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EFFECTS OF TABLET CORE DIMENSIONAL INSTABILITY ON THE GENERATION OF INTERNAL STRESSES WITHIN FILM COATS

PART II: TEMPERATURE AND RELATIVE HUMIDITY VARIATION WITHIN A TABLET BED DURING AQUEOUS FILM COATING IN AN ACCELA-COTA

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ABSTRACT

Temperature and relative humidity variations within a tablet bed were measured during a complete typical aqueous film coating procedure in an Accela-Cota Model 10. Characteristic thermal and moisture patterns on which it was possible to distinguish the stages of coating process were obtained. Inlet air temperature as a processing variable and different locations within the tablet bed were found to influence these patterns significantly.

INTRODUCTION

Aqueous film coating methods have received a great deal of practical and fundamental attention in recent years. The Accela-Cota (Manesty Machines Ltd.) is one of the most commonly used equipment for this purpose due to its air flow system through the perforated drum which ensures rapid continuous drying of the tablets. A typical aqueous film coating process in an Accela-Cota can be divided into three stages:

a) *Pre-warming stage* at which the tablet cores are warmed to minimise the initial penetration of water into the tablet surface.

b) *Spraying stage* where the actual tablet film coating takes place in which the coating solution is atomised through a spray-gun onto the rotating tablet cores.

c) *Post-spraying stage* is where the spraying is stopped and the inlet air continues to flow for two or three minutes. In some circumstances, however, this period may be prolonged in order to ensure that the solvent is fully evaporated from the tablets, and that the film coated tablets are sufficiently dried .

Water as a solvent for film coating has a high heat of evaporation. Results of many experiments have shown that optimum inlet air conditions for most aqueous film coating operations lie in the range of 50-80°C which, due to evaporative cooling taking place, the tablet bed temperature is maintained at approximately 40-45°C. The temperature changes in the outlet duct and/or at several locations in tablet bed have been measured and the effects of certain processing variables on these thermal patterns have been evaluated by many workers; but very little work has been carried out on the relative humidity changes in tablet bed during film coating processes.

Early work on this general area was focused on organic solvent-based film coatings. Lantz et al. (1) used a thermocouple and thermistors placed in the tablet bed to record temperature changes during organic solvent film coating in a conventional pan. They found that a variation in coating solution application rates and tablet drying times caused distinguishable differences in the tablet bed thermal patterns. Similar work was performed by Lindberg and Jonsson (2) who reported that the bed temperature rose at the beginning of the run, but gradually an equilibrium was reached with only periodic cyclic variation in temperature. These authors also found that rotation rate of the pan, duration of spraying and drying periods, inlet air temperature and velocity and temperature of the coating solution had significant influences on the tablet bed temperature. More recently, Franz and Doonan (3) determined the effects of some of these processing variables on the surface temperature of the tablet bed during an aqueous film coating in an Accela-Cota. Their equilibrium temperature measurements taken at different locations indicated that temperature differences existing on the *surface* of the bed of rotating tablets were small.

In the present study, typical temperature and relative humidity patterns occurring at various locations of the tablet bed during a complete actual aqueous film coating process were measured and the effects of inlet air temperature variations on these patterns were investigated. In a recent work, dimensional changes occurring in tablet cores exposed to temperatures only which mimic the film coating process were examined and significant expansion of tablets due to moisture absorption were detected during re-equilibration to the ambient conditions (4). Hence, the thermal and humidity patterns arising within tablet bed during a film coating process is of a particular interest due to their influence on the dimensional stability of individual tablet cores subjected to these cycles.

MATERIALS AND METHODS

10kg of placebo tablets, with normal concave shape, were coated by spraying an aqueous coating dispersion (Opadry-OY-2890, Colorcon Ltd.) containing 15% (w/w) total solids (hydroxypropyl methylcellulose as the film former, red iron oxide as pigment and polyethylene glycol 400 as plasticiser). The coating pan used was a side vented perforated drum type automated Accela-Cota Model 10 (Manesty Machines Ltd.) equipped with mixing baffles. The spray-gun model was a Walther waxv with a liquid aperture of 1mm. With the automated coating system (Profile Automation, Bromley, UK), it was possible to operate the process as well as record certain processing variables (such as inlet air temperature, outlet air temperature, spray rate, weight of coating solution added and total process time) during the run. Figure 1 illustrates the instrumentation of the system. The measurements of temperature and relative humidity changes in the tablet bed were taken by a thermocouple and a Humidity Indicator HMI 31 (Vaisala, Sweden), respectively.

