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*J. Pharm. Pharmacol.* 1983, 35: 112–113  
Communicated August 3, 1982

0022-3573/83/020112-02 \$02.50/0  
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## A reappraisal of the equations used to predict the internal stresses in film coatings applied to tablet substrates

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It is now generally accepted that when a polymer film coating is applied to a substrate an internal stress ( $P$ ) is invariably developed. This is composed of the sum of the internal stress due to shrinkage of the film on evaporation of the solvent ( $P_s$ ), and the thermal stress due to differences in the thermal expansion of the film coating and substrate during changes in temperature arising out of the coating process ( $P_T$ ). Recently Croll (1979) and Sato (1980) presented equations for the calculation of  $P_s$  and  $P_T$  respectively in organic coatings:

$$P_s = \frac{E}{1 - \nu} \left[ \frac{\phi_s - \phi_r}{3(1 - \phi_r)} \right] \quad (1)$$

$$P_T = \frac{E}{1 - \nu^2} \Delta\alpha\Delta T \quad (2)$$

Where  $E$  is the Young's modulus of elasticity of the coating;  $\nu$  is the Poisson's ratio of the coating;  $\phi_s$  is the volume fraction of the solvent at the solidification point (i.e. where the coating solution first behaves as a solid rather than a viscous liquid);  $\phi_r$  is the volume fraction of the solvent remaining in the dry coating at ambient conditions;  $\Delta\alpha$  is the difference between the coefficient of linear expansion of the coating,  $\alpha_c$ , and the substrate,  $\alpha_s$ ;  $\Delta T$  is the difference between the glass transition temperature of the coating,  $T_g$ , and the ambient temperature,  $T$ . Unfortunately, Sato (1980) did not report any derivation of his equation and hence the assumptions made can only be a matter for conjecture. However, a detailed study of several other treatments (Chow et al 1976; Croll 1978, 1979; Hoffman 1981) has revealed that equation (2) may not be totally applicable to tablet film coatings.

As usual in all problems of elasticity (in all cases the coating is regarded as a Hookean solid) the strains and corresponding stresses are connected by means of the

elastic constants. The strains in the two cases are different in origin; Croll (1979) assumed the linear shrinkage strain at the interface to be one third of the internal bulk strain within the coating due to volume of solvent lost from the film after solidification, while Sato (1980) assumed the differential thermal strain to be equivalent to the difference in the linear expansion of both the coating and substrate over the temperature range  $T_g - T$ . Both assumptions are valid in the context of tablet film coatings. Since both processes give rise to what is known as a plane stress situation, i.e. the coating has no stress normal to its plane, all stresses lying within the plane of the coating, then the relevant equation relating the induced stress in an arbitrary direction,  $\sigma$ , to the strains is given by:

$$\sigma = \frac{E}{1 - \nu^2} (\epsilon + \nu\epsilon_1) \quad (3)$$

where  $\epsilon$  and  $\epsilon_1$  are the strains parallel and perpendicular to the stress.

It can be seen that if  $\epsilon_1 = \epsilon$  then:

$$\sigma = \frac{E}{1 - \nu} \epsilon \quad (4)$$

but if  $\epsilon_1$  is zero then:

$$\sigma = \frac{E}{1 - \nu^2} \epsilon \quad (5)$$

Sato (1980) appears to have considered the latter case as used by Chow et al (1976) in defining the stress at the film/substrate interface along a coated cantilever beam. It does not take into account shrinkage of the coating across the cantilever resulting in an equal strain perpendicular to its length. A consideration of this more general situation results in equation (4) as used by Croll (1978, 1979) and Hoffman (1981). For tablet film

coatings, a biaxial stress system, equation (2) should be modified:

$$P_T = \frac{E}{1-\nu} \Delta\alpha\Delta T \quad (6)$$

The results for thermal stress predicted from this equation will be some 35% higher than those predicted from equation (2).

In the case of film coatings applied to tablet substrates, the concept of linear expansion is rather difficult to visualize. Equation (6) can be further modified by introducing cubical or volumetric expansion coefficients since these can be relatively easily determined by known practical methods and, to the first approximation, can be taken as being equivalent to three times the corresponding linear expansion coefficients. If this is done, equation (6) becomes:

$$P_T = \frac{E}{3(1-\nu)} \Delta\alpha(\text{cubic}) \Delta T \quad (7)$$

and hence the total stress,  $P$ , is given by:

$$P = \frac{E}{3(1-\nu)} \left[ \frac{\phi_s - \phi_r}{1 - \phi_r} + \Delta\alpha(\text{cubic}) \Delta T \right] \quad (8)$$

A factor not previously considered is that of the stress induced in the film coating by swelling of the tablet substrate when stored at high humidity. Work on various tablet formulations (Sangekar et al 1972) has shown that volume changes of up to 68% can occur when certain tablets are stored at 100% R.H. and proportionately less for tablets stored at lower humidities. Of course, in the case of hygroscopic polymers  $\phi$ , will also change with humidity and this will need to be taken into account, but for all film coatings such volume changes in the substrate will invariably create high internal stresses in the coatings. An equation for this stress due to swelling,  $P_v$ , can be derived as follows.

If the fractional volume change in a tablet on storage is given by  $\Delta V/V$  where  $\Delta V$  is the volume change and  $V$  the volume before storage, and if it is assumed that this volume change creates an internal bulk strain equivalent to  $3\epsilon$ , where  $\epsilon$  is the isotropic linear strain, then:

$$\epsilon = \frac{\Delta V}{3V} \quad (9)$$

If it is assumed that the strains at all corresponding points in the coating and substrate are identical (an

assumption made and substantiated by Stanley et al (1981), then the stress in the coating corresponding to this strain will be given by:

$$P_v = \frac{E}{1-\nu} \frac{\Delta V}{3V} \quad (10)$$

It can be seen that for a polymer film coating with a Young's modulus of elasticity of  $10^3$  MPa and a Poisson's ratio of 0.35, a 1% volume increase in the tablet on storage will lead to a  $P_v$  of 5.13 MPa while a 10% volume increase will lead to a  $P_v$  of 51.3 MPa—a value very close to the tensile strength of such a film. These values would suggest that coated tablet formulations based on direct compression excipients, as exemplified by Sangekar et al (1972), could produce problems on storage at high humidities. This has indeed been found to be the case in our laboratories where bridging of the intagliations has been found to occur on the high humidity storage of tablets produced from a variety of direct compression excipients coated with hydroxypropyl methylcellulose films.

A feature of all the equations presented is that they are concerned only with the equilibrium values of the induced stresses and that these stresses are both uniform and isotropic. Despite the fact that the tablet coating process is, by its very nature, a dynamic one and that stress concentrations will invariably occur especially around pigment particles included in the coating formulation, the equations do provide a basis for further studies especially in the prediction of the in-situ behaviour of film coatings from various external measurements on their mechanical and physico-chemical properties. This should then provide a basis for a more fundamental and more scientific approach to the formulation of film coatings.

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