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THE EFFECT OF APPLICATION RATE OF COATING SUSPENSION ON THE INCIDENCE OF THE BRIDGING OF MONOGRAMS ON AQUEOUS FILM-COATED TABLETS

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ABSTRACT

The debossed tablets were aqueous film coated with three different film formulations. The application rate of the coating suspension was varied. A slow application rate of coating suspension decreases the incidence of film bridging and reduces the weight gain required for uniform and complete coating. However, the effect of minor variation in coating formulation seems comparatively small.

INTRODUCTION

Film coating is often carried out with tablets engraved for product identification. The depressed monograms are often obscured, in some cases, by film bridging. In a series of

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communications, Rowe and Forse have shown that the incidence of bridging could be minimized by decreasing the thickness of the film (1), by using a plasticizer with a strong affinity for the polymer (2), and by careful selection of the monogram shape (3). Even though those approaches are invaluable to the formulator, each has corresponding limitations: e.g., a certain minimum film thickness is required for even and complete coating, or coating formulation and/or monogram shapes are often fixed. In these cases, bridging problems may be overcome by modifying the coating process variables such as application rate of coating suspension. When a coating suspension is applied at a slower rate under the same fixed conditions, the slower buildup of coating material may give enough time before application of the next coat for relaxation of the stress being formed in the film during the coating process. This will decrease residual stress and thus aftermath shrinkage of the film. These mechanisms may decrease the incidence of bridging and allow a more uniform coating with less weight gain. This hypothesis has been tested by coating debossed engraved tablets at different application rates of the same coating material under the same conditions. Also, the effect of minor variations in coating formulation was studied.

EXPERIMENTAL

Placebo tablets (200 mg) were prepared from a lactose anhydrous (86.4%), sodium starch glycolate (2.5%), microcrystalline cellulose (10.05%), and FD&C blue No. 1 aluminum lake (0.05%), magnesium stearate (1%) direct compression mix and compressed on 8 mm standard concave punches having a debossed slant logo (USV in 0.19 mm depth, 0.33 mm width, 2.16 mm height and 6.68 mm length) and identification number (25 in 0.25 mm depth, 0.50 mm width, 3.22 mm height and 4.32 mm length). A blue color was included in the tablet formulation for easier evaluation of coating uniformity and completeness.

The tablets were coated with three different aqueous film formulations having the same amount of color material (2.8% w/w as solid content of Opaspray K-2-2433, Colorcon, Inc.) but different composition of hydroxypropyl methylcellulose (HPMC) (Methocel E-15, 60 HG, Dow Chemical) and polyethylene glycol 4000 (PEG 4000). Formula A contained 4% w/w HPMC and 1% w/w PEG 4000; Formula B, 3% HPMC and 0.8% PEG 4000; and Formula C, 5% HPMC and 1.2% PEG 4000.

Film coating was performed at a 24-inch Accela-Cota (Manesty Machines Limited) using an airborne spray system (Binks model 610 gun with fluid nozzle No. 66 and air nozzle No. 66PE) with 50 psi of cylinder air pressure and 25 psi atomizing air pressure. The drying air of 85°C was applied at 250 cfm. The application rate of coating suspension was varied at 20, 30, 40, 50 and 60 g/min. To determine the incidence of bridging and the uniformity of coating, 500 tablets were withdrawn at various intervals, visually inspected, and the number with any defects counted and expressed as a percentage. The % weight gain was calculated from the average weight of 100 tablets.

