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Tablet–tablet contact and mutual rubbing within a coating drum — an important factor governing the properties and appearance of tablet film coatings

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Summary

Surface roughness measurements taken over the exposed surface and within the intagliation of a film coated tablet have shown that the roughness within the intagliation is always higher than that on the exposed surface. This effect has been interpreted in terms of the magnitude of the shear stresses induced by surface tension forces and mutual rubbing due to tablet–tablet contact within the coating drum. The implications of these findings in the applicability of using sprayed free films as models for tablet film coatings is discussed.

Introduction

Film coating is a process which involves the deposition of a polymeric membrane containing plasticizers, colourants and possibly other additives onto the surface of a tablet. Compared to the conventional sugar coating, the film is relatively thin (typically 10–100 μm thick) but, unlike in sugar coating where tablet–tablet contact and mutual rubbing within the coating drum has always been considered as an important factor in the distribution of the coating and hence the appearance of the product (Anderson and Sakr, 1966), in film coating this aspect has largely been ignored with the emphasis being placed on the spreading and coalescence of the film under the influence of surface tension forces. Recent findings during studies on the alignment of certain optically anisotropic particles (e.g. talc) in film coatings (Rowe 1983a) and film appearance especially surface roughness (Trudelle et al., 1988) have implicated tablet–tablet contact and shearing of the partially solidified film in governing the final appearance of the film coatings.

In this paper the factor of tablet–tablet contact and mutual rubbing in the coating drum is reappraised using controlled experiments and the practical implications are discussed.

Materials and Methods

The method chosen for monitoring changes in the surface of the film coating was surface roughness measurement using a stylus (Rowe, 1978)

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since this method is accurate, rapid, simple and non-destructive. However, since the surface roughness of a coated surface is the sum of 3 components (one due to the coating formulation, one due to the method of application and one due to the inherent roughness of the substrate) definitive evidence of mutual rubbing can only be achieved if all 3 components are kept constant and the substrate to be coated has two distinct surfaces — one exposed to contact and rubbing and one protected. The substrate chosen was a standard biconvex tablet plain on one face and possessing a standard 'U'-shaped intagliation across the crown of the other face thus enabling surface roughness measurements to be made over the same area (i.e. the crown of the tablet) on each face.

Surface roughness measurements were made using a Surfcom Model 113A (Advanced Metrology System Ltd, Leicester) fitted with a diamond-tipped stylus 5 μm radius under a 4 mN force. The stylus was used skidless and measurements were made on 10 tablets using a 1.25 mm traverse length and a 0.25 mm cut-off. The arithmetic mean roughness (R_a) values were computed and the means ± S.D. calculated.

Five products were monitored. The film coating formulations varied slightly with each product but consisted either of a mixture of four parts hydroxypropyl methylcellulose (Pharmacoat 606-Shin-Etsu Chemical Co., Tokyo, Japan) and one part of ethylcellulose (Grade N7, Hercules Inc., Wilmington, Delaware, U.S.A.) or hydroxypropyl methylcellulose alone containing either glycerol or polyethylene glycol 300 (20% w/w based on polymer) as plasticizer. The formulations were applied either in an organic solvent mixture (70 : 30 v/v dichloromethane : methanol) at a polymer concentration of 4.5% w/w or in aqueous solution at a polymer concentration of 6.0–7.8% w/w. Coating was carried out at the 10-kg, 120-kg and 360-kg scale using the appropriate side-vented coating drum (AccelaCota, Manesty Machines Ltd., Liverpool).

Results and Discussion

The accrued results for all 5 products are shown in Table 1. It can be seen that in all cases the roughness of the film coating within the intagliation is higher than that on the plain exposed surfaces. Scanning electron photomicrographs (Fig. 1) show that, whereas on the exposed surface the film is relatively smooth and continuous, within the intagliation the film is undulating, rough and contains some surface debris.

