



Lubripharm[®] SSF
Sodium Stearyl Fumarate



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 showed that Lubripharm SSF was superior with regard to the functional impact on tablet hardness, ejection force, friability, and disintegration time.

Lubripharm SSF is a lubricant used in capsule or tablet formulations. SSF has superior performance when compared to magnesium stearate:

- ◆ Higher tablet hardness
- ◆ Lower ejection forces
- ◆ Less impact on disintegration times, which is especially important for orally disintegrating tablets
- ◆ Less sensitive to overblending
- ◆ Less residue in solution than magnesium stearate makes it more effective for effervescent applications

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.

The ejection forces (Figure 2) for the magnesium stearate blends were 50 to 150 newtons higher than blends containing Lubripharm SSF. 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.

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

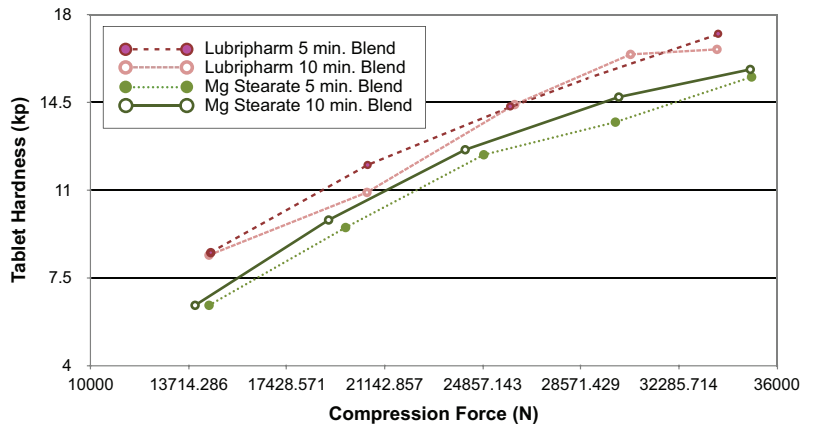
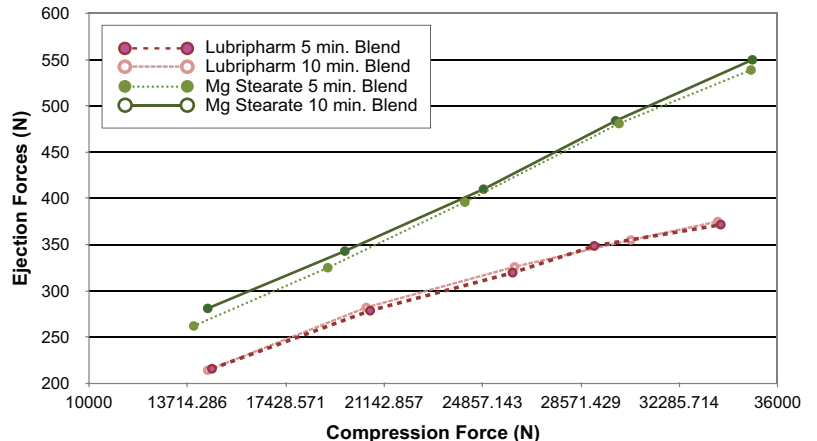


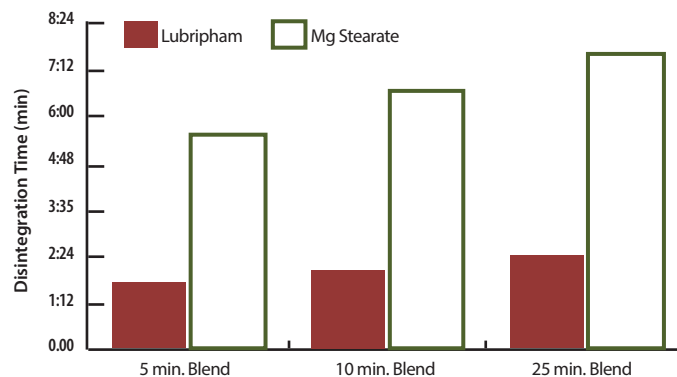
Figure 2. Effect of Blend Time on Ejection Force Using 2% Lubripharm or Mg Stearate as Lubricants- Mannogem EZ Carrier



Lower Disintegration Times

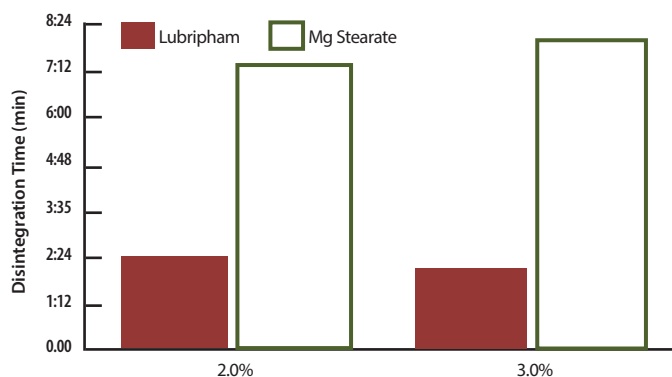
Prolonged mixing with magnesium stearate can result in a reduction in dissolution rate, due to the excessive coating of granules by this highly hydrophobic lubricant. Improving disintegration time is essential in the design of ODT-based systems, as well as systems containing BCS Class II and Class IV 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



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 produced only a negligible increase in disintegration time, as shown in Figure 4. Usage levels of Lubripharm SSF are typically between 0.25–3.0% w/w concentrations.

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



Conclusions

Lubripharm SSF provides for increased tablet robustness, reduced disintegration times, and decreased lubrication sensitivity as compared with magnesium stearate employed at equal levels. The use of Lubripharm SSF is indicated for disintegration- and dissolution-sensitive formulations such as orally disintegrating tablets and tablet formulations containing BCS Class II and Class IV APIs.

Additionally, Lubripharm SSF is indicated for tablet formulations containing APIs which exhibit stability issues with magnesium stearate such as strongly acidic APIs (e.g. aspirin), iron salts, APIs containing ester groups (e.g. moexipril), and strongly basic APIs (e.g. erythromycin).

Lubripharm® SSF

Typical Properties

Description	White powder
Mean Particle Size (D50)	10 µm
Recommended Use Level	0.25 – 3.0 % w/w
Surface Area	3.09 m ² /g
Melting point	224–245°C

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