Coating of Sugar Spheres for the Production of Slow Release Oral Dosage Forms

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INTRODUCTION

Parameters monitored in the coating process are inter-related and have an effect on characteristics, like surface roughness, of the final product.[1] Many studies conducted to establish the role of parameters controlled during the coating process assessed the role of these parameters during the coating of tablets. In this study, the correlation between parameters was assessed during the batch production of pellets.

AIMS

To determine which parameters show a statistically significant correlation with each other during the production of slow release pellets.

METHOD

Eight batches of pellets coated for slow release in a non-perforated coating pan were assessed. The application of the active pharmaceutical ingredient (API) onto the sugar spheres and the subsequent application of two slow release coatings were analysed.

Parameters monitored included the temperature of the air entering the coating pan, temperature of the product, spray pressure, pistols' distance and surface roughness of the produced pellets.

The parameters were varied during the production of the batches to achieve the best possible yield, for example when the pellets were visibly over-wet, parameters such as temperature of the air entering the coating pan and pistols' distance were varied to correct the degree of wetting. Pellets produced were intended to be marketed and all the parameter changes during the study were undertaken within the limits stipulated in the marketing authorisation.

Surface roughness of the pellets was assessed using a microscope and rated from 1 to 5 according to a pre-defined description (Table 1).

Statistical analysis was carried out using One-Way Anova. The statistical package SPSS® version 20.0 was used to conduct the statistical analysis.

RESULTS

When the temperature of the product was correlated with the temperature of air entering the coating pan during the application of the API solution onto the sugar spheres, a statistically significant difference was observed for batches 2, 4 and 6 (p-value 0.010, 0.002 and 0.030 respectively). The temperature of the product is affected by the temperature of the surrounding air since heat from the product is lost into or absorbed from the surrounding environment.

The temperature of the product was also found to be correlated with the velocity of the pump in batch 4 with a p-value of 0.034. The velocity of the pump affects the volume of solution sprayed which may have a cooling effect.

The surface rating of the pellets after the application of the API solution was found to be statistically correlated to the pump flow and the air inflow (p-value=0.000 and 0.005 respectively). The pump flow and air inflow have an effect on the droplet size which affects the surface roughness.

Rating	Description of pellet surface
1	Surface is densely packed with large spikes
2	Surface is densely packed with small spikes
3	Surface has some spikes
4	Surface is irregular but no spikes
5	Surface is very smooth

Table 1. Pellets' surface roughness rating and corresponding description

Correlated parameters	p-value
Product temperature vs pump velocity	0.034
Surface rating vs pump flow	0.000
Surface rating vs air inflow	0.005

Table 2. Correlated parameters and the p-value obtained when conducting One-Way Anova

CONCLUSION

Parameters monitored during the production of slow release pellets are inter-related to each other. The variation of one parameter may have an effect on other parameters.

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Reference

1. Rege BD, Gawel J, Kou JH. Identification of critical process variables for coating actives onto tablets via statistically designed experiments, Int J Pharm. 237, 87-94 (2002).