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Short Communications

Pitting—a defect on film-coated tablets

R.C. Rowe and S.F. Forse

ICI Pharmaceuticals Division, Macclesfield, Cheshire SK102TG (U.K.)

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Pitting on film-coated tablets is a defect where pits occur in the surface of the tablet core without any visible disruption of the film coating (Fig. 1). It was first reported by Rowe (1977) in the context of the increased film/tablet adhesion seen when stearic acid was used as a lubricant. At that time it was reasoned that the pits were caused by the dissolution of the stearic acid particles by the organic solvent system used for film coating. However, we have recently found that pitting can also occur on aqueous film coating of a similar tablet core and that the incidence of the defect is susceptible to both changes in the process conditions and the quality of the stearic acid used. The results of our work are summarized in this report.

The tablet substrate used contained 1.5% w/w of stearic acid as lubricant and was one that we had previously evaluated during a development exercise and found to be susceptible to pitting. The tablets were coated with a 7.5% w/v aqueous solution of hydroxypropyl methylcellulose (a mixture of 3 parts of Pharmacoat 606 (Shin-Etsu Chemicals, Tokyo, Japan) and 1 part of Methocel E50 (Dow Chemicals, MI, U.S.A.) containing polyethyleneglycol 6000 (20% w/w of polymer) as plasticizer and titanium dioxide (30% w/w of polymer) as pigment. Film coating was carried out in a 24 inch Accela-Cota (Manesty Machines, Liverpool) rotating at 12 rpm using a low pressure airborne spray at an application rate of 55 ml · min^{-1}. The inlet air temperature was kept constant at 60°C and the exhaust air temperature was monitored by means of a thermometer inserted in the exhaust plenum of the Accela-Cota. Two coating cycles were used, one in which the tablets were preheated to 55°C for 5 min before commencing spraying and the other in which spraying was commenced without any preheating. At the end of each run the tablets were visually inspected for any signs of pitting.

It was found that whereas pitting occurred when the tablets were subjected to the cycle involving preheating, none was seen in the tablets prepared using the 'cold start' cycle. The only difference monitored in the process conditions was in the exhaust temperature (Fig. 2), and even this indicated that for both cycles the

Correspondence: R.C. Rowe, ICI Pharmaceuticals Division, Alderley Park, Macclesfield, Cheshire SK102TG, U.K.

Fig. 1. A film-coated tablet showing pitting in the surface of the tablet core.

equilibrium temperature was the same and that this was held for some 65% of the total coating time. This would imply that pitting must be associated with temperatures in excess of 40°C and may well be due to melting of the stearic acid particles since the material used in these studies was of BPC quality with a melting point of

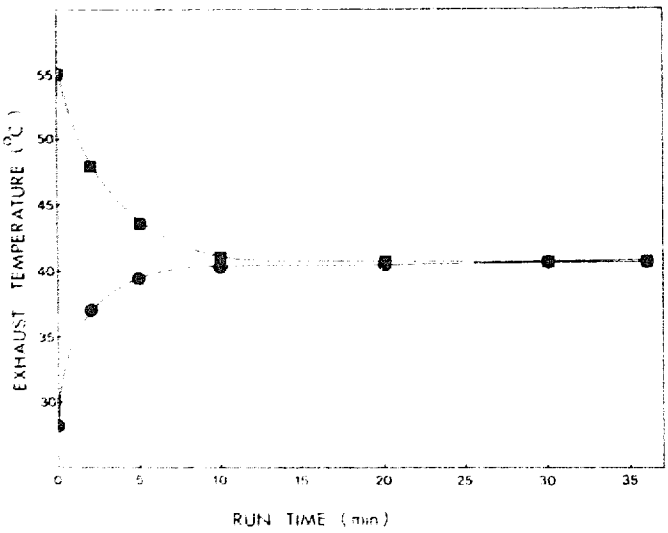

Fig. 2. Exhaust temperature measurements on the two coating cycles used: ■, cycle with preheating; ●, cycle without preheating.

54°C. If this is the mechanism then the defect should be eliminated by the use of a purer grade of stearic acid with a higher melting point, and indeed this was found to be the case on using a specially pure grade of stearic acid with a melting point of 69°C.

In conclusion, it would appear that, in this case, pitting is a function of the melting point of the stearic acid used as lubricant. This is not to imply that pitting is only found when stearic acid is used as a lubricant, since it is likely that the defect could also occur with other materials used in tablet formulation, e.g. polyethylene glycol 6000 and vegetable stearin with melting points of 60°C and 62°C, respectively, especially if preheating exceeded 60°C. In all cases the defect can be eliminated by modifying the process conditions such that the temperature of the tablet core does not exceed the melting point of the batch of additive used.

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