

## THE PROPERTIES OF ENTERIC TABLET COATINGS MADE FROM POLYVINYL ACETATE-PHTHALATE AND CELLULOSE ACETATE-PHTHALATE

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The efficacies of polyvinyl acetate-phthalate (PVAP) and cellulose acetate-phthalate (CAP) as enteric coating materials have been determined by applying various solutions of each polymer to placebo tablets in a standard coating pan, using a spray-coating technique. The resultant tablets were tested using the B.P. 1968 procedure, and the effect of variation in plasticiser content of the film on their performance in this test was determined. The plasticiser chosen was diethyl phthalate.

A physical examination of the mechanical properties of the polymer films has also been carried out. Free films of the polymers were produced in known thicknesses by a draw-knife casting technique, and were subjected to tensile testing on a machine to determine their resistance to deformation and their ultimate tensile strength. For both polymers, the effect of increasing the plasticiser content was to increase the ultimate tensile strength up to approximately 10% plasticiser, after which it declined again. From the force-displacement curves, the energy absorbed by the film in stressing it to rupture could also be obtained: the behaviour of this quantity with plasticiser content was more complex.

The diametral crushing strengths of tablets coated with different thicknesses of films were measured, again using a testing machine of great stiffness at a constant deformation rate. For thin coatings there was a decrease in tablet strength, but as the thickness increased so did the crushing strength until it surpassed that of the untreated cores. The failure mechanism also underwent a change. At constant film thickness, the effect of increased plasticiser content was to reduce the crushing strength: this was progressive as the concentration increased.

The indentation surface hardness of the applied films were measured using a micro-indentation apparatus (Ridgway et al.1970). At low plasticiser contents, films made from CAP had a surface hardness much greater than those made from PVAP, but as the quantity of plasticiser was increased the surface hardnesses of both types of film decreased and approached one another more closely.

Combining the results enables a tablet and its coating to be designed ab initio to have any combination of dissolution time, coating thicknesses and diametral crushing strength that may be requested by the formulator.