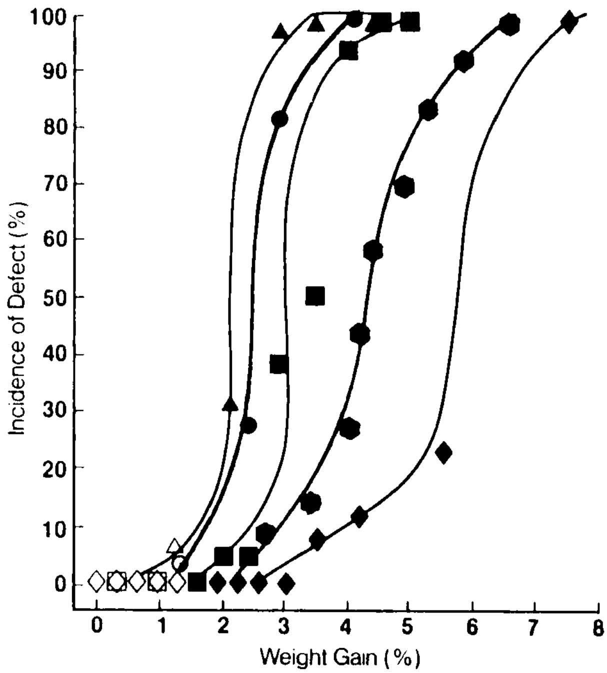


Fig. 1 Effect of application rate of coating suspension on incidence of film bridging (Formula A). △, 60 g/min.; ○, 50 g/min; □, 40 g/min.; ⬡, 30 g/min.; ◇, 20 g/min. Closed symbols indicate uniform and complete coating.

RESULTS AND DISCUSSION

The application rate of Formula A on the incidence of bridging is shown on Figure 1. At the highest application rate studied (60 g/min), about 2% weight gain was required for uniform and complete coverage of the tablets; however, approximately 30% of the coated tablets exhibited film defects. The film of some of these tablets was peeled off indicating incomplete or weak film adhesion. However, at a slower application rate (40 g/min), uniform and complete coverage could be achieved with about 1.5% weight gain

(A) 20 G/MIN

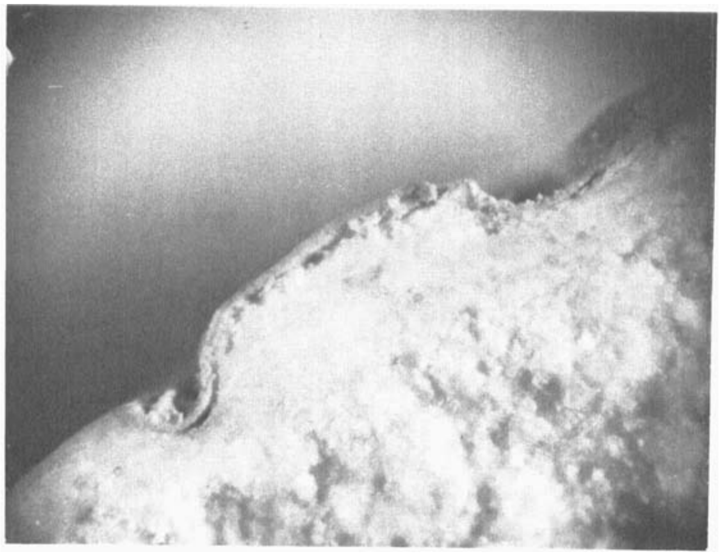
Fig. 2 Face view of film coated tablets with about 3% weight gain (Formula A). (A) 20 g/min; (B) 60 g/min.

and without any incidence of film bridging or other defects observed. At the slowest spray rate studied (20 g/min), no incidence of defects was observed up to about 3% weight gain; uniform coating was achieved at about 1.5% weight gain as with 40 g/min of application rate. Other defects, such as peeling and

(B) 60 G/MIN

Fig. 2 continued. Part B.

film cracking, were not observed at slower application rates (20-40 g/min). Photographs taken of these film-coated tablets illustrate the effect of the suspension application rate on film adhesiveness. In Figure 2, it can clearly be seen that the slower application rate resulted in a distinguishable monogram, while a



(A) 20 G/MIN

(B) 60 G/MIN

Fig. 3 Cross-sectional view of film coated tablets with about 3% weight gain (Formula A). (A) 20 g/min; (B) 60 g/min.