The thermocouple and the humidity indicator were bound together and positioned firmly at three different locations in the bed of tablets (i.e. (1) at the surface, (2) in the centre and (3) at the base of the tablet bed close to the exhaust air duct) as illustrated in Figure 2. The inlet air was fed at a volumetric flow rate of $8.5m^3/min$ and at temperature settings of 54, 65 and 68°C in order to achieve tablet bed temperatures of approximately 30, 40 and 45°C, respectively. The room temperature during these experiments was constant at 23°C, with a relative humidity of 38%.

The coating process was started by pre-warming of the tablets for 5 minutes while they were tumbled occasionally. This was followed by atomisation of the coating dispersion at

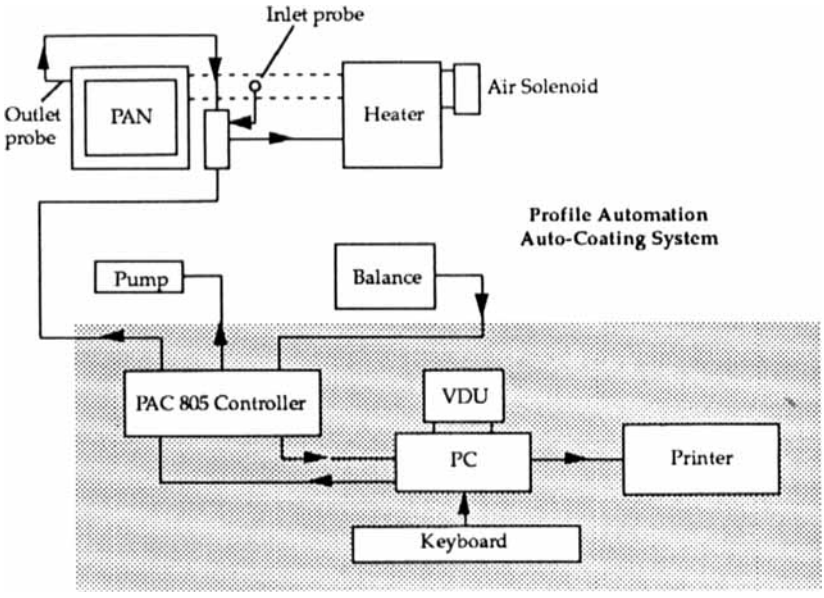

FIGURE 1
System Block Diagram of the Automated Coating Systems. © Profile Automation, Bromley, Kent, BR2 8BS, UK

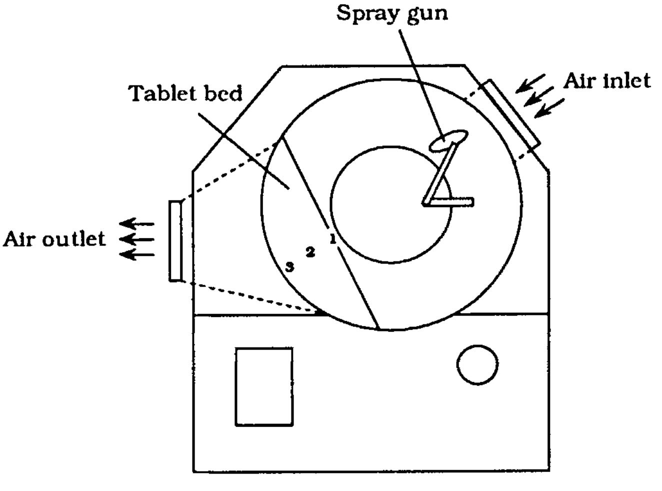

FIGURE 2
Diagram of Manesty Accela-Cota Model 10 Showing the Measurement Locations in the Tablet Bed. Position 1, at the Surface of Tablet Bed; Position 2, at the Centre of Tablet Bed; Position 3, at the Base of Tablet Bed, Close to the Exhaust Air Duct

