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Predicting film thickness on film coated tablets

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Abstract

Film thicknesses on film coated tablets have been predicted based on the assumption that the increase in volume of a tablet core after coating is a result of a uniform thickness of polymer coating, i.e. a calculation of the dry volume increase in film coating per unit area of a tablet surface will be equivalent to an average film thickness. The correlation between predicted and measured values is very good with predicted values being, on average, some 14% higher consistent with the fact that 100% coating efficiency is never achieved in practice.

Keywords: Film thickness; Coated tablets; Prediction

1. Introduction

The amount of film coating applied to a tablet or granule and hence its thickness is an important variable in determining the appearance (i.e. colour, gloss) of the product (Rowe, 1985), the opacity of the coating and hence the degree of protection provided against light degradation of an active component (Rowe, 1984a,b, 1985; Bechard et al., 1992), the incidence of the defect bridging of the intagliations (Rowe and Forse, 1980; Kim et al., 1986), the degree of protection against moisture permeation (Banker et al., 1966) and the rate of drug release if the film coating is used as a diffusion barrier (Shah and Sheth, 1972). Generally the amount applied is simply expressed as a dry weight increase or, for comparison against other tablet cores of varying weight, a dry weight percentage increase of the tablet core weight. Some authors (Lehmann and Dreher, 1979) have suggested the use of a dry weight increase per unit area of the tablet or granule surface with a factor of 1 mg/cm^2 being equivalent to a film thickness of 10 μm. However, such a procedure requires a knowledge of the surface area of the tablet or granule, a property not generally measured.

Recent work on opacity prediction for film coated tablets (Rowe, 1995) has highlighted the need for a prediction of the film thickness. An approach to this problem is presented in this communication.

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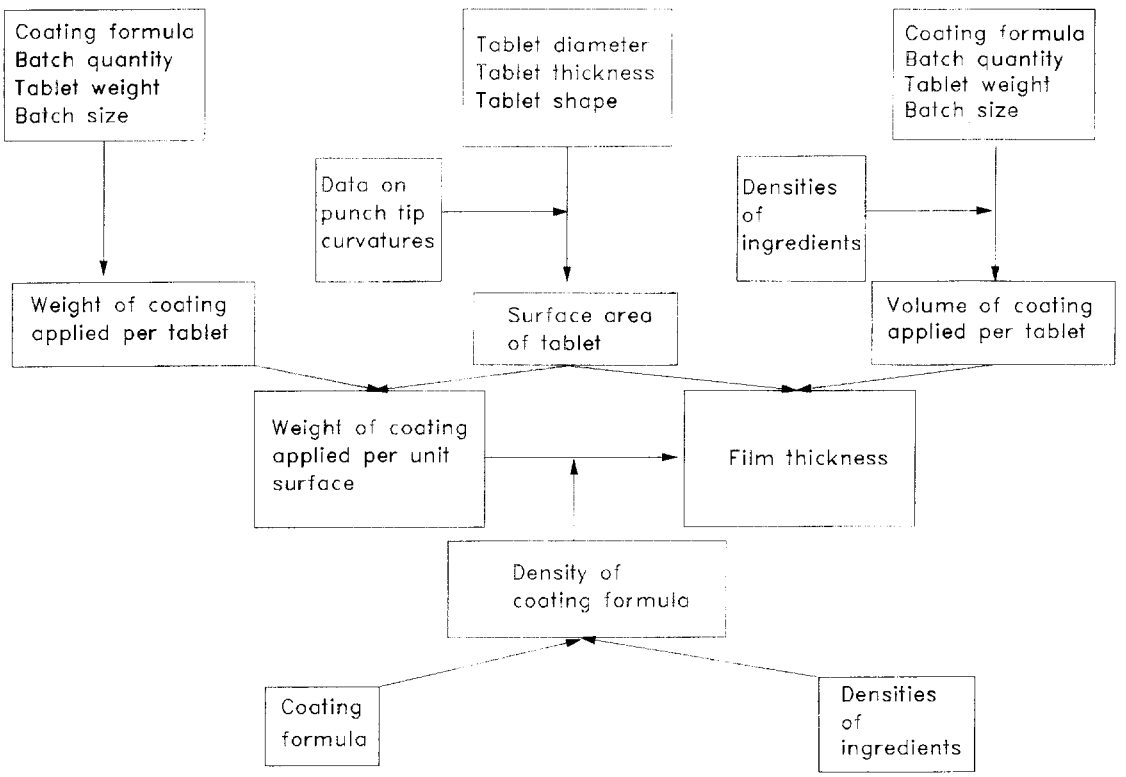

Fig. 1. Interrelationships between the data used to calculate average film thickness.

2. Hypothesis

The approach chosen is based on the assumption that the increase in volume of the tablet core when coated is a result of a uniform thickness of coating evenly spread over its surface. Hence a calculation of a dry volume increase of a film coating per unit area of a tablet surface will be equivalent to an average film thickness. Interrelationships between the data used for this calculation are shown in Fig. 1.

The calculation of the surface area of a tablet core is based on that given by Munzel (1963), i.e. for a round biconvex tablet the surface area, S, is given by the sum of the surface area of a cylinder and the surface area of two segments of a sphere:

$$S = \pi dh + 4\pi Rz \quad (1)$$

where d is the diameter of the tablet, h is the height of the tablet edge, R is the radius of curvature of the tablet cap or crown and z is the height of the tablet cap.