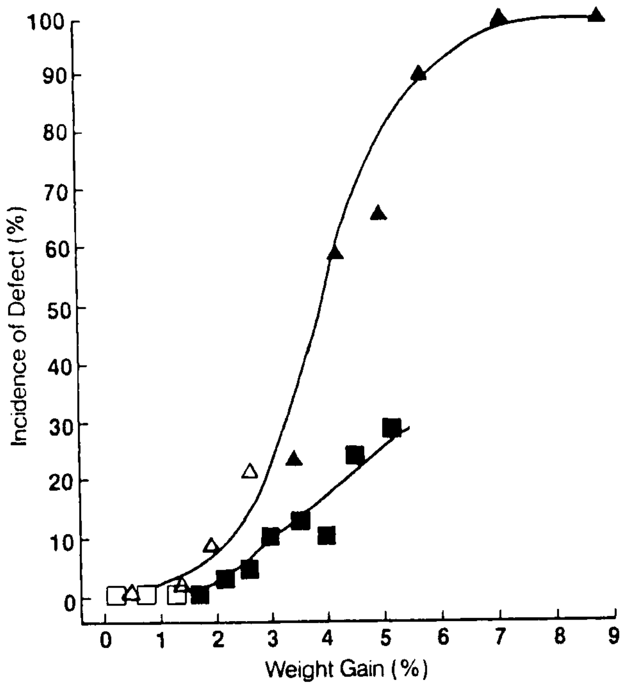


Fig. 4 Effect of application rate of coating suspension on incidence of film bridging (Formula B). △, 50 g/min.; □, 30 g/min. Closed symbols indicate uniform and complete coating.

rapid (60 g/min) application rate essentially obscured the monogram.

In Figure 3, it can be clearly seen that a slow application rate results in deposition of the film contiguous to the debossed monogram (A), while at the higher 60 g/min rate, "logo bridging" occurs (B).

A similar trend was shown with Formula B (Figure 4) and Formula C (Figure 5). However, the effect of minor variation in

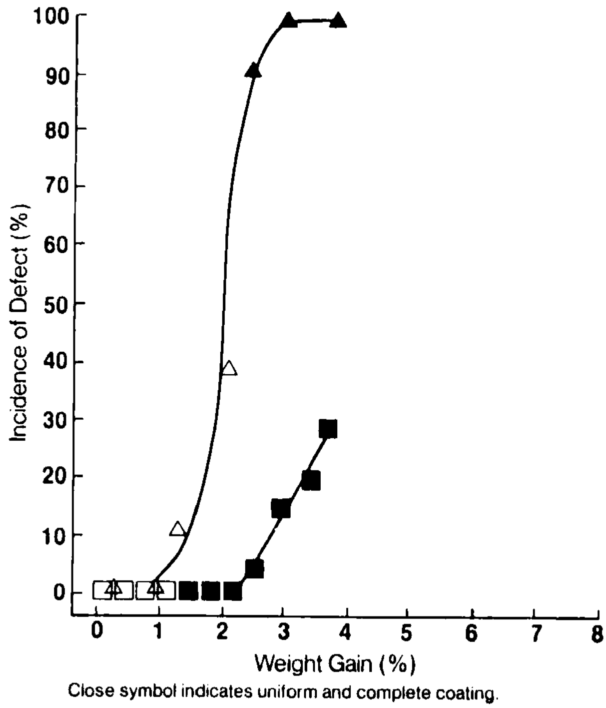


Fig. 5 Effect of application rate of coating suspension on incidence of film bridging (Formula C). △, 50 g/min.; □, 30 g/min. Closed symbols indicate uniform and complete coating.

coating formulation seems comparatively small. In conclusion, a slow application rate of coating suspension decreases the incidence of film bridging and reduces the weight gain required for uniform and complete coating.

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