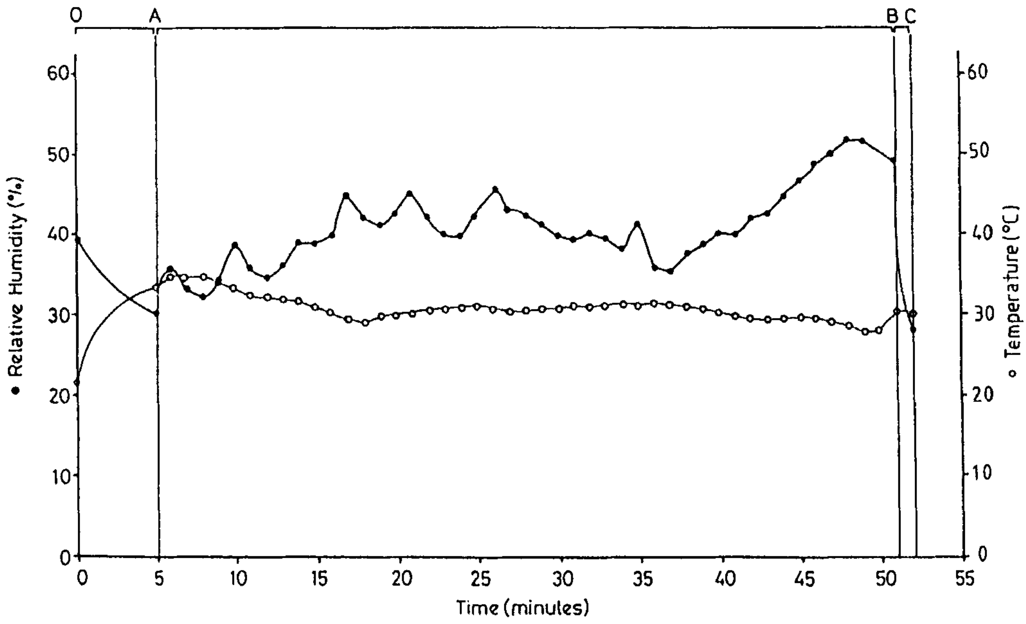

FIGURE 3
Temperature and RH Changes at Position 2; Average Inlet Air Temperature 48.7°C. OA, Pre-warming Stage; AB, Spraying Stage; BC, Post-spraying Stage

345kPa pressure in continuous spraying mode whilst the coating pan was rotating at 12rpm pan speed. Approximately 40 minutes later, the spraying was stopped automatically with the inlet air supply and the exhaust continuing to operate for a further 2-3 minutes, until the whole system was shut down. The readings of temperature and relative humidity in the tablet bed were taken before the process was started, at the end of warming stage, then at 1 minute intervals until the end of the process.

RESULTS AND DISCUSSION

The temperature and relative humidity variations occurring in tablet bed during a typical film coating process exhibited a characteristic profile (Figures 3-7). The pattern of the temperature, in particular, was found to be very similar to the typical infrared thermal pattern obtained by Franz and Doonan (3). A good correlation was always observed between the temperature and the relative humidity of the tablet bed. The different stages of the coating process were also easily distinguishable. At the initial warming stage (OA), the relative humidity gradually decreases with increasing temperature of the tablet bed. Initiation of the spraying cycle at point A causes a rapid increase in the relative humidity and a drop in the temperature of the bed until an equilibrium is attained after approximately 10 minutes. At the end of the spraying cycle (B), the relative humidity in the tablet bed drops rapidly and significantly whereas the temperature rises only a little until the inlet air flow is shut down (C). Tables 1 and 2 present the effect of inlet air temperature and different locations in tablet

