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An alternate mechanism responsible for the bridging of intagliations on film-coated tablets

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In a recent communication (Rowe & Forse 1980a), a mechanism responsible for bridging of the intagliations on film-coated tablets was postulated. It was shown that the incidence of bridging could be minimized by decreasing the thickness of the film. Later reports showed the effects of plasticizer (Rowe & Forse 1980b) and intagliation shape (Rowe & Forse 1981) on the incidence of bridging.

The postulated mechanism, that of the residual stresses during film shrinkage exceeding the adhesive forces of the film to the tablet surface, has been experienced in our work. An alternate phenomenon of bridging has also been observed by us and has been noted with tablet formulations coated with aqueous hydroxypropyl methylcellulose (hpmc) solutions in air-suspension columns.

Fig. 1 is a scanning electron micrograph of a typical tablet in cross section coated in an 18″ air-suspension column with a 7% w/v aqueous solution of hpmc (Pharmacoat 606-Shinetsu Chemical Co., Japan), containing pigments (50% w/w based on polymer) and plasticized with propylene glycol (20% w/w based on polymer). The coating was applied using an airborne spray system at a rate of 270 g min^{-1} and an inlet temperature of 80 °C (outlet temperature 55 °C).

As can be seen from the micrograph, the intagliation has been filled with air pockets surrounded by thin polymer lamellae. It is proposed that the primary reason for bridging in this case is the inability of the foam, formed by air spraying of the surface active polymer solution, to break.

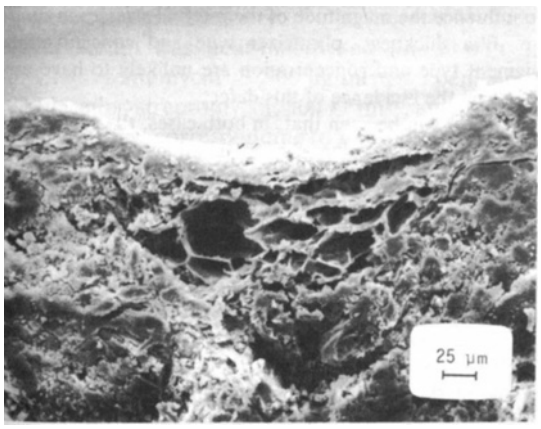

FIG. 1. Micrograph of a tablet in cross section illustrating a bridged intagliation. Note that the foam structure is covered by a continuous film giving the intagliation the typical bridged appearance.

The foam droplets on the surface of the tablet break down readily due to tablet-to-tablet attrition. The intagliations form a 'protected' area free from abrasion and allow the foam to accumulate and 'set'. Once the foam has accumulated to a level approaching the outer contour of the tablet, normal attrition can occur, allowing the foam structure in the intagliation to be covered over with a continuous film.

The mechanism has been further demonstrated by vigorous agitation of the coating solution and brushing the resulting foam onto a glass slide held at 55 °C. The foam,

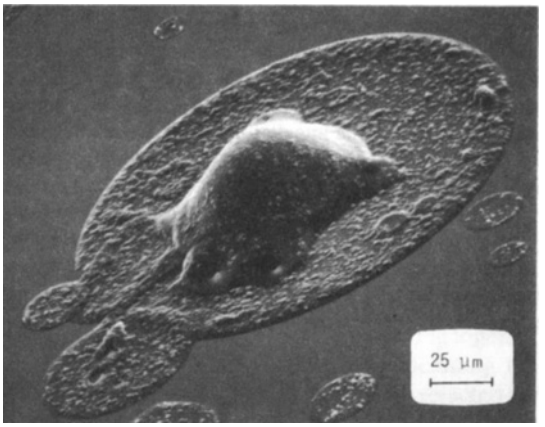

FIG. 2. Micrograph of several discrete coating droplets sprayed onto a heated glass slide. The large protuberance is an intact bubble with several smaller partially collapsed bubbles on its periphery.