Before discussing the mechanism for this 'effect' it is pertinent to discuss how paint technologists have treated the surface levelling tendencies of paint films. By assuming the driving force to be a combination of surface tension and gravity and the levelling tendency to be opposed by viscosity, in the case of liquids, or by elasticity (up to the yield point) in the case of gels, Orchard (1962) was

TABLE 1

Roughness of film coatings

Product	Run	Batch size (kg)	Surface roughness R_a (μm ± S.D.)			
			Core		Film-coated tablet	
			Surface	Intagliation	Surface	Intagliation
A (aqueous)	1	360	–	–	1.43 ± 0.19	3.49 ± 1.04
B (aqueous)	1	360	–	–	1.28 ± 0.11	4.83 ± 0.90
C (solvent)	1	120	0.84 ± 0.05	0.64 ± 0.11	1.67 ± 0.16	3.36 ± 1.89
	2	120	0.83 ± 0.05	0.74 ± 0.11	1.53 ± 0.20	2.94 ± 1.18
	3	120	0.87 ± 0.10	0.68 ± 0.12	1.68 ± 0.24	3.57 ± 1.72
D (solvent)	1	120	0.96 ± 0.05	0.61 ± 0.13	1.73 ± 0.70	3.65 ± 1.75
	2	120	0.90 ± 0.04	0.72 ± 0.12	1.61 ± 0.18	2.73 ± 1.90
	3	120	0.87 ± 0.05	0.57 ± 0.12	1.52 ± 0.19	2.67 ± 1.90
E (aqueous)	1	10	–	–	1.54 ± 0.29	3.26 ± 0.35

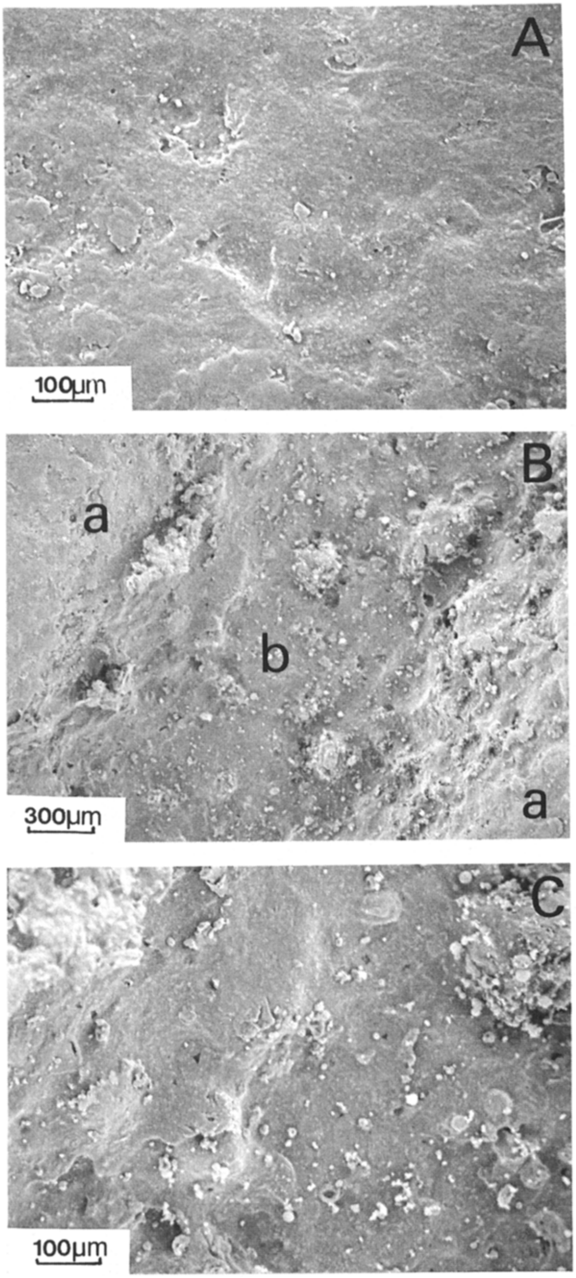

Fig. 1. Scanning electron photomicrographs of product A with film coating. A: the exposed surface. B: both the exposed surface (a) and intagliation (b). C: within the intagliation.

able to derive equations to study the rate of decay of surface irregularities within an applied paint film and the maximum shear stress induced in the system. Although the analysis was restricted to flow in two dimensions to simulate the flow out of brush marks in a fresh paint coating and hence is not strictly applicable to the flow out of a droplet of film coating formulation in 3 dimensions, it does provide a basis for discussing our problem. Of importance are the equations to calculate the half time for the disappearance of the amplitude of given unevenness ($t_{1/2}$):

$$t_{1/2} \simeq \frac{\eta \lambda^4}{\gamma h^3} \tag{1}$$

and the maximum shear stress induced by surface tension (τ_{max}):

