

# The Effect of Particle Size and Shape on the Coating Level Required for Taste Masking Multi-Particulates Utilizing Dry Polymer Layering

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## PURPOSE

Taste masking of multi-particulate dosage forms has become widespread in the pharmaceutical industry, particularly with small particles used in ODT applications. The amount of coating required to fully mask the API can be variable as the size and shape of the substrate changes. This study attempts to quantify the effect of size and shape on the coating requirements to fully taste mask multi-particulates.

## METHODS

Six 20% Acetaminophen (APAP) loaded materials; 800-850 micron sugar spheres, 300-400 micron sugar spheres, 100-200 micron sugar spheres, 800-900 micron granulated particles, 300-400 micron granulated particles and 100-200 micron granulated particles; were used as substrates. Each of the substrates underwent size and shape analysis prior to coating. 2 KG of each material was loaded into a Freund-Vector Granurex®GXR-35 rotor insert. A 50/50 blend of Eudragit® E PO (Evonik) and Talc was dry layered onto the APAP loaded substrate utilizing a K-Tron loss in weight powder feeder. Samples were taken at 5% coating level increments up to 60% coating levels. Taste analysis was completed to determine taste masking effectiveness and size/shape analysis was done post coating.

## EQUIPMENT



Freund-Vector Corporation  
Granurex® GXR-35



Sympatec QICPIC

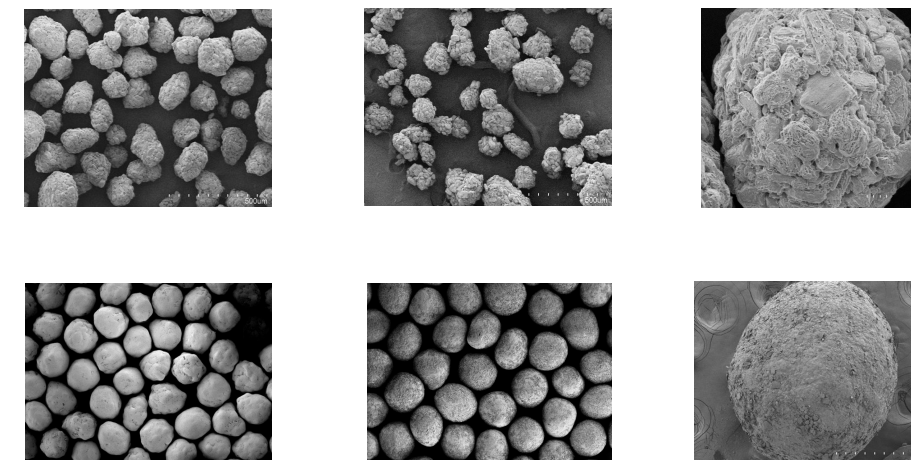
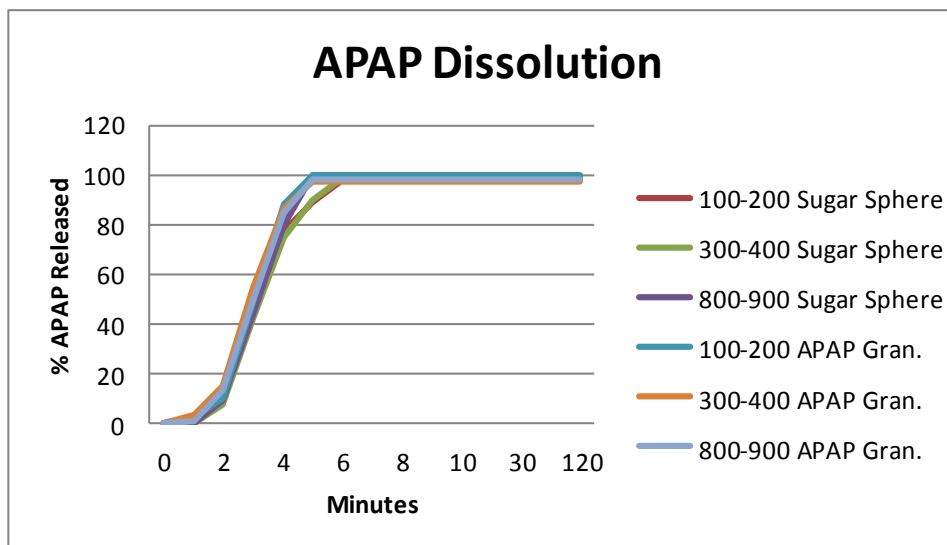
## RESULTS

### PROCESS DATA

CORE MATERIAL	PARTICLE SIZE RANGE	SPHERICITY	ASPECT RATIO	COATING REQUIRED*	PROCESS TIME
Sugar Sphere	100-200 Microns	0.81	0.82	40%	86 minutes
Sugar Sphere	300-400 microns	0.86	0.88	25%	53 minutes
Sugar Sphere	800-900 microns	0.92	0.93	5%	25 minutes
APAP Granulation	100-200 microns	0.65	0.71	62.5%	186 minutes
APAP Granulation	300-400 microns	0.70	0.73	40%	86 minutes
APAP Granulation	800-900 microns	0.71	0.75	15%	37 minutes

\*Determined by minimum amount of coating required to achieve taste masking for 1 minute in the mouth

### DISSOLUTION AND SEM IMAGES



Significant differences in coating requirements were observed in the different sized and shaped particles. The sugar sphere based substrates which had aspect ratio and sphericity values ranging from 0.81-0.92 required 20-35% less coating than their granulated counterparts at the same size ranges, which had aspect ratio and sphericity values ranging from 0.65-0.71. The larger particles also required significantly less coating to achieve taste masking than the small particles, regardless of shape.

## CONCLUSIONS

Size and shape characteristics have a significant impact on the amount of coating required to achieve taste masking of a multi-particulate system. Quantifying the size and shape values of the substrate prior to applying the taste masking coating can help to ensure the proper formulation for achieving a taste masked particle with the highest possible drug content. Sphericity, aspect ratio and size are critical characteristics of the particles that effect the required coating amount.

