INTERBATCH VARIATION IN COMPRESSION PROPERTIES OF ELCEMA G250

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Interbatch variation in the physical properties of excipients can cause problems in the routine production of pharmaceutical dosage forms. We have observed such large differences in the compaction properties of two batches of Elcema G250, a brand of microfine cellulose (Degussa, West Germany), that the tensile strength of tablets prepared from batch A was up to 4 times that for batch B. Preformed tablets of batch A also deformed more than those of batch B before they failed in a diametral compression test, so the work of failure - a parameter indicating the toughness of tablets (Rees & Rue, 1978a) - of batch A was up to 7 times that of batch B.

Tests showed that both batches conformed to the manufacturer's specifications. Further tests including particle size analysis, scanning electron photomicrographs, and carbon and hydrogen analysis revealed no differences which could account for the different compression properties.

Elsewhere (Rees & Rue, 1978b) we have reported on the strain-rate-dependent deformation of several excipients during compaction. The strain rate sensitivity of the Elcema batches A and B was examined using two techniques - stress relaxation studies and measurement of non-recoverable deformation (NRD) of preformed compacts loaded to 75% of their breaking force in a diametral compression test.

To examine stress relaxation, a tablet was compressed to a known force in a reciprocating tablet machine; without altering the position of the instrumented upper punch, the force on the punch was monitored as a function of time. After 360 seconds the decrease in force as a function of the maximum upper punch force was 29% for batch A and only 27.5% for batch B. However during the first 0.5 second period the relaxation of batch A was 19% and of batch B, 14%. The greater difference in relaxation between the batches at shorter times compared with the longer time suggests that the plastic deformation of batch B is more time dependent than that of batch A.

We have shown (Rees & Rue, 1978b) that an increase in the negative gradient of the linear relationship between log NRD of tablets and log rate of platten movement, indicates that plastic deformation of the material is more sensitive to strain rate. For batches A and B, the gradients were -0.082 and -0.145 respectively, again showing that the plastic deformation of Elcema batch B is more strain rate sensitive.

It is likely therefore, that at the high strain rates which operate during powder compaction, a higher proportion of the total deformation of Elcema batch B will be elastic compared with batch A. Elastic recovery during decompression will then cause bond rupture and, combined with the reduced plastic flow during compaction which results in less extensive bonding, this will lower the tensile strength of batch B tablets compared to that of batch A tablets.

Problems of the type described in this communication might be avoided if a physico-mechanical quality control parameter which measures the deformation behaviour of a material were introduced into the specifications. Such a parameter could be stress relaxation values after a given time or the gradient of the relationship between NRD and platten rate.

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