

## 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

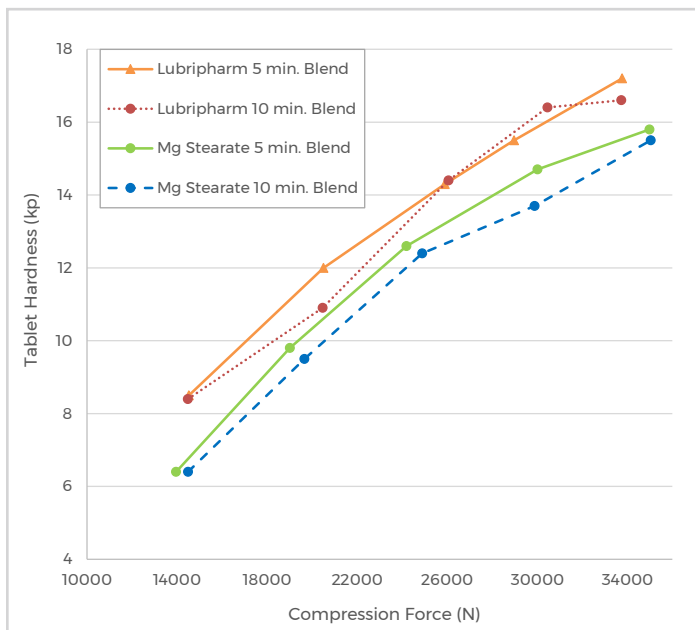
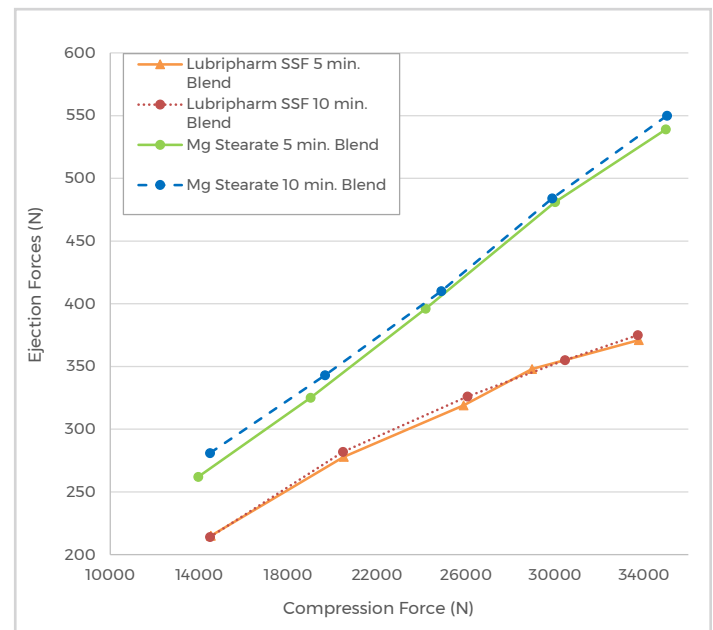


Figure 2: Effect of Blend Time on Ejection Force Using 2% Lubripharm or Mg Stearate as Lubricants- Mannogem EZ Carrier



### Benefits of Lubripharm SSF

Less Impact on Disintegration Times

Lower Ejection Forces

Less Sensitive to Overblending

## 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

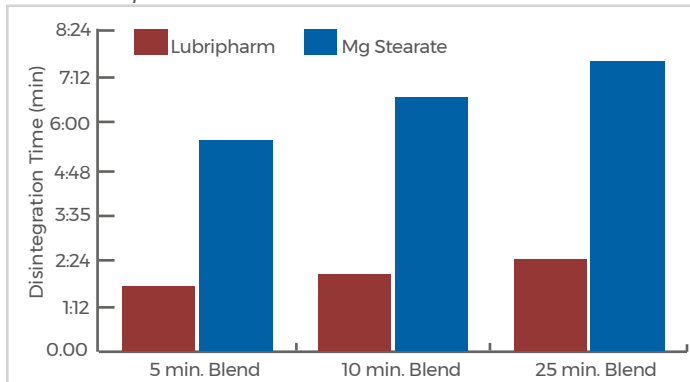
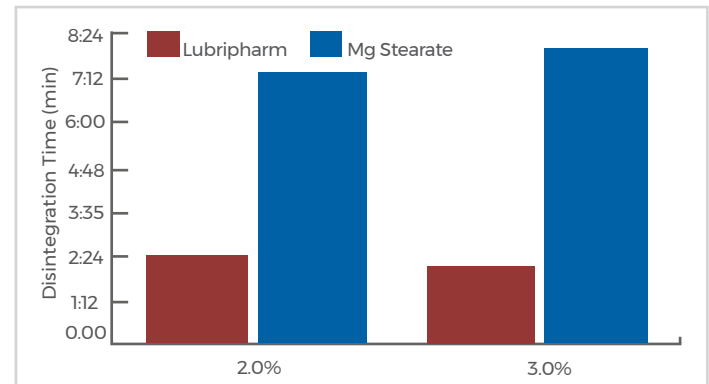


Figure 4: Effect of Lubricant Level on Disintegration Using 2% and 3% SSF and Mg Stearate as Lubricants Mannogem EZ Carrier - 12 kp Tablets



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

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