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SHORT COMMUNICATION

The possible use of polytetrafluoroethylene (Fluon) as a tablet lubricant

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The preparation of free flowing granules usually obviates the need for a lubricant to be selected for improved glidant action alone. The reduction of wall friction during the compression and ejection of the tablet is the most important criterion for selecting a particular lubricant.

To obtain lubrication at the die wall a material of low shear strength must be incorporated in the granules. Magnesium stearate in particular possesses such qualities and acts suitably as a die wall lubricant in the tabletting process (Lewis & Shotton, 1965). However, magnesium stearate has the disadvantages that it can be converted to stearic acid and thus react with other ingredients; it may also reduce the hardness of the tablets produced by weakening the bonds between particles (Lewis & Shotton, 1964).

Polytetrafluoroethylene (Fluon) is reputedly non-toxic and chemically inert below about 250°, with a very low coefficient of friction. It possesses a low shear strength, 110 kg cm^{-2} at zero applied load together with a high yield pressure resulting in an extremely low coefficient of friction (Hersey, 1960). Polytetrafluoroethylene has been successfully bonded to the tips of punches to reduce the adhesion between tablet and punches.

A patent describing the use of polyfluorocarbon type polymer as a tablet lubricant has been granted to Hotko (1967) in the U.S.A. but no experimental evidence is given.

This paper describes a limited trial with fluon L169 lubricant powder (ICI Ltd.) to compare its usefulness as a lubricant in the compression of powders.

Experimental

Spray dried lactose (120–150 mesh) was compacted in an instrumented Lehman single punch reciprocating tablet machine. The instrumentation used was essentially similar to that previously described by Shotton & Ganderton (1960). Five tablets were prepared at each of four different pressure levels (machine settings, PI, PII, PIII and PIV) and the mean value of force calculated for the purpose of the figures. The tablet weight (0·6895 g) taken was sufficient to give a tablet of 0·4 cm length at zero porosity using a 1 cm diameter punch and die set.

One per cent magnesium stearate and one per cent Fluon L169 powder were separately incorporated into identical lots of the lactose by tumbling on rollers for 1 h. Tablets were then prepared from each of these two mixtures as described for spray-dried lactose above.

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The strength of the tablets was assessed immediately after preparation using the diametral crushing test (Shotton & Ganderton, 1960) and the disintegration time measured using the official B.P. method.

Results and discussion

These preliminary results show that 1% of Fluon L169 reduces the die wall friction and also the force needed to eject the tablet, by an amount similar to 1% magnesium stearate in lactose tablets (Fig. 1A, B).

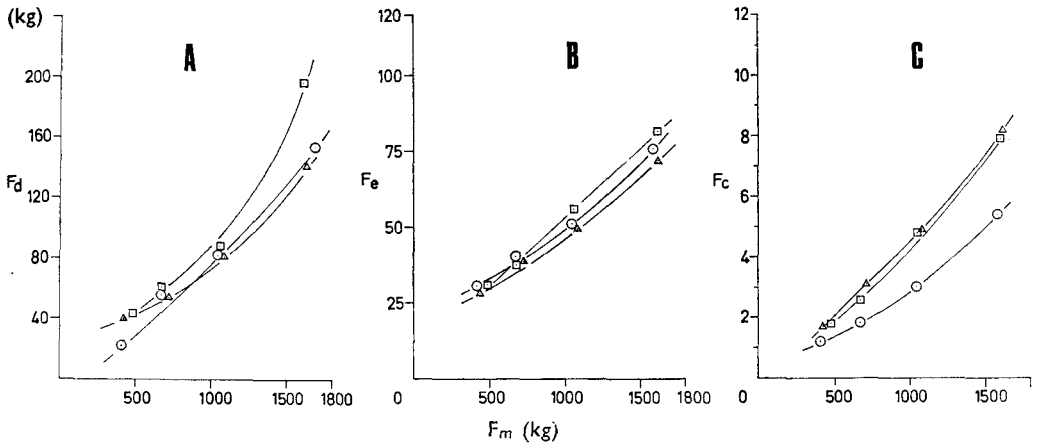

FIG. 1. The effect of compression force on (A) die wall friction, (B) the ejection force and (C) on the crushing strength of tablets for: □ Spray-dried lactose. △ Spray-dried lactose with 1% Fluon L169. ○ Spray-dried lactose with 1% magnesium stearate. (F_m = the mean compression force).

Fig. 1C shows the effect of the two lubricants on the crushing strength of the tablets. The results show that the presence of the Fluon powder does not impair the crushing strength of the lactose tablets, whereas a reduction is obtained when magnesium stearate is used as a lubricant.

The results of the disintegration tests are given in Table 1. The presence of Fluon does not increase the disintegration time of the lactose tablets whereas the magnesium stearate produces a marked increase.

Table 1. *Disintegration times*

Pressure levels	Disintegration time (s)		
	Spray dried lactose unlubricated	Spray dried lactose 1% Fluon	Spray dried lactose 1% Mg stearate
PI	7	6	420
PII	9	8	960
PIII	14	10	1080
PIV	—	20	1200

In this preliminary trial with a single tablet excipient (lactose), Fluon powder does not appear to be much better as a tablet lubricant than magnesium stearate. Fluon is chemically inert and tablets incorporating Fluon powder disintegrate much more

rapidly than those with magnesium stearate; it would also appear that the Fluon is less likely to bring about "water-proofing" of the tablet. This is probably due to the yield value of Fluon being high, the particles do not break down and spread by shear at the die wall or between the lactose particles.

The remaining problem is that because of the nature of the thermal decomposition products (above 250°) of polytetrafluoroethylene, doubts have arisen as to its toxicity. However, the polymer has been shown to be non-irritant and harmless when implanted in the peritoneal cavity of dogs over a period of 70 days (LeVeen & Barberio, 1949), it produces no reaction when implanted in human tissues (Charnley, 1960) and has been shown to be safe for use in cooking utensils (Coppock & Knight, 1957). Further chronic toxicity studies must be encouraged, with the view to deciding whether this possibly very useful lubricant may be added to the armoury of the tablet formulator.

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