

# COATING PROCESS STEP DEVIATIONS MONITORED VIA USE OF A GRAPHICAL IMAGING TOOL

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## PURPOSE

To study the particle size and shape changes during coating of ibuprofen coated beads and determine if process changes could be detected.

## METHODS

1 Kg of 25/30 mesh NP's were loaded into a Vector Corporation GXR-35 rotary fluid bed. 500g of micronized ibuprofen was loaded into a K-Tron KT-20 powder feeder, and was dry layered onto the cores using 5% PVP K-30 as a binder. A 2% coating of Eudragit RS-30D was applied following the powder addition. Talc was added as a final processing step to keep the coated beads separated.

Product samples that were removed during the process were analyzed with a graphical imaging device (QicPic, Sympatec) to study particle size, aspect ratio, and sphericity changes.

## Process Equipment



VFC-Lab 3 fluid bed with GXR-35 (conical rotor insert)

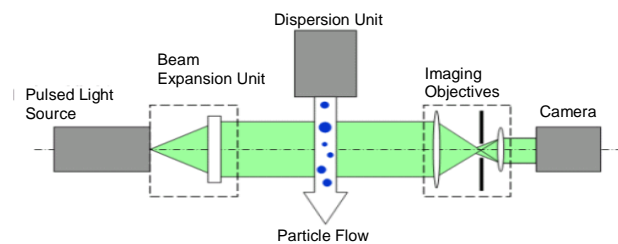
## Image Processing



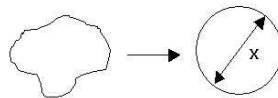
QICPIC with RODOS (dry dispersion feeder)

### Imaging Process Parameters

Conveying Pressure = 1.0 Bar  
 Image Capture Rate = 400 Frames per second  
 Image Trigger = 0.20% Optical Concentration

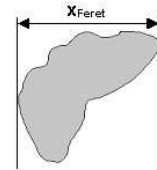


**Diameter of the Circle of Equal Projection Area (EQPC)**  
 Equals the diameter of a circle that has the same area as the projection area of the particle.



### Feret Diameter

This is not a diameter in its actual sense but the common basis of a group of diameters derived from the distance of two tangents to the contour of the particle in a well defined orientation (see figure).



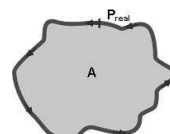
Orientation: horizontal position (0°)

### Aspect Ratio or Roundness

Aspect ratio is the ratio of Feret<sub>min</sub> to Feret<sub>max</sub>. An aspect ratio of 1.0 indicates that the particle is perfectly round.

### Sphericity or Smoothness

Sphericity, S, is the ratio of the perimeter of the equivalent circle, P<sub>EQPC</sub>, to the real perimeter, P<sub>real</sub>.



P<sub>real</sub> = perimeter  
 A = area