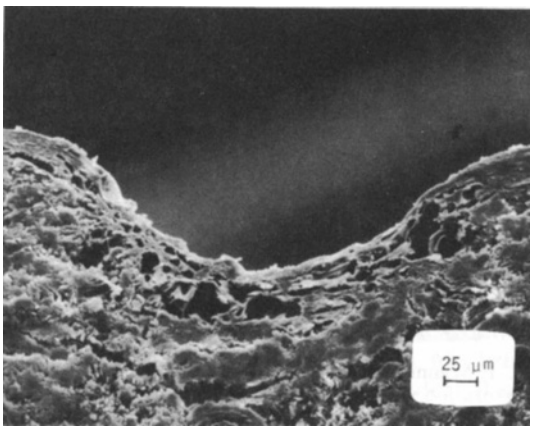

FIG. 3. Micrograph of a tablet in cross section illustrating an intagliation free of bridging.

after an initial period of incomplete bubble coalescence, 'set' in place. The same foam brushed on a slide at ambient temperature eventually dissipated leaving a clear film. Fig. 2 is a micrograph of several discrete droplets formed by momentary spray application of a coating solution from an airborne spray gun onto a glass slide held at 55 °C.

We have attempted to reduce this type of bridging by a variety of methods. It has been found that the addition of 50 ppm of a silicone antifoam agent (Dow Corning FG-10 emulsion—Dow Corning Corp., Midland, Michigan, USA) to the coating solution does not have a marked effect on the degree of bridging. On the other hand, bridging was reduced by (1) simultaneous lowering of the viscosity and surface tension of the coating solution by the addition of alcohol (>20% v/v ethanol), and (2) the use of spray nozzles capable of finer atomization of the coating solution (see Fig. 3).

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Bridging of the intagliations on film coated tablets

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Accurate definition of terms is essential when describing film defects on coated tablets and comparing data from different sources. In the light of a recent communication (Down 1982) purporting to present an alternative mechanism for bridging of the intagliations on film coated tablets, we feel it is pertinent to redefine our terminology on this defect.

In bridging of the intagliations as previously defined (Rowe & Forse 1980, 1981) the film coating, under the influence of internal stresses due to shrinkage on evaporation of the solvent and differences between the thermal expansion of the coating and substrate, pulls out of the intagliation forming a bridge across the edges of the mark. Fig. 1 shows a scanning electron photomicrograph of a typical bridged intagliation. The film has a normal structure and there is some evidence of small amounts of tablet substrate adhering to the underside of the film indicating that at some time during the coating process the film had actually followed the contours of the intagliation. There is no evidence of solidified foam within the intagliation and the 'bridge' can be easily deformed and pushed back into the intagliation by means of a rounded pin-head. The latter provides a simple confirmatory test for this type of defect.

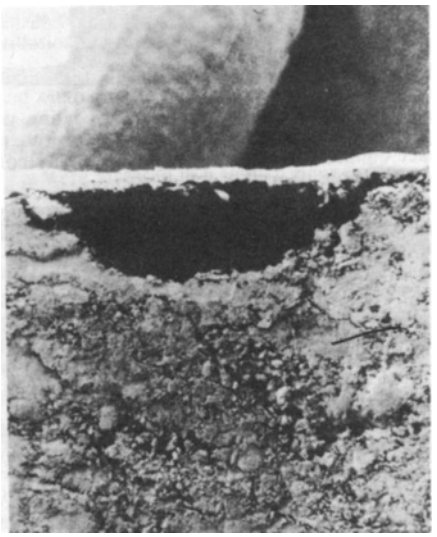

Fig. 1. Scanning electron photomicrograph of a tablet in cross section showing a typical bridged intagliation. Note the presence of small amounts of substrate adhering to the underside of the film.

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This should now be compared with the data presented by Down (1982). In this case the intagliation is filled with a foam structure due to the intagliation forming a protected area free from abrasion thus allowing the foam to accumulate and solidify. It is unlikely that this defect will be specific to certain tablet core formulations, as in the case of true bridging defined above, and hence factors which are known to influence the magnitude of the internal stresses in films, i.e. film thickness, plasticizer type and concentration, pigment type and concentration are unlikely to have any effect on the incidence of this defect.

While it can be seen that, in both cases, the end effect, i.e. that of rendering the intagliations indistinct and illegible thus losing the advantage of using intagliated tablets for product identification, is the same, the defects themselves are totally different in origin. It would appear logical, therefore, to restrict the terminology 'bridging of the intagliations' to that previously defined by Rowe & Forse (1980) and redefine the defect reported by Down (1982) as 'foam infilling of the intagliations'.

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