

Lubripharm™ SSF

Sodium Stearyl Fumarate, NF, EP, JP

Lubripharm Sodium Stearyl Fumarate (SSF) is an inert, less hydrophobic alternative to magnesium stearate as a pharmaceutical tablet lubricant. Tablets made with Lubripharm SSF exhibit less sensitivity to variations in blending time and lubricant levels and have functionally superior hardness characteristics compared to tablets produced with magnesium stearate. In addition, Lubripharm SSF does not exhibit incompatibility with active pharmaceutical ingredients (APIs) that are susceptible to oxidation or degradation in alkaline conditions or contain primary amines.

Compactibility studies comparing Lubripharm SSF to magnesium stearate show that Lubripharm SSF was superior with regard to the functional impact on tablet hardness, ejection force, friability, and disintegration time.

Blend Time Study

Spray dried mannitol (Mannogem® EZ) was blended for 5 and 10 min. with Lubripharm SSF or magnesium stearate at a 2.0% level and compressed at 15, 20, 25, 30, and 35 kN. Results (Figure 1) showed that the tablet hardness for the magnesium stearate blends was 1-2 kp less than the Lubripharm SSF blends over the compaction profile.

Lower ejection force reduces the attrition to the tablet during ejection, which can result in destruction of tablet bonding, leading to tablet capping and tablet lamination. The ejection forces (Figure 2) for the magnesium stearate blends were 50 to 150 newtons higher than blends containing Lubripharm SSF.

Figure 1: Effect of Blend Time on Tablet Hardness Using 2% Lubripharm or Mg Stearate as Lubricants - Mannogem EZ Carrier

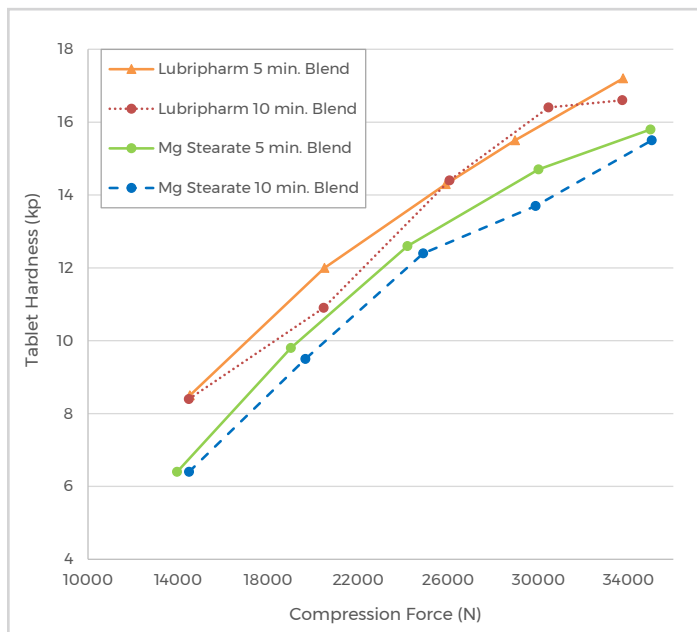
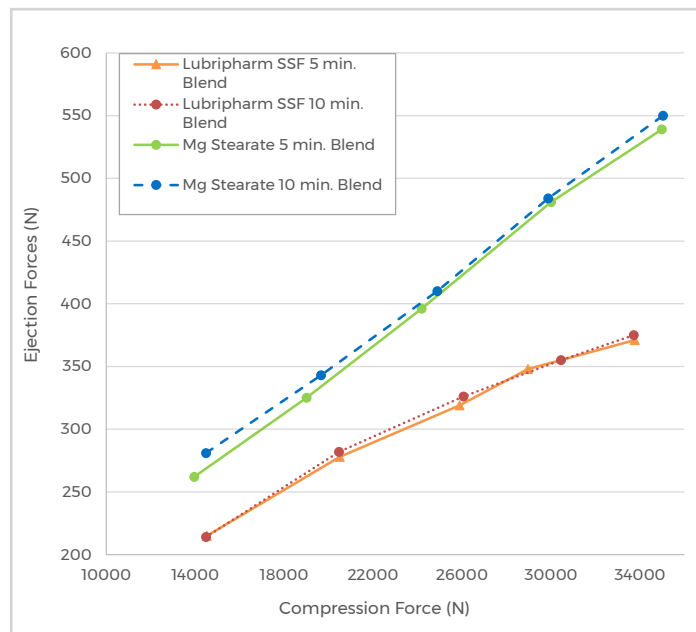


Figure 2: Effect of Blend Time on Ejection Force Using 2% Lubripharm or Mg Stearate as Lubricants- Mannogem EZ Carrier



Faster Disintegration Times

Prolonged mixing with magnesium stearate can result in a reduction in dissolution rate, due to the excessive coating of granules by this highly hydrophobic lubricant. Improving disintegration time is essential in the design of ODT based systems, as well as systems containing BCS Class II and Class IV APIs. The greater hydrophobicity of magnesium stearate leads to increased disintegration times (Figure 3), as compared to tablets manufactured with Lubripharm SSF.

