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THE EFFECT OF RUN TIME ON THE INTER-UNIT UNIFORMITY OF AQUEOUS FILM COATING APPLIED TO GLASS BEADS IN A HI-COATER

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ABSTRACT

Coating experiments were conducted to assess the inter-unit uniformity using individual weight gains of glass beads. Applying more aqueous film coating and prolonging the film-coating process by diluting the coating suspension did improve the coating variability among glass beads. It appears that run time is an important underlying factor which affecting the inter-unit coating uniformity.

INTRODUCTION

In a film-coating process, there are many variables that may lead to non-uniformity of film coat from tablet to tablet within a coating batch. Previous work has been performed by using a photometric analysis (1) or a dye tracer to study the coating uniformity(2,3). However, the results are somewhat controversial. Skultety et. al. concluded that the coating variability increased as more film coating material was applied to the tablets. In contrast, Lord reported that the longer the run time, the more uniform the coating. In addition, coating is a versatile process that imparts various useful properties, such as enteric and sustained release films, to the product. Uniformity of coating is important to ensure the consistent release profile from tablet to tablet within a coating batch. Coating technique also has been used to apply a second drug in the immediate release film coat onto an extended release core. Non-uniformity in the distribution of the second drug in the film coat is quite common. It is justifiable to further elucidate the effects of run time on the coating uniformity due to the discrepancies in the literature. The outcome of this study may provide a lead of improving

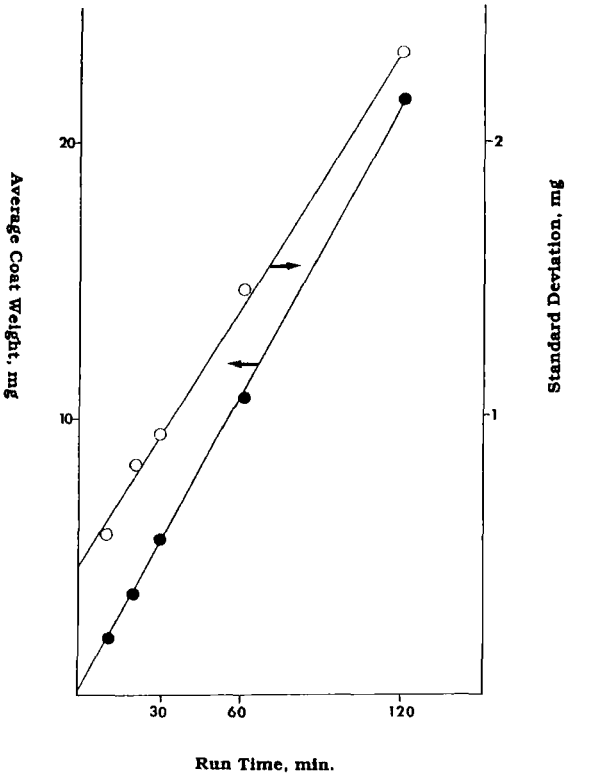

FIGURE 1
Effect of run time on the average coat weight and standard deviation of various coating batches

film coat uniformity and the content uniformity of the second drug in the film coat.

METHODS

Spherical borosilicate glass beads, approximate diameter 6 mm, were selected as coating substrates. The glass beads (1.7 kg) were coated by using a Mini-Hi-Coater HCT-30 (Vector Corp., Marion, IA). The dry air temperature was 80 ± 5° C and exhaust air temperature was 43 ± 4° C. Coating suspensions were pumped to the atomizer at a rate of 8 ml/min. using a peristaltic pump (Cole Parmer, Niles, IL), operating at a spray pressure of 0.9 Bar. The running conditions remained constant throughout all the experiments. The pan speed was set at 12 rpm to study the effect of run time on the coat uniformity. Run time was varied either by increasing the coat weight and keeping the coating system constant (15% w/w coating suspension) or by diluting the

