MAGNESIUM STEARATE LUBRICANT CHARACTER: PROCESSING EFFECTS

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Magnesium stearate is a lubricant used extensively in tabletting with unpredictable effects on formulations associated with batch variation (Billany and Richards 1982). Previously, using high purity batches of magnesium stearate and palmitate (Miller et al 1982), inherent frictional differences were observed between powders of different solid-state character, including a pharmaceutical grade magnesium stearate (Miller et al 1983). Here we have assessed the lubrication of an inert granulation by three magnesium stearates under production tabletting conditions. The aim is to discern magnesium stearate characteristics which are important in lubrication and which might lead to deleterious tablet effects.

Two batches of high purity magnesium stearate were prepared - powder H under acid conditions to give flat, regular plate-like particles and powder J under alkaline conditions to produce particles of irregular morphology (see Miller et al 1982, 1983). The third powder, X, is a commercial, pharmaceutical grade magnesium stearate. (Supplier Croxton and Garry, Surrey) Lubricant powders at a concentration of 1% w/w were blended for five minutes with 6.3kg of inert starch/lactose granules using standardised conditions. Each batch was tabletted on a strain gauged Manesty B rotary press and lubrication assessed in terms of ejection force. Tablet machine settings were not altered between batches and tablets produced were periodically assessed for thickness, crushing strength and disintegration time. Mean tablet weights were 510 ± 10mg.

Fig. 1 shows that the high purity magnesium stearates H and J are superior lubricants to the commercial powder X as assessed by ejection force measurement. The tablets produced have equivalent crushing strength (see Table 1). This may be due to the presence of lactose in the granules producing lubricant clear surfaces for bonding following fragmentation during compression. The reduced disintegration times for tablets containing high purity magnesium stearates may be linked to reduced host surface coverage on mixing compared with sample X. Magnesium stearate H, with flat crystalline particles has the highest inherent frictional quality (Miller et al 1983) but powder J with smaller irregular particles may have a better covering potential for the irregular granules (Miller 1984). The amorphous powder X has the best coating propensity but produces inferior lubrication due to the unfavourable solid-state characteristics of the material.

Table 1. Properties of tablets containing 1% w/w of different magnesium stearates.

Magnesium stearate	Mean tablet crushing strength (kp)	Mean tablet thickness (mm)	Tablet disintegration range (min:sec)
H	8.7	5.5	3:35- 4:30
J	8.4	5.5	4:10- 4:40
X	8.5	5.4	8:30-10:00

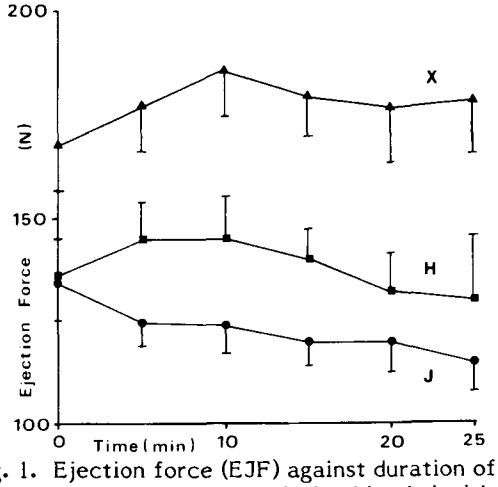

Fig. 1. Ejection force (EJF) against duration of tabletting for an inert granulation blended with 1% w/w magnesium stearates. (Miller 1984)

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