Figure 3: Effect of Blend Time on Disintegration Using 2% Lubripharm or Mg Stearate as Lubricants- Mannogem EZ Carrier- 12 kp Tablets

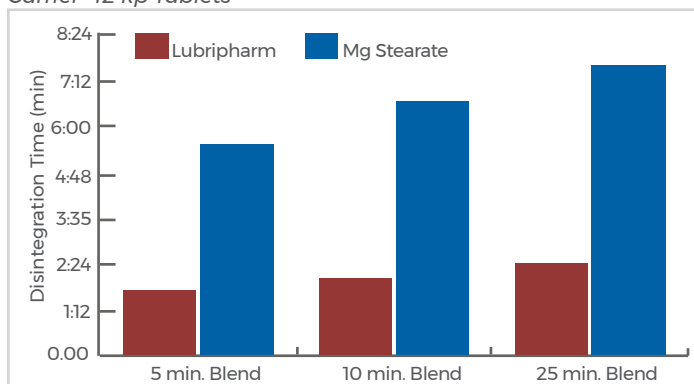
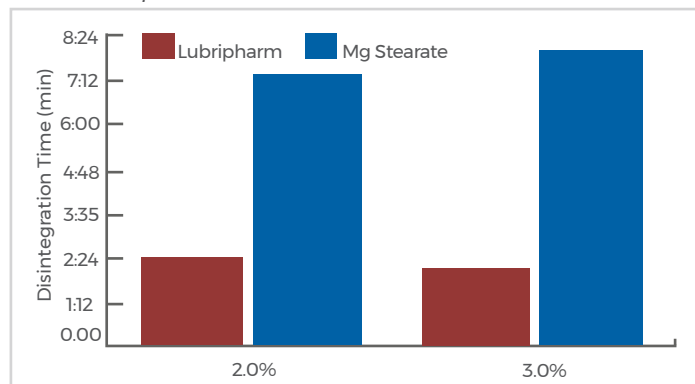


Figure 4: Effect of Lubricant Level on Disintegration Using 2% and 3% SSF and Mg Stearate as Lubricants Mannogem EZ Carrier - 12 kp Tablets



Tablets made using Lubripharm SSF are not highly sensitive to the levels of lubricant employed; the incorporation of 3.0% Lubripharm SSF as compared to 2.0% Lubripharm SSF did not negatively effect disintegration time, as shown in Figure 4. Usage levels of Lubripharm SSF are typically between 0.25-3.0% w/w concentrations.

Conclusion

Lubripharm SSF is a lubricant used in capsule or tablet formulations. SSF has superior performance which results in higher quality tablets and improved processing rates.

Benefits of Lubripharm:

- Lower ejection force
- Less impact on disintegration times
- Less sensitive to overblending

✉ salesinfo@spipharma.com

💻 www.spipharma.com



ABbiotech
Health
An ABF Ingredients Company

ABENZYMES
An ABF Ingredients Company

ABITEC
An ABF Ingredients Company

Fytexia
An ABF Ingredients Company

ohly
An ABF Ingredients Company

PGP
INTERNATIONAL
An ABF Ingredients Company

SPI Pharma
An ABF Ingredients Company

All information and statements given in this brochure are believed to be accurate at the time of publication. However, neither SPI Pharma nor any of their affiliates make any representations or warranty with respect thereto, including, but not limit to, any results obtained in the processing of the products by customers or any third party. All information and statements are intended for persons having the required skill and know-how and do not relieve the customer or user from verifying the suitability of information and statements given for a specific purpose prior to use of products. It is entirely the obligation of the customer or user to comply with applicable laws and regulations, and also with all patent or other intellectual property rights of third parties.

SPI PHARMA EXPRESSLY DISCLAIMS ANY REPRESENTATIONS OR WARRANTIES OF ANY KIND, WHETHER EXPRESS OR IMPLIED, AS TO THE ACCURACY, CURRENCY, COMPLETENESS AND/OR THE MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF ANY INFORMATION CONTAINED IN THIS BROCHURE AND/OR ANY PRODUCT DESCRIBED OR PROMOTED IN THIS BROCHURE, INCLUDING WARRANTIES WITH RESPECT TO INFRINGEMENT OF ANY PATENT, COPYRIGHT, OR OTHER RIGHTS OF A THIRD PARTY. We reserve the right to change product specification and not specified properties of the products without prior notice.

Order# SPI-EXC-LUB-6000-08201900
09-2025 | All rights reserved
© 2025 SPI Pharma