J. Pharm. Pharmacol. 1980, 32: 647

COMMUNICATIONS

The effect of film thickness on the incidence of the defect bridging of intagliations on film coated tablets

R. C. ROWE*, S. F. FORSE, *I.C.I. Pharmaceuticals Division, Alderley Park, Macclesfield, Cheshire, SK10 2TG, U.K.*

Over the past decade there has been an increase in the use of coding of unit dosage forms for product identification. In this respect film coating offers advantages over sugar coating in that intagliated or engraved tablets can be used. However, if the intagliations are obscured in some way, e.g. by the film bridging across them (Fig. 1) then this advantage is lost. We have investigated this defect known as bridging of intagliations and have found that the incidence of the defect is susceptible to changes in the film coating thickness. This study reports our results and conclusions.

The tablet substrate used was one we had previously evaluated during a development exercise and which was known to be susceptible to bridging. The tablets were coated with varying amounts (to give varying film thickness) of a 5% w/v aqueous solution of hydroxypropyl methylcellulose (Pharmacoat 606—Shinetsu Chemical Co. Limited, Japan) containing glycerol as plasticizer (20% w/w based on polymer). Film coating was carried out in a 24 inch Accelacota (Manesty Machines Limited) using an airborne spray system at an application rate of 50 ml min^{-1} and inlet air temperature of 60 °C. In order to assess the incidence of bridging, 1000 tablets were withdrawn at the end of the run, visually inspected, and the number with any signs of the defect counted and expressed as a percentage. The film thicknesses on 20 tablets were measured using a micrometer and the mean calculated.

The effect of increasing the amount of polymer applied, and hence the film thickness, on the incidence of bridging is shown in Fig. 2. It can be seen that below a film thickness of approximately 10 μm all the intagliations are clear but as the film thickness is increased to approximately 16 μm the proportion of tablets showing the defect increases markedly. The mean and standard deviation results on four repeat coating runs at a mean film thickness of 18 μm shows the reproducibility of the method. These film thicknesses are similar to those used previously in a study of the effect of film thickness on the adhesion of films of hydroxypropyl methylcellulose to placebo substrates (Rowe 1978a). In that study it was found that the measured adhesion of the film to the tablet substrate decreased as the film thickness was increased to 35 μm and that this was attributable to an increase in the residual stresses due to film shrinkage on evaporation of the solvent, which consequently influenced the stress distribution at the film/tablet interface. If we assume that a polymer film coat on a substrate is under the influence of two main stresses; that due to the forces of adhesion holding it to the substrate and that inherent in the film due to shrinkage, and that bridging of the intagliations is a manifestation of the relative magnitude of these two stresses, then the effect of film thickness on the incidence of this defect can be fully explained.

It is well known in polymer technology that the residual stresses in a film on shrinkage increase with thickness until some limiting value is reached at some defined thickness (Meissner & Baldauf 1951; Gardon 1967). On the other hand, the intrinsic adhesion at the molecular level at the film tablet interface will be constant at all thicknesses. For very thin films, therefore, the residual stresses will be very small and the adhesive forces will predominate and hence the intagliations will be clear. However, as the film thickness increases with the consequential increase in the residual stresses their relative effect will also increase until they become predominant. In this case all the intagliations will be totally obscured.

In the context of film formulation optimization these results have several important implications. Varying the film thickness offers the formulator scope for minimizing the incidence of this defect without changing the materials used in the film formulation. However, it is also apparent that in order to reduce the residual stresses and hence the incidence of this defect to a minimum, it is only necessary to apply enough polymer to give a mean film thickness of approximately 9 μm, i.e. a mean theoretical increase in tablet weight of approximately 0·5% w/w. This is, of course, practically very difficult for not only coloured films but also enterosoluble or sustained release films, the former because of the difficulties with intrabatch colour variation, the latter because of the possibility of fast dissolution rates with thin films. An interesting facet of the effect of varying film thickness has been noted on studying the surfaces of coated tablets using a

* Correspondence.

A

B

FIG. 1. Photographs of a film coated tablet showing A—Normal intagliations. B—Bridging of intagliations.

scanning electron microscope and a surface roughness measuring device (Rowe 1978b). This revealed that films of approximately 9 μm thick had a very fine structure and were very smooth but films of approximately 160 μm thick were very rough and had a distinct flake like appearance not unlike the splitting and peeling

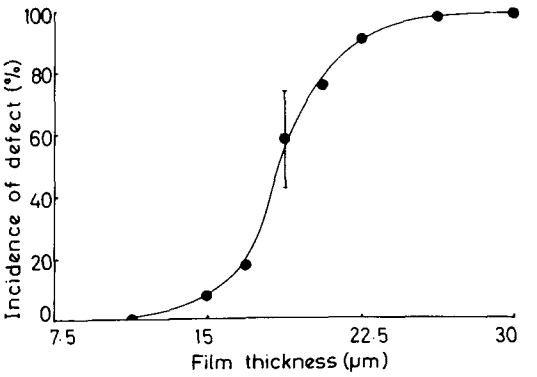

FIG. 2. The effect of film thickness in the incidence of bridging of intagliations.

seen on a macroscopic scale, and also thought to be due to the build up of residual stresses during shrinkage (Rowe & Forse 1980).

In conclusion, it appears that bridging is a manifestation of the stress distribution within a polymer film and occurs when the residual stresses due to shrinkage on evaporation of the solvent are greater than the sum of the adhesive forces holding the film into the intagliation. A knowledge of this stress distribution and the effect of film thickness is invaluable to the formulator in optimising film formulations.

The authors would like to thank Mr L. Jessop for his invaluable technical assistance.

April 18, 1980

REFERENCES

Gardon, J. L. (1967) in Patrick, R. L. (ed) Treatise on Adhesion and Adhesives. Marcel Dekker Inc., New York. Vol. 1 pp 269–324

Meissner, H. P., Baldauf, G. H. (1951) Trans. Am. Soc. Mech. Eng. 697–704

Rowe, R. C. (1978a) J. Pharm. Pharmacol. 30: 343–346

Rowe, R. C. (1978b) Ibid. 30: 669–672

Rowe, R. C., Forse, S. F. (1980) Ibid. 32: 583–584