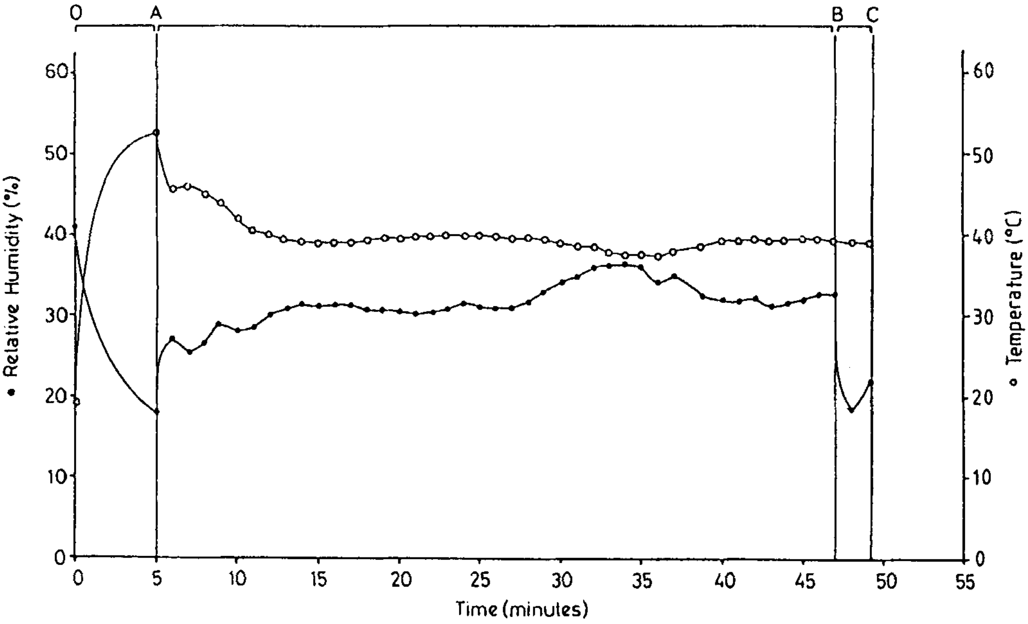

FIGURE 4
Temperature and RH Changes at Position 2; Average Inlet Air Temperature 63.9°C. OA, Pre-warming Stage; AB, Spraying Stage; BC, Post-spraying Stage

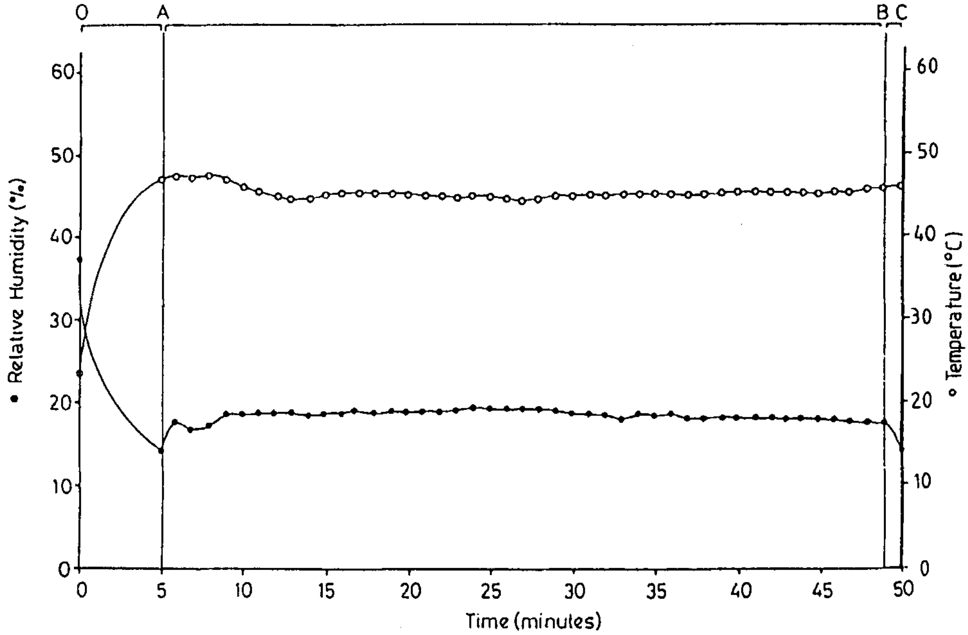

FIGURE 5
Temperature and RH Changes at Position 2; Average Inlet AirTemperature 68.5°C. OA, Pre-warming Stage; AB, Spraying Stage; BC, Post-spraying Stage

