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# THE INFLUENCE OF MAGNESIUM STEARATE ON TIME DEPENDENT STRENGTH CHANGES IN TABLETS.

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## ABSTRACT

Changes in the mechanical strength of tablets with time are well documented. Sodium chloride tablets increase in strength by over 100% in the first hour after manufacture. It is shown that when mixed with magnesium stearate, this strength change does not occur. Results are also presented for lactose tablets, and possible mechanisms are discussed.

## INTRODUCTION

Changes in the mechanical strength of tablets with time are well recognised. Rees and Shotton (1) reported increases in strength of over 100% during one hours storage of sodium chloride tablets. Similar changes were reported by Rue and Barkworth (2), who used an acoustic emission technique to determine the mechanism

of the increase. Other workers have accepted that a time factor was important when measuring the strength of tablets. (3,4).

This paper reports the influence of magnesium stearate on the strength of tablets of sodium chloride and lactose tablets stored for increasing time intervals.

## MATERIALS AND METHODS

### Materials.

Sodium chloride (analar grade, B.D.H.Ltd, UK) was from a single batch and was sieved (Alpine Air Jet Sieve) to obtain a 125-150μm size fraction. Lactose (Unigate Foods Ltd. UK) was also from a single batch and was similarly sieved to obtain the same size fraction. Magnesium stearate (Halewood Chemicals, UK) was added at a concentration of 0.1% $^{w}/_{w}$ and mixed with each material for 30 minutes using a Turbula mixer (W.A. Bachoven, Switzerland) at 90 r.p.m. This time takes into account the work of Bolhuis et al (5) on the influence of mixing time of magnesium stearate with excipients, and is such that further mixing time does not cause any change in the strength of tablets prepared from the mix.

### Methods.

0.5g samples of the appropriate material were compressed at a crosshead speed of 0.1cm/min with a ½" diameter, flat faced punch and die system mounted on an Instron physical testing instrument (6). The pressure used was 155MN/$m^2$. Tablets were either tested immediately, or stored over silica gel until

required. The strength of the tablets was measured by diametral crushing using a T22K testing instrument (J.J. Lloyd Ltd. Southampton, UK). At least five tablets were tested at each time interval.

## RESULTS AND DISCUSSION.

The results are shown graphically in Figure 1 as plots of breaking load against time. Statistical treatment of the data was carried out using a one way analysis of variance, followed if required, by Duncan's new multiple range test. These treatments show that there is a significant effect of time on the breaking load of tablets for sodium chloride alone and lactose with magnesium stearate, but time does not have a significant effect on lactose alone or sodium chloride with magnesium stearate. Significant changes occur in the 1st hour for sodium chloride, and the 24 and 48 hour results for lactose with magnesium stearate are significantly different from the other results.

Magnesium stearate dramatically reduces the strength of sodium chloride tablets as found previously by Bolhuis et al (5). The large increase in strength occurring in the first hour for sodium chloride tablets, is not observed when sodium chloride is mixed with magnesium stearate prior to compaction. On the basis of acoustic emission studies, Rue and Barkworth (2) explained the increase in strength of sodium chloride tablets as follows. Sodium chloride undergoes work hardening (7,8) and during compression, the crystals at the die wall and punch faces will be subjected to high shear, resulting in a tablet with a "work

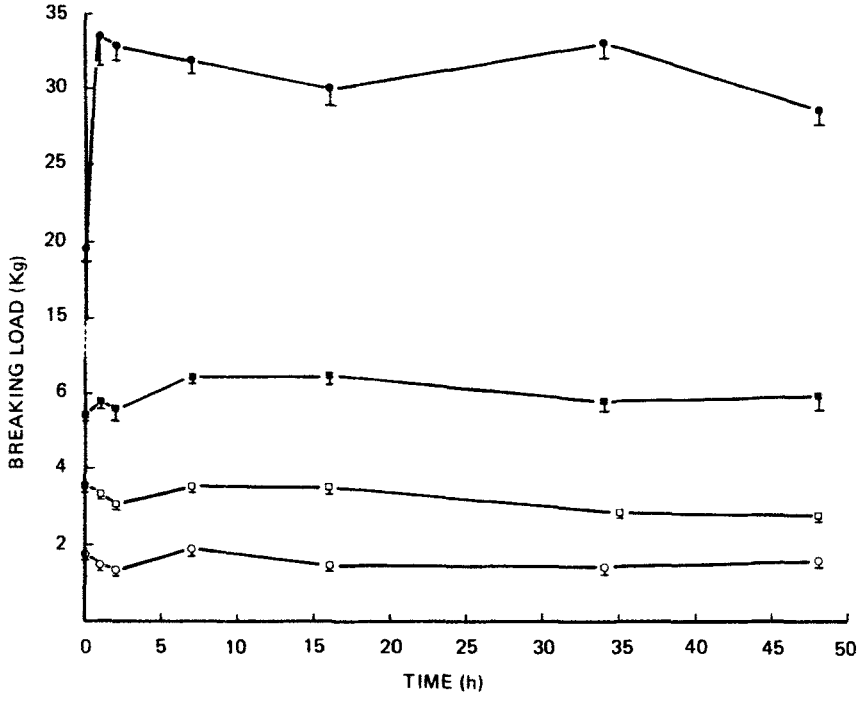


FIGURE 1

The effect of time on the breaking loads of tablets prepared from: ■ = lactose alone □ = lactose, with magnesium stearate ● = sodium chloride alone ○ = sodium chloride with magnesium stearate. Bars indicate the standard error of the mean.

hardened shell". Such a shell prevents strain recovery of the tablet and internal rearrangement of the particles occurs, producing increased areas of bonding and an increase in tablet strength.

Magnesium stearate may act in two ways to prevent this increase in strength. Firstly, by coating the particles of

sodium chloride, it will prevent increases in bonding occuring even if internal rearrangement of the particles takes place. Secondly, by acting as a lubricant, it could reduce the work hardening of the outer shell of the tablet, and allow strain recovery to take place.

Lactose tablets undergo a greater strain recovery than sodium chloride tablets (9) and increases in strength do not occur in measurable time periods. Magnesium stearate reduces the strength of lactose tablets, but not by the same degree as sodium chloride. This is due to lactose undergoing fragmentation during compaction, allowing the creation of magnesium stearate free surfaces, and hence better bonding (5). The results obtained indicate that lactose tablets with magnesium stearate undergo a small reduction in strength after 24hrs storage which is not found for lactose alone. Further investigation is required to substantiate this effect.

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