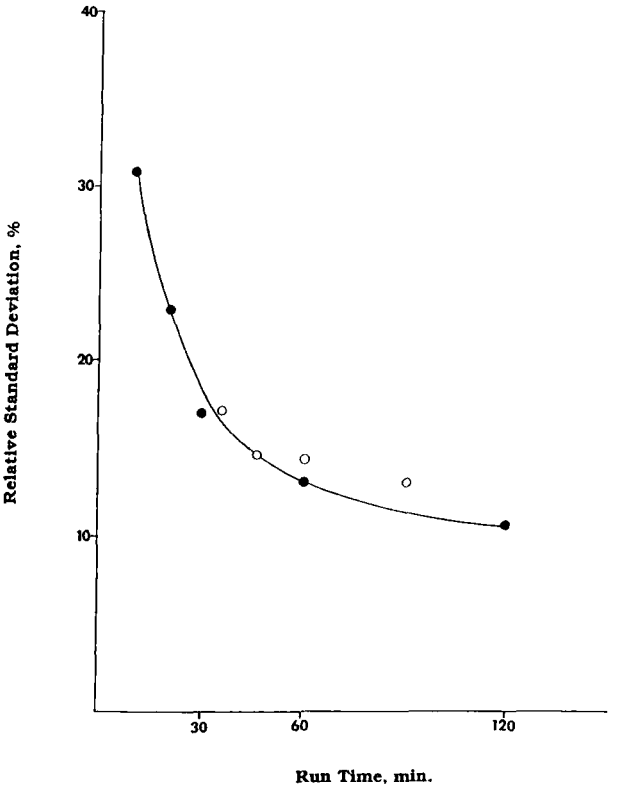

FIGURE 2
Effect of run time on the relative standard deviation of various coating batches
● prolonging run time by applying more film coating
○ prolonging run time by diluting the coating system

aqueous film coating system (12.5%w/w, 10%w/w, 7.5%w/w, and 5% w/w) and keeping the coat weight constant. In addition, the effect of pan speed (12 rpm, 16 rpm and 20 rpm) on the coat uniformity has been investigated by using 15% coating suspension and 30 min. run time. After the coating and drying cycle, the coated glass beads were unloaded and a representative sample (192 glass beads) was randomly selected for coat weight determination. The coated glass beads were accurately weighed, then placed sequentially in a tray and washed thoroughly to remove the coating material. The glass beads were air dried and reweighed. The individual coat weights, the mean and standard deviation of the coat weights of 192 glass beads form each experiment were calculated.

RESULTS AND DISCUSSION

As expected, by keeping the coating suspension constant, the means and standard deviations of coat weight linearly increased with run time (figure 1). The standard deviation commonly serves as a basic measure of variability. However, from a practical viewpoint, the standard deviation is not unitless and most of times is not a convenient statistical parameter when hundreds of the data sets are considered. Therefore, the relative standard deviation (RSD) is a better measure of variability in comparing the variability of several sets of data, especially when great differences in mean values exist among the data sets. Figure 2 shows a plot of the relative standard deviations from the measured means against run times. Applying more aqueous film coating did improve the coating variability between glass beads. The data generated by diluting the coating suspension and keeping the same coat weight as 30 minute run time follow almost the same RSD versus run time curve. The excess dilution of the coating suspension significantly alters the physico-chemical properties of the coating system and causes some deviations from the trend, e.g., coating runs using 7.5% and 5% w/w coating systems. It appears that run time is an important underlying factor which affecting the inter-unit coating uniformity.

The frequency of the coating substrates going through the spray zone also can be increased by increasing drum speed or decreasing spray rate. However, the effect of these variables on the inter-unit coat uniformity may be confounded with other coating factors, such as spray drying effect, erosion and transfer of the coating material between the cascading substrates. This may be a reason that there is no specific trend regarding the effect of pan speed on coat uniformity, i.e., 17.2% RSD for 12 rpm, 20.6% RSD for 16 rpm and 20.1% RSD for 20 rpm. In the current study, 120 minute run time has achieved coating uniformity of 10.75% RSD, which is much greater than USP content uniformity limit (<6% RSD or <7.8% RSD). Besides prolonging the run time, improvement of mixing mechanism in a pan (4,5) and spray pattern will be alternate approaches to reduce the coating variation.

CONCLUSION

Prolonging run time either by applying more film coating or by diluting the coating system did improve the inter-unit coating uniformity. However, extremely long coating time may be required to achieve the desired coating uniformity. Other factors, such as a baffle system, the shape of the coating pan, the inclination of the axis of rotation and the spray pattern, should be considered to reduce the coating variation.

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