$$\tau_{max} = \left(\frac{2\pi}{\lambda}\right)^3 \gamma a h \frac{\cosh(2\pi h/\lambda)}{(2\pi h/\lambda)^2 + \cosh^2(2\pi h/\lambda)} \tag{2}$$

where η is the viscosity of the coating formulation

γ is the surface tension of the coating formulation

λ is the width of the unevenness

a is the amplitude or height of the unevenness

h is the film thickness

Unfortunately data for the solution of these equations for film coating systems are not available. However, if it is assumed that the surface tension of the coating formulation is of the region of 40×10^{-3} Nm^{-1} (Rowe, 1976) with a film thickness of 30 μm and values of λ and a are of the same order as seen in paint films (100 μm and 7.5 μm, respectively—Quach, 1973; Quach and Hansen, 1974) then the maximum shear stress in the system will be of the order of 5 Pa. This stress is unlikely to cause alignment of filler particles. Another important finding is that use of Eqn. (1) predicts that, for a constant film thickness and surface tension, levelling will only occur within a reasonable time if low viscosity coating solutions are used. Hence one would expect that water-based film coating formulations with a much higher viscosity than organic solvent-based formulations would flow out very slowly, producing rougher films. This does not appear to be the case for the systems studied here (Table 1) although there are indications from previous work on the small scale that aqueous film-coated tablets were less glossy and hence, by implication, more rough than organic solvent film-coated tablets (Rowe, 1985).

An estimation of the stress to cause alignment of filler/pigment particles in a polymer film can be obtained by studying the conditions under which the paint defect "silking" is produced. This defect occurs when the needle shaped yellow iron oxide pigment particles orientate in paint films during brushing and manifests itself as the presence of stripes or streaks which appear darker or lighter than the surrounding surface depending on the direction in which they are viewed (Kresse, 1966). Since for brushing it is known that the strain rate is of the order of 10^4 s^{-1} (Kornum, 1979) and that freshly applied paint has a viscosity of $2–5 \times 10^2$ mPa · s (Patton, 1966) then the maximum shear stress will be of the order of $2–5 \times 10^3$ Pa — some 3 orders of magnitude higher than that of the shear stress induced by surface tension).

From these considerations it can be concluded that the effects seen both in this study and in others with the alignment of optically anisotropic filler particles (Rowe, 1983a) are due entirely to the shear stresses applied to the film coating formulation on drying. Within the intagliations the shear stresses are dominated by those induced by surface tension forces and hence are small and although some levelling and smoothing does take place no alignment of particles is possible. However, on the main exposed surface of the tablet the shear stresses are dominated by those induced by mutual rubbing of the tablets and are high enough both to smooth out even the most viscous of partially gelled coating formulations and to cause alignment of particles.

These findings have important practical implications not only in the optimisation of both film coating formulations and process conditions for the production of smooth, high-gloss, film-coated tablets (this will be promoted by the use of low-viscosity coating solutions, large-scale coating drums and increased drum speed) but also in the applicability of using sprayed free films as models for tablet film coatings since the mutual rubbing due to tablet–tablet contact is a factor that cannot be reproduced in spray systems used to prepare free films. The applicability of using sprayed films as opposed to cast, poured films as models for tablet film coating has been a bone of contention unresolved for many years especially in reference to water vapour transmission experiments (Banker et al., 1966a and b; Allen et al., 1972; Pickard et al., 1972). Although water vapour transmission in tablet film coatings is an important factor, it is less important than the mechanical properties of the films and the correlation between these and the incidence of such defects as film cracking and splitting and bridging of the intagliations seen in the production of film-coated tablets (Rowe, 1986). In this respect it is interesting to note that whereas direct correlations have been found between the incidence of such defects and mechanical data from the tensile testing of cast films (Rowe, 1983b), only rank order correlations have been found when the tensile testing was performed on films prepared by spraying into a rotating cylinder (Okamafe and York, 1985).

This apparently anomalous result is not unreasonable if one considers that the high shear induced by the mutual rubbing of the tablets will certainly promote flow and hence more cohesion and less discontinuities within the film coating and hence the comparison with a sprayed film where the induced shear stresses will be very low resulting in less cohesion and more discontinuities is not valid. In cast, poured films the shear stresses will again be low but in this case cohesion will be high because of the method of preparation. It could be argued, therefore, and the limited data available would support the argument, that cast, poured films are better models for tablet film coatings for the correlation of mechanical properties and incidence of film coating defects.

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