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Short Communications

Formulation effects on capping tendencies

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A common defect in tablet manufacturing is capping and lamination during or after the compression process. This has been attributed to many factors, viz.: (i) strong interparticulate bonding which results in failure under recovery stresses (Shotton and Ganderton, 1961); (ii) low degree of plastic flow and bonding as measured by residual die wall pressure (Obiorah and Shotton, 1976; Doelker and Shotton, 1977); (iii) brittle fracture index, capping and lamination problems are severe when medicament has the high brittle fracture propensity (Hiestand et al., 1977; Hiestand and Smith, 1984); (iv) expansion of elastically deformed particles in a peripheral ring parallel and near to the points of greatest pressure (Shlanta and Milosovich, 1964; Carless and Leigh, 1974); (v) presence of entrapped air within the interstices of the tablet during compression, which then expands on decompression causing failure (Burlinson, 1968; Long and Alderton, 1960); and (vi) punch tolerance or badly matched tooling has also been associated with capping (Mann et al., 1981). There are reports suggesting that capping and lamination are related to high granule porosity as well as punch velocities achieved by modern high-speed tablet presses (Mann et al., 1981). Attempts to examine the effect of entrapped air on capping suggest that the capping pressure is related to the amount of air present in the granule bed prior to compression and that removal of the majority of this air by reducing the surrounding air pressure causes a reduction in the incidence of capping (Mann et al., 1983).

In the present work, causes of capping and lamination in the absence of both granule porosity and high speed compression have been investigated using isotropic, homogeneous polymeric systems. Interrelationships between crushing strength, friability together with capping, lamination and dimensional changes of tablets prepared from solid dispersed polymeric systems have been examined using various formulation components given in Table 1. It would appear that, in the case of the formulations studied, certain of these produce defective tablets at the applied compression forces. Most pharmaceutical tablets are anisotropic and non-homogeneous and as a result, pressure distribution varies in different directions. Risk of tablet defects occurring will be more in highly curved tablets because of higher localized energy at the centre and edges of the tablet. The homogeneity and compactibility of formulations I and II resulted in tablets of good quality with low friability and uniformity of weight and dimensions (Table 2). The ejection of these tablets from the die cavity involved such a low stress relaxation (elastic re-

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TABLE 1

FORMULAE USED IN THIS STUDY

Formula	Quantities listed are per cent by weight [a]				
	I	II	III	IV	V
Ethyl cellulose	40	40	20	10	10
Eudragit	20	20	20	10	10
PEG 6000	40	20	20	20	30
Paracetamol	–	20	20	40	10
Sucrose [b]	–	–	20	20	40

[a] Mixture fused at 105°C, shock cooled and the resultant dispersions were ground, sieved and fraction between 220 and 420 μm was compressed using 7.5 mm diameter standard concave punches.

[b] Sucrose was added to the final mixtures before compression.

covery) that they could be readily re-inserted into the die cavity. By contrast, formulations III, IV and V gave tablets which showed high stress relaxation upon ejection and consequently re-insertion into the die cavity was impossible. These tablets were of high friability and lacked uniformity of weight and dimensions. Such poor quality resulted in capping and lamination (Table 2). This work shows that in addition to the causes of capping and lamination already reported, the homogeneity of the solid dispersion used for tablet compression is of major importance. Thus homogeneous systems (dispersions) are more likely to produce tablets of good physical characteristics. High granule porosity has been reported as a common cause of tablet failure (Mann et al., 1981). We have found that using fused dispersions with resultant negligible porosity, capping and lamination could still readily occur. Thus porosity, is not an important factor in capping and lamination. It is significant that although a final tablet compact is unlikely to be homogeneous this parameter is of great importance in the dispersion used for compression and could well be extended to other formulations for qualitative prediction of tabletting performance in scaling-up production.

Our results suggest that, in the case of formulations studied, capping is neither related to granule porosity nor the speed of compression. It would appear from these results that the physicochemical nature of the substance (paracetamol and sucrose powders have a low plasticity index), its homogeneity and the control of process variables (low stress gradients during tableting, precompression) are important factors in capping and lamination.

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TABLE 2

PHYSICAL PROPERTIES OF TABLETS PREPARED AT A TARGETED CRUSHING STRENGTH (ONE TABLET PER MINUTE)

Formula	Friability [a] % Loss	Weight [b] (mg)	Crushing strength (kg) [b]		Thickness [b] (mm)		Elastic recovery [d] (%)
			After ejection	24 h later	Compact under pressure	24 h later	
I	0.20	205	4.50	4.61	5.32	5.34(0.003) [c]	0.37
II	0.35	208	4.20	4.15	5.41	5.43(0.004)	0.36
III [e]	0.91	199	4.35	4.31	5.44	5.47(0.005)	0.55
IV [e]	–	208	4.15	3.95	5.33	5.41(0.006)	1.50
V [f]	–	220	4.50	4.22	5.52	5.59(0.001)	1.26

[a] 20 tablets used.

[b] Average of 12 tablets.

[c] Standard deviation.

[d] Percentage elastic recovery (E) was calculated using equation $E = 100 \times (H - Hc)/Hc$, where Hc and H are the thickness of the tablet under pressure and 24 h later, respectively.

[e] Partially laminated.

[f] Partially capped-laminated.

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