

Lubripharm® SSF Sodium Stearyl Fumarate, NF



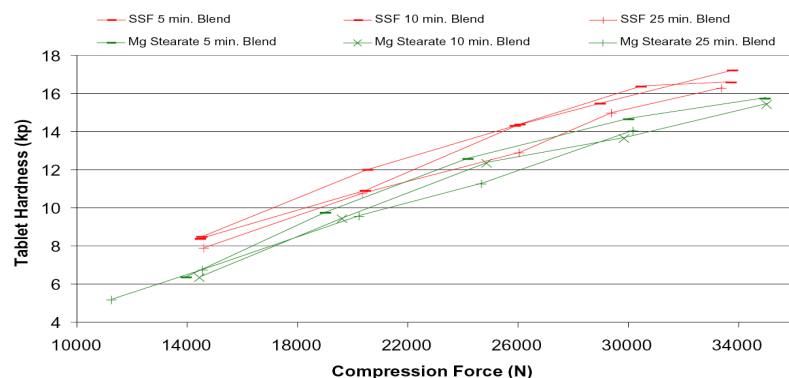
Sodium stearyl fumarate (SSF) is a tablet lubricant for use in ODT tablets, in effervescent formulas, or in formulas where the active is incompatible with magnesium stearate. It is an inert, less hydrophobic tablet lubricant than magnesium stearate. Tablets made with SSF exhibit less sensitivity to variations in blending time and lubricant levels and have superior hardness characteristics compared to tablets produced with magnesium stearate.

Compactibility studies comparing SSF to Mag. Stearate showed that SSF was superior with respect to impact on tablet hardness, ejection forces, friability and disintegration. The compactibility of blends was reduced when using magnesium stearate. Ejection forces and friability were also higher for tablets made using magnesium stearate. The disintegration times were longer for magnesium stearate and varied with level.

Blend Time Study

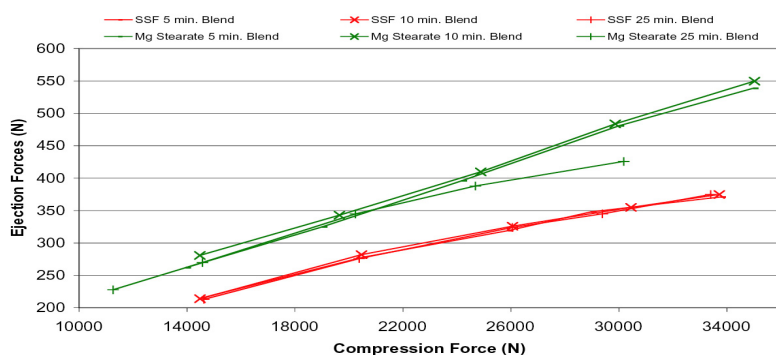
Spray Dried Mannitol (Mannogem® EZ) was blended for 5, 10, and 25 minutes with SSF and Mag Stearate at a 2.0% level and compressed at 15, 20, 25, 30, and 35 kN. Results showed that the tablet hardness for the mag stearate blend were 1-2 kp less than the SSF blends.

Figure 1. Effect of Blend Time on Tablet Hardness



The ejection forces (Figure 2) for the magnesium stearate blends were 50 to 150 Newton higher than blends containing SSF. Additionally, the magnesium stearate showed sensitivity to blend time.

Figure 2. Effect of Blend Time on Ejection Forces



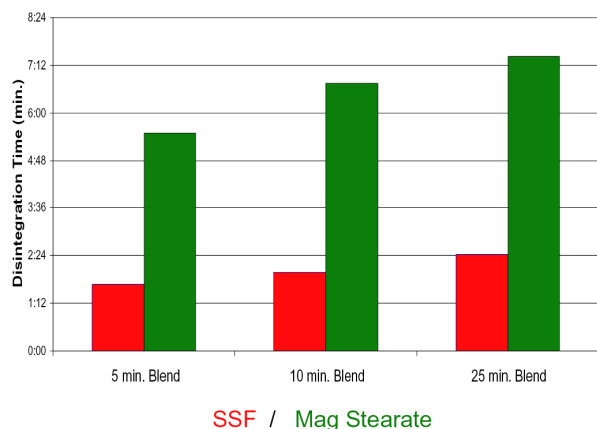
Lubripharm® Sodium Stearyl Fumarate (SSF) is a lubricant used in capsule or tablet formulations. SSF has superior performance when compared to magnesium stearate:

- Higher tablet hardness
- Lower ejection forces
- Less impact on disintegration times
- Less sensitive to blending time
- Semi-soluble so lower residue when in solution or effervescent
- Especially effective in ODT Tablets
- Usage level of 0.25 – 3.0% w/w concentration

Lower Disintegration Times:

The disintegration times for magnesium stearate tablets were considerably higher than with Lubripharm® SSF (Figure 3). This makes SSF especially suitable for all types of ODT formulas.

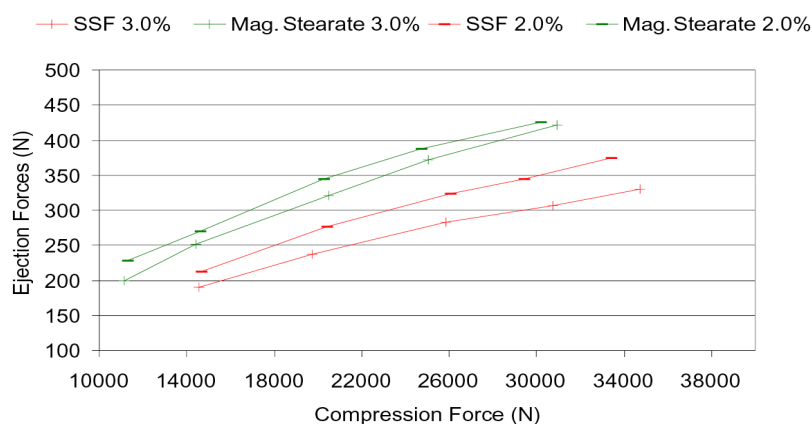
Fig. 3. Effect of Blend Time on Disintegration using 2% SSF and Magnesium Stearate:



Lubricant Level Study

Mannitol (Mannogem® EZ) was blended with SSF and Mag. Stearate at 2.0% and 3.0% levels. Lubricant level had a notable effect on the ejection forces. Figure 4 shows that the 3.0% level had lower ejection forces than the 2.0% level. SSF was more effective at reducing die-wall friction as indicated by magnesium stearate having ejection forces 50-100 N greater.

Figure 4. Effect of Lubricant Level on Ejection Force Using SSF and Mag. Stearate:



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