Values for R and z can be obtained for all types of tablet, i.e. shallow, normal/standard and deep biconvex using tables of punch tip curvatures produced by tablet punch manufacturers. Generally R and z are related by the equation:

$$z = R - \frac{\sqrt{4R^2 - d^2}}{2} \quad (2)$$

A variable in Eq. (1) not directly related to punch geometry is the height of the tablet edge. This is not generally measured by formulators who prefer to measure the total thickness, t, of the tablet. In this case h can be calculated using:

$$h = t - 2z \quad (3)$$

Rearranging Eqs. (1) and (3) gives:

$$S = \pi d(t - 2z) + 4\pi Rz \quad (4)$$

thus allowing surface areas to be easily computed.

The calculation of the volume of the dry film coating applied is easily calculated from the pro-

Table 1
Densities of ingredients used in tablet film coating (data taken from Rowe, 1984c)

Polymers	
Hydroxypropyl methylcellulose	1.26
Ethyl cellulose	1.14
Hydroxypropyl methylcellulose phthalate	1.28
Cellulose acetate phthalate	1.37
Plasticizers	
Glycerol	1.26
Propylene glycol	1.04
Polyethylene glycol 400	1.13
Dimethyl phthalate	1.19
Diethyl phthalate	1.12
Dibutyl phthalate	1.05
Triacetin	1.16
Castor oil	1.44
Pigments/fillers	
Titanium dioxide	3.78
Red iron oxide	5.41
Black iron oxide	4.98
Yellow iron oxide	4.32
Calcium carbonate	2.65

portions of the various ingredients (e.g. polymer, plasticizer, pigment, etc.) and their densities (Table 1). It is interesting to note that since the density of a film coating formulation (especially one containing pigments) will certainly be significantly greater than unity, the rule of thumb used by Lehmann and Dreher (1979) for a dry weight increase of 1 mg/cm^2 will over-estimate film thickness.

3. Observations

Results on six products produced by coating a variety of tablet core formulations with a variety of film coating formulations applied as either aqueous or organic solvent based suspensions at various batch sizes using side vented perforated coating drums are show in Table 2. The correlation between the predicted film thickness and those measured using a micrometer is very good considering the assumptions made. The predicted film thicknesses are on average some 14% higher than those measured, not surprising since the prediction assumes a 100% coating efficiency with no loss of coating solids in the ducting of the machine. Accurate values for coating efficiency are difficult to obtain; Pickard (1979), using both aqueous and solvent based suspensions, has recorded coating efficiencies, determined by weighing the tablet before and after coating, of between 78–94% while Kara et al. (1982), using solvent based suspensions in a side-vented perforated drum, recorded coating efficiencies determined by gas borne dust sampling in the ducting of between 96–99%. The discrepancy in values underlies the difficulty in the determination, and industrial experience with aqueous based suspen-

Table 2
Comparison of predicted and measured film thicknesses

Diameter (mm)	Product description	Film thickness (μm)			
		Batch size	Predicted	Measured[a]	
		(kg)		Mean	Range
8	Coloured/intagliated	100	24	22	15–27
9	Coloured/plain	10	28	31	25–35
10	White/plain	50	34	28	20–43
10[b]	Coloured/intagliated	100	27	23	15–30
11	Coloured/breakline	100	34	27	14–44
11	White/plain	50	54	46	37–62

[a]Mean thickness measured using a micrometer across the diameter of the tablet.
[b]This product was solvent coated; all other products were aqueous coated.

sions would err towards a value of 80%. Of course, if an accurate value for the coating efficiency is known, an allowance for it can easily be made in the calculation providing a more accurate prediction of film thickness.

The presence of intagliations and breaklines in the tablet core would be expected to increase the surface area. However, practically this would be difficult to measure. The results in Table 2 would indicate that the differences obtained are likely to lie within the ranges of measured thicknesses and hence of little relevance considering all the assumptions made.

If mixtures of varying sized tablet cores are used, for instance in development work where placebo tablet cores of a smaller size are used to bulk up tablets containing active ingredient to allow film coating on a laboratory scale coating drum, then provided the diameter and weight of each tablet core formulation are known, corrections can be made for the total surface area of the combined batch. Such an assumption relies on efficient mixing within the coating drum and hence drum speed and the presence of baffles, etc.

Although there are intrinsic weaknesses in the approach adopted, especially concerning the assumptions and simplifications made, the results indicate that the predictions of film thickness are adequate enough to be used to study the consequences of changes in formulation variables and provide insights into approaches that could be used to improve such matters as the incidence of bridging of the intagliations, opacity and rate of drug release. The approach could easily be combined with others previously described to predict opacity (Rowe, 1995) and cracking (Rowe et al., 1994) together with the previously described expert system on film coating defects (Rowe and Upjohn, 1993a) to run within an advanced software tool such as the Product Formulation Expert System (PFES, Logica Cambridge, UK) as described by Skingle (1990) and Turner (1991). This would provide a comprehensive formulation expert system for tablet film coatings comparable with that already described for tablet cores (Rowe, 1993; Rowe and Upjohn, 1993b).

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