THE EFFECTS OF A DRY-BINDER ON TABLET TOUGHNESS

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Elsewhere we have shown (Rees, Rue & Richardson, 1977; Rees & Rue, 1978) that work-of-failure or toughness is a more useful property than breaking strength to quantify the resistance of tablets to mechanical failure. Tablets formulated with brittle materials are less tough than those composed of plastic excipients. We have therefore examined changes in toughness when a plastically deforming dry-binder is incorporated into tablets of a brittle, direct-compression diluent.

Tablets of Emcompress (dicalcium phosphate dihydrate, K. K. Greef Ltd., Croydon, U.K.) were compressed from samples of 500 ± 2 mg, using 12.7 mm diameter, plane-faced punches in a Manesty E2 tableting machine. Ten tablets were prepared at each of five compaction forces from 5 to 25 kN; the die was lubricated by previously compressing a powder sample containing equal parts of Emcompress and magnesium stearate. Using the same procedure, tablets were prepared from dry powder mixes of Emcompress with 2.5, 5, 10, 20 and 40% w/w methyl cellulose (Celacol Gum M 2500 BPC, British Celanese). In one experimental series, the powders and the tablets were stored at 50% RH, 24°C for 24 hours before compression and testing. In a second series, the trials with Emcompress containing 0, 5 and 40% w/w methyl cellulose (MC) were repeated using storage conditions of 65% RH, 24°C. The dimensions and mechanical properties of the tablets were measured as described by Rees & Rue (1978), toughness being the area under the load-displacement curve for a tablet during a diametral compression test. All tablets showed a rectilinear increase in tensile strength with compaction force up to 25 kN and the relation was apparently unaffected by an increase in RH from 50 to 65%. Surprisingly, MC had no beneficial effect on the tablet strength irrespective of humidity or compaction force; in fact MC slightly decreased the tensile strength, presumably because interparticulate bonds "contaminated" by MC were weaker than those formed directly between particles of Emcompress. Tablet toughness also increased rectilinearly with compaction force except that tablets containing 40% MC at high humidity exhibited very little increase in toughness above 20 kN compaction force. At 50% RH, toughness remained unchanged as the MC content increased to 5% but 10, 20 and 40% MC produced rank order increases in tablet toughness, up to a maximum of 3 times the value for Emcompress alone. The toughness versus compaction-force profile of Emcompress alone was the same at 50 and 65% RH. However the toughness of tablets containing 40% MC was increased slightly by an increase in RH, this effect being most significant for tablets compressed at 20 kN; the relatively minor effect is probably due to the small change in moisture content of MC between 50 and 65% RH.

We conclude that an important property of a binder is to increase the toughness of tablets by facilitating plastic deformation of interparticulate bonds. This will reduce the friability of a tablet and increase its resistance to mechanical shock even if the binder fails to increase tablet strength. It is interesting that in this study a conventional strength test would have rejected MC as producing no improvement in tablet properties whereas our toughness test confirms the usefulness of this excipient as a dry binder. Thus even a slight <u>decrease</u> in tablet strength provides no guarantee that a formulation additive has an adverse effect on tablet properties.

Rees, J. E. & Rue, P. J. (1978). Drug Development and Industrial Pharmacy, in press.
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