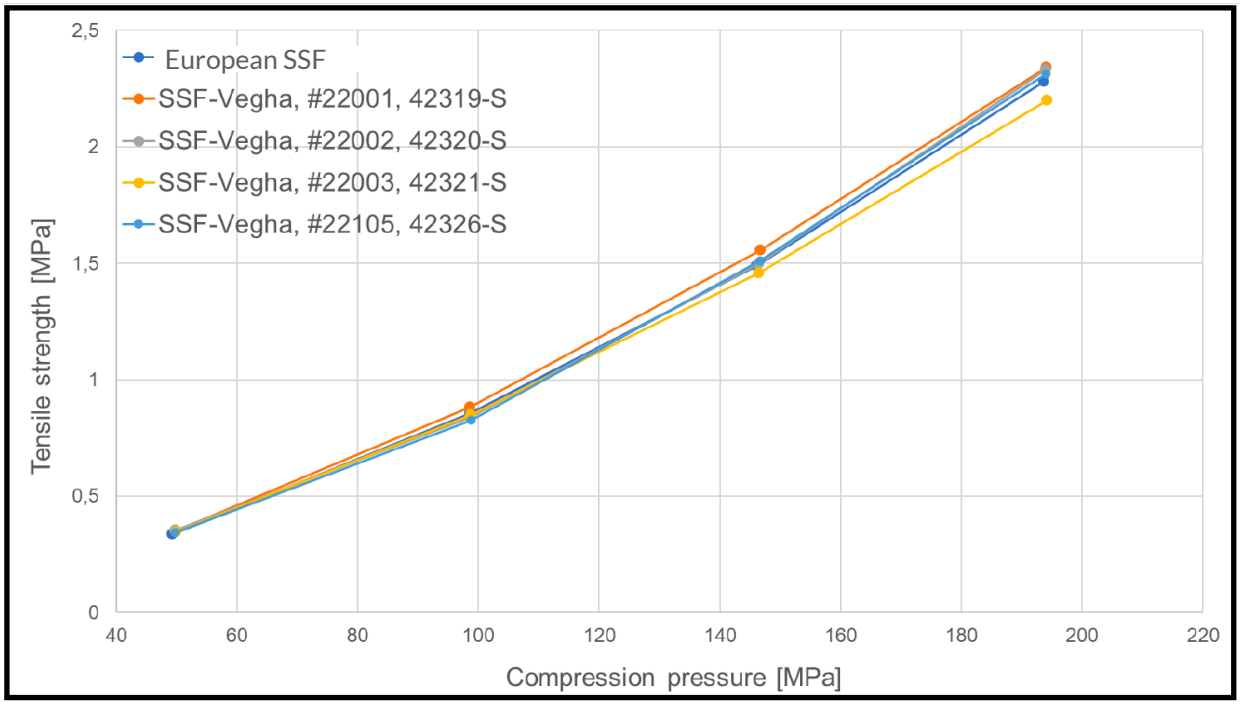
Compression force	4 kN, 8 kN, 12 kN , 16 kN
Tablet weight	500 mg
Formulation	1.0 % SSF 99.0 % Ludipress



3) DI-CAFOS-based formulation

Compression force	4 kN, 8 kN, 12 kN , 16 kN
Tabletweight	500 mg
Formulation	2.0 % SSF 98.0 % Di-CAFOS





Conclusion:

The equivalency assessment reveals that VEGHA and European Manufacturer are identical in specifications, physical parameters, and performance in pharmaceutical tablet formulations and can select either VEGHA or European Manufacturer based on availability and operational preferences, without compromising on tablet quality or manufacturing efficiency. This case study underscores the importance of thorough evaluation in lubricant selection, ensuring optimal performance and regulatory compliance in pharmaceutical manufacturing processes.

Recommendation:

Based on the findings of this study, we recommend the adoption of VEGHA as an equivalent alternative to European Manufacturer in pharmaceutical tablet formulations.

The interchangeability of VEGHA and European Manufacturer offers flexibility and operational efficiency, empowering pharmaceutical manufacturers to achieve consistent tablet quality and streamline production processes.

Contact Information:

For further inquiries or assistance in lubricant selection and optimization, please contact

Pehel Specialities LLP,
501 Swastik Chambers, 39 S.V. Road, Vile Parle West, Mumbai 400056
Email Id - sales@pehelspecialities.com
Contact Number - +91 22 26185050
Website - https://pehelspecialities.com