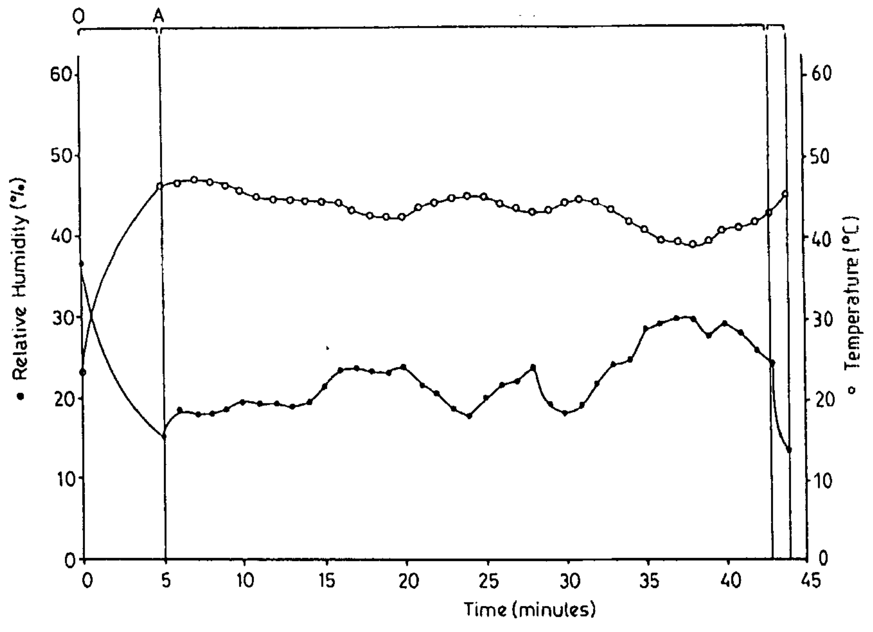

FIGURE 6
Temperature and RH Changes at Position 1; Average Inlet Air Temperature 63.8°C. OA, Pre-warming Stage; AB, Spraying Stage; BC, Post-spraying Stage

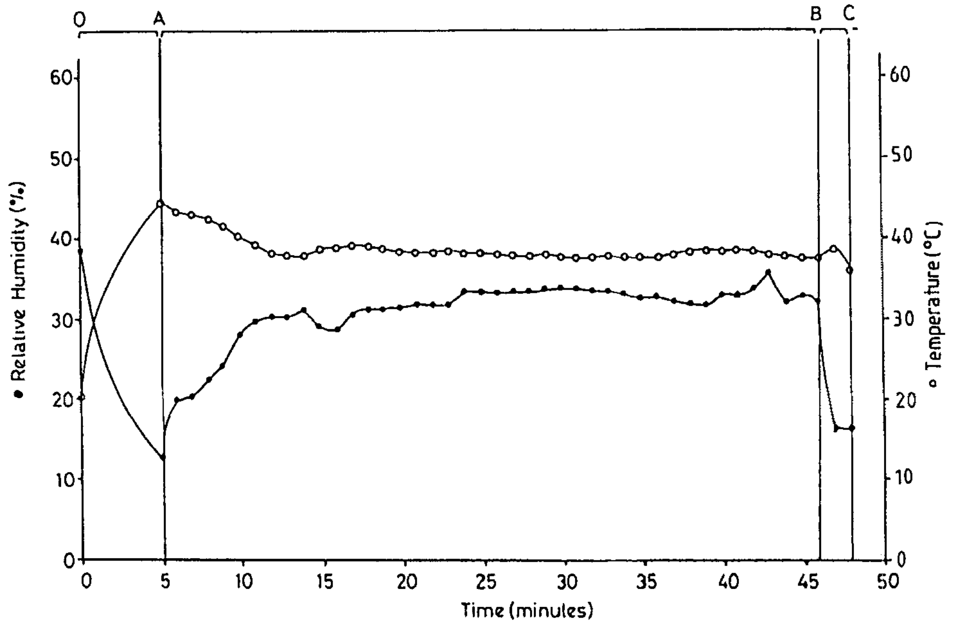

FIGURE 7
Temperature and RH Changes at Position 3; Avarage Inlet Air Temperature 63.0°C. OA, Pre-warming Stage; AB, Spraying Stage; BC, Post-spraying Stage

TABLE 1

Effect of Inlet Air Temperature on Mean Equilibrium Values of Tablet Bed Temperature and Relative Humidity During the Spraying Stage

Average Inlet Air Temp.(°C)	Mean[a] Tablet Bed Temp.(°C)	Mean[a] Tablet Bed Rel. Hum.(%)	Average[a] Outlet Air Temp.(°C)
48.7	30.3	42.7	31.6
63.9	39.3	32.5	43.6
68.5	45.2	18.1	46.2

([a]) All readings are taken at Position 2 which is illustrated in Figure 2.

