Investigation of a New Coating Process for the Application of Enteric Coatings to Small Tablet Samples

INTRODUCTION

The purpose of this study was to investigate the rapid application of an aqueous enteric coating system onto very small batch sizes of tablets using a novel coating process technology. The supercell process involves rapid rotation of tablets as they pass continuously through the coating zone potentially allowing for very uniform film formation on all surfaces of the tablets. This technology could be advantageous where the quantity of active tablets is limited and not sufficient for successful coating in a rotating pan.

EXPERIMENTAL METHODS

Aspirin tablets (325mg) were used as the coating substrate. Acryl-EZE®, aqueous acrylic enteric system, was chosen for this evaluation since coated tablet defects can be quantitatively assessed using acid resistance testing. Even small defects in the tablet coating can result in failure of the enteric system.[1]

Acryl-EZE is a fully formulated, pigmented aqueous enteric (methacrylic acid copolymer type C) coating system. The dispersion was prepared at 20% solids concentration. No subcoat was applied to the tablets prior to enteric coating.

Supercell Process

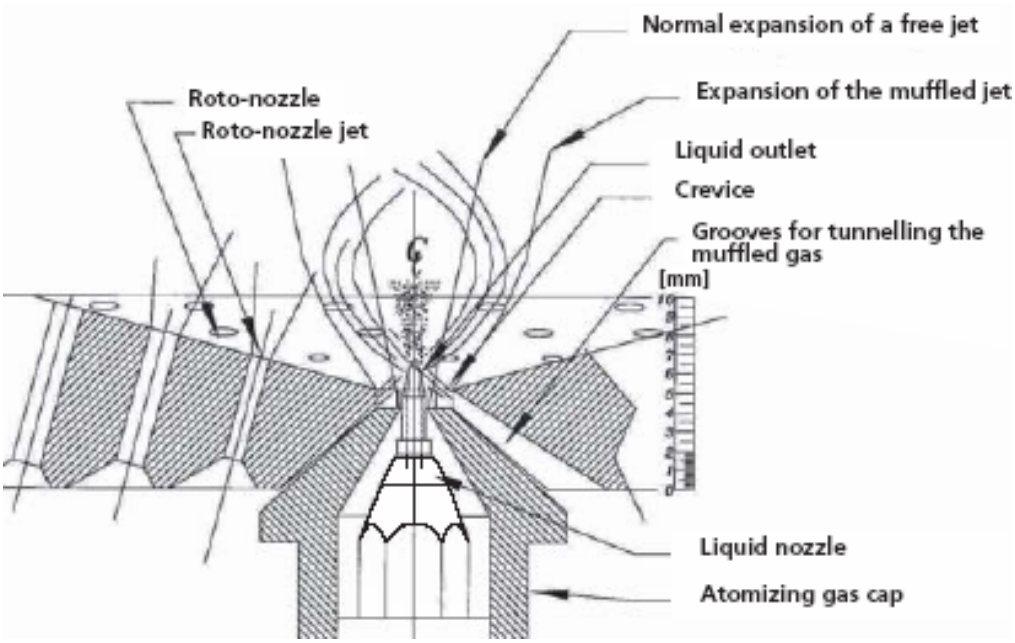
In the Supercell process individual batches of 15 to 100 grams of tablets or capsules can be coated concurrently with heated drying air. The tablets are rapidly rotated as they pass through the coating zone ensuring intimate contact with the coating material (Figure 1).

Figure 1. Tablet Movement

Tablets are loaded into the chamber and conveyed through the coating

zone in a ballistic flight path. Coating material is atomized by means of a specially designed low-momentum two-fluid spray nozzle located below the air distribution plate (Figure 2).

Figure 2. Schematic of Spray Nozzle and Air Distribution Plate



The atomizing air is mixed with low-pressure drying air to dissipate the momentum generated in the atomizing process and reduce the potential for edge attrition of the tablets when striking the coater surfaces.[2] After coating, the tablets or capsules are pneumatically conveyed out of the coating chamber.

Six coating trials were conducted with batch sizes from 45g to 48g and target weight gains from 6 to 11% w/w. The coating machine automatically pre-weighed the tablets and fed them into the coating chamber with automated discharge at the completion of each coating cycle in a semi-continuous process. Batch recipes were programmed into the control system in advance of coating (Table 1).

Table 1. Main Process Parameters

Trial	Airflow (m^3/hr)	Inlet Air Temp. (°C)	Atomizing Air Pressure (bar)	Liquid Volume Applied (mL)	Spray Rate (mL/min)
1	20.03	70	2.5	13.5	3.8
2	20.96	70	2.5	15.8	3.8
3	20.37	70	2.5	18.0	3.8
4	20.36	70	2.5	20.3	3.8
5	20.48	70	2.5	22.5	3.8
6	20.57	70	2.5	24.8	3.8

The resultant tablet samples were tested in 0.1N HCl for 2 hours for enteric properties using a modified disintegration apparatus.

In this modified disintegration method, 50 enteric-coated tablets from each trial were placed in a modified disintegration basket capable of holding 25-200 tablets. The tablets were subjected to 0.1N hydrochloric acid (37.5°C) for 2 hours. Results were reported as the percentage of tablets which exhibited no signs of cracking, peeling, bloating or disintegration after 2 hours.

RESULTS

Tablet Appearance

The coating process for each of the six trials ran smoothly with no difficulties. Visual examination of the tablets after coating revealed no signs of edge defects or other tablet damage. Edge defects were a concern due to random tablet impact with other tablets and various machine surfaces. The Acryl-EZE coated tablets exhibited exceptionally smooth and glossy surfaces (Figure 3).

Figure 3. Coated Tablet Appearance (10% Weight Gain)

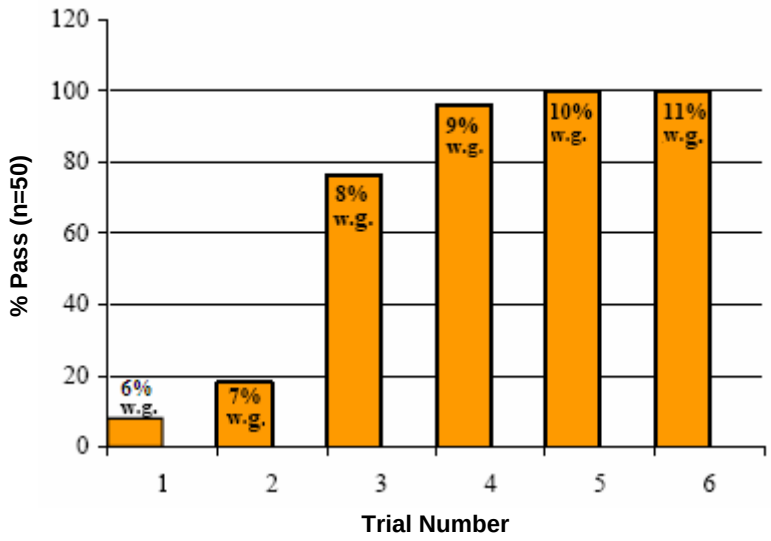
Coating Time

The tablets were exposed to the coating process for a very short period of time. The longest trial with a coating target of 11% weight gain was completed in 6.5 minutes. Trial 1 with a target weight gain of 6% was completed in 3.5 minutes. This short coating duration may have the potential to minimize the risks associated with temperature or moisture sensitive actives exposed to coating conditions for long periods of time.

Enteric Testing

The enteric test results were very good with the tablets coated to a 9, 10, or 11% theoretical weight gain (trials 4-6) passing the enteric test requirements with less than 10% of the tablets exhibiting signs of defects. Trials 5 and 6 remained 100% intact after 2 hours exposure to acid (Figure 4). Tablet samples from trial 6 were tested for dissolution performance and met the USP criteria for delayed release aspirin.

Figure 4. Enteric Test Results



CONCLUSIONS

The results indicate that the Supercell process enables a fast, uniform application of functional enteric coatings to very small batch sizes. The Acryl-EZE enteric coating system used in the study resulted in good enteric performance at application levels that would be typical in rotating pan technology. In early stage drug development where active materials may be in short supply, this coating technology will allow for evaluation of coating systems on a very small scale. It may also be possible to coat friable tablets successfully due to the fast development of the coating but care must be taken if scaling up the process to a rotating type coating pan. With the automated, semi-continuous operation of the machine and the very rapid coating application, it may be possible to link multiple machines together for full scale production of coated tablets.

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REFERENCES

1. G.R.B. Down et.al., Drug Dev. Ind. Pharm. (19) page 2746, 1993.
2. Birkmire et al., Poster presentation, AAPS National Meeting, Baltimore, 2004.

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