

Investigating the Role of Lubricants during Roller Compaction

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Roller compaction is a dry granulation technique used in the pharmaceutical industry, in which a powder formulation is compressed into a ‘ribbon’ compact between two counter rotating rolls. The ribbon is subsequently milled into granules of a desired size range. Whilst simple in principle, successful control of a roller compaction process is often difficult as it is multivariate in design. Further complicating the process is the ‘*ad hoc*’ addition of magnesium stearate. Magnesium stearate is commonly used in formulations as a lubricant to reduce frictional forces during tableting. However, inclusion of magnesium stearate within a formulation can have adverse effects on the final product, such as;

- formation of a hydrophobic film
- reduction in tablet strength
- interaction with some drugs

The extent of these effects is related to the degree of magnesium stearate coverage on the surface of a host particle. As such the general strategy employed during pharmaceutical tablet manufacture is to limit the amount of mixing of the formulation with magnesium stearate, see Figure 1, such that magnesium stearate is not homogenously mixed. As a result of this inhomogeneity of magnesium stearate in the blend it is difficult to ensure reproducible lubricity. More over the extra mixing that can occur during further downstream processing is likely to increase the degree of surface coverage and hence accentuate the deleterious effects.

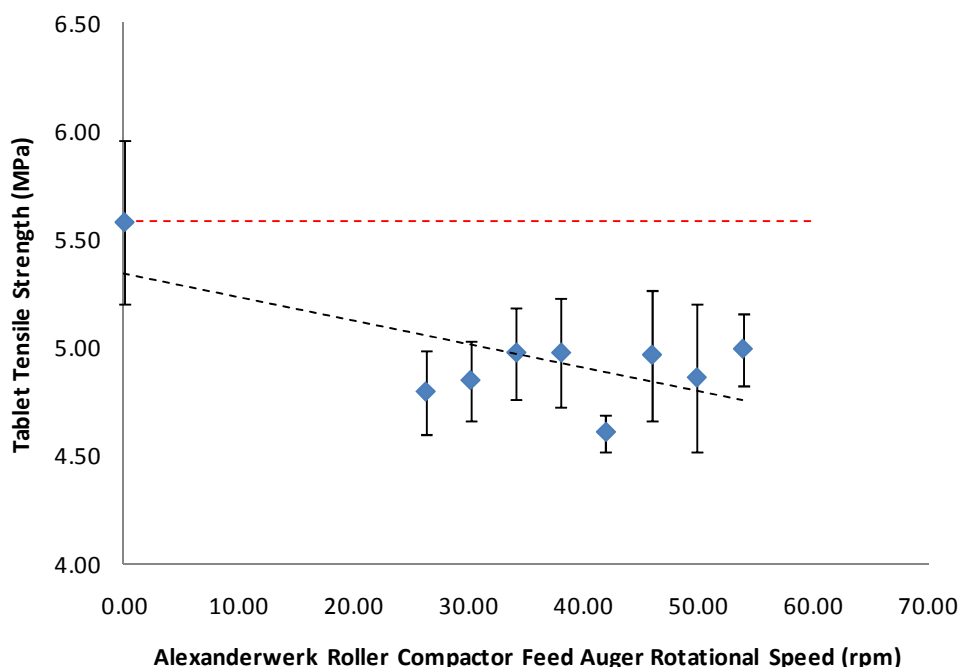


Figure 1 - ‘Virgin’ powder, point 0.00, contains 0.5 % w/w magnesium stearate blended for 7 minutes at 15 rpm. Decrease in tablet tensile strength is due to further mixing within the feeding system of the roller compactor.

The presence of magnesium stearate was observed to have a marked influence on the roller compaction process; mass throughput was greatly increased with a corresponding increase in roll gap (Figure 2), however, it had a negligible impact on the in-gap ribbon porosity. Frictional condition at the powder roll interface had no significant influence on the unlubricated formulation; however, moving from knurled rollers to knurled-smooth rollers reduced the mass throughput and corresponding roll gap for the lubricated (0.5 % w/w) formulation (Figure 2). Roller compaction was not possible for the lubricated (0.5 % w/w) formulation when using two smooth rollers. The presence of magnesium stearate on the equipment surfaces was demonstrated to lead to an increase in mass throughput and corresponding roll gap; however, the effects were only temporary as the magnesium stearate is displaced from the surface as the process continued. Powder sticking to the roll surface was only observed for the unlubricated formulation and knurled roll surface condition. Further mixing of the formulation within the feeding system was confirmed which could have an undesirable effect of increasing the lubricity of the formulation. The beneficial effects of magnesium stearate were still apparent even at a much lower level than the typical 0.5 % w/w used in industry. However, due to the much smaller amount, mixing can be increased to homogeneity without the worsening the adverse effects. Lower magnesium stearate level blended more homogeneously throughout the blend could be less sensitive to the mixing that occurs within the roller compactor feeding system.

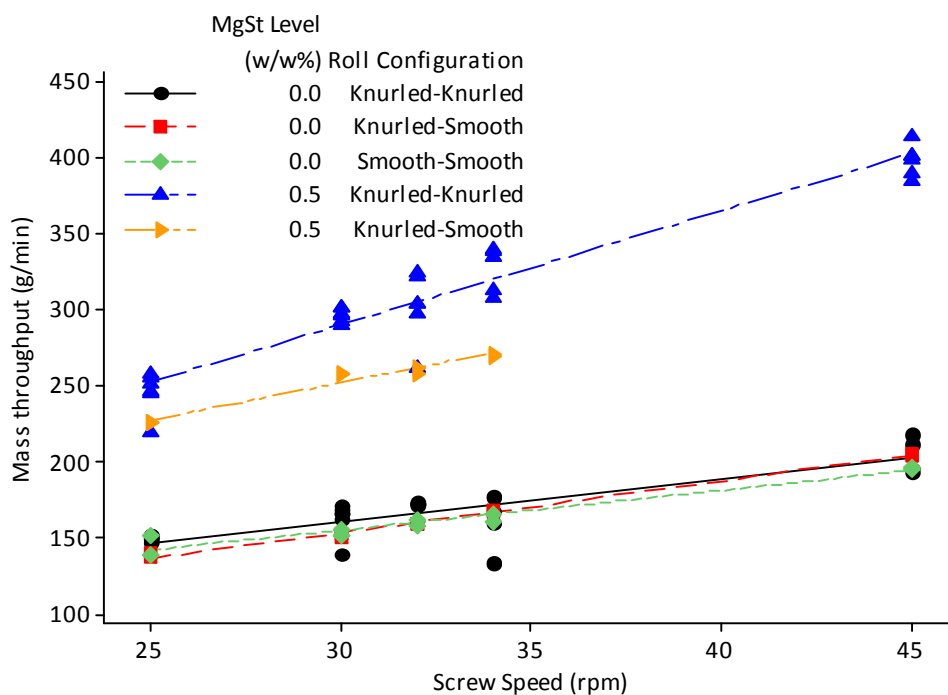


Figure 2 - Comparison of mass throughput for two levels of magnesium stearate (0, 0.5 % w/w) with various roll configurations