TABLE 2

Effect of Locations Within the Tablet Bed on Mean Equilibrium Values of Tablet Bed Temperature and Relative Humidity During Spraying Stage[a]

Position[b]	Tablet Bed Temperature(°C)	Tablet Bed Relative Humidity(%)
1 (surface)	43.2	22.4
2 (centre)	39.3	32.5
3 (base)	38.3	32.4

([a]) All readings are taken at an average inlet air temperature of 63.5°C and an average outlet temperature of 43.1°C
([b]) The position numbers indicating the test locations are illustrated in Figure 2.

bed on the mean equilibrium values of tablet bed temperature and relative humidity attained during the spraying cycle of each process, respectively.

Effect of Inlet Air Temperature:

Although the tablet bed temperature and the relative humidity changes during the initial tablet warming stage (OA) depend on the initial ambient values of these parameters, it can be generalised that at the end of this stage (A), the peak tablet bed temperature increased and the final relative humidity decreased with increasing inlet air temperature (Figures 3-5). During the spraying stage (AB), as the inlet air temperature decreased, the relative humidity of the bed increased and became more uneven (see Figures 3-5, and Table 1). These results are in good agreement with the findings of previous workers who have reported that increasing the drying air temperature increases the tablet bed temperature at a constant spray rate (2,3,6). The wide variations in relative humidity when inlet air temperature is low is caused by the inefficient solvent evaporation (Figure 3). It has been noted that the mean values of tablet bed temperatures and outlet air temperatures at the spraying stage were very close as shown in Table 1. This confirms the suggestion made by Hogan (7) that the bed temperature is most conveniently registered by recording the temperature of the exhaust air.

At the end of spraying stage (B), the rapid drop of relative humidity of the tablet bed was more pronounced at lower inlet air temperatures. This is also a result of higher value of relative humidity of the tablet bed achieved during spraying stage at these temperatures.

Effect of Location Within Tablet Bed:

The circulation of heat and the distribution of coating solution in a rotating pan is always of concern. At a constant inlet air temperature, the temperature of the tablet bed during the spraying stage was highest at the surface of tablet bed (Position 1) and lowest at the base of tablet bed (Position 3) whereas the relative humidity of the tablet bed was the lowest at Position 1 and usually about the same at the centre of tablet bed (Position 2) and Position 3 as shown in Figures 6, 4 and 7 respectively, and in Table 2. The tablet bed surface is the location where the product first experiences the direct exposure to heat and spray. Therefore, evaporation of the solvent and drying of the tablet cores are almost immediate at that point. This can be better observed from the thermal and humidity patterns obtained from the trial which had been carried out at Position 1 (Figure 6) showing that the tablet bed temperature and the relative humidity did not exhibit any significant difference with the initiation of the spraying cycle at the end of the initial tablet warming (A).Under the same conditions, 7-10 minutes would be needed for the temperature to attain the equilibrium in the tablet bed at Positions 2 and 3 (Figures 4 and 7). The heat transmission is relatively slower through the inner parts of the tablet bed due to the distance to the inlet air duct as well as to closer arrangement of the tablet cores. This results in cooler and wetter tablet bed at these points.

CONCLUSIONS

The temperature and the relative humidity changes arising in a tablet bed in an Accela-Cota during the application of hot air and coating solution develop characteristic patterns during the coating process. Following the initial warming of tablet cores, the initiation of the spraying cycle rapidly drops the temperature and raises the relative humidity in the tablet bed until equilibrium is reached. At the end of spraying cycle the opposite is observed until the inlet air flow is shut down. Distinguishable differences in thermal and humidity patterns and in their equilibrium values were found when the inlet air temperature and the test location within the tablet bed were varied. Measuring the temperature and relative humidity changes produced within the tablet bed helps to control the optimum processing variables during a film coating process and consequently, enables the prediction of possible premature drying or overwetting problems which may result in poor appereance and film quality or have detrimental effects on moisture and/or heat sensitive tablet cores.

The investigation on the dimensional changes occurring in tablet cores exposed to both temperatures and relative humidities which mimic the film coating process, based on the data taken from the present study, is carried out in the third part of this series of work and their possible effects on the generation of internal stress within the film coats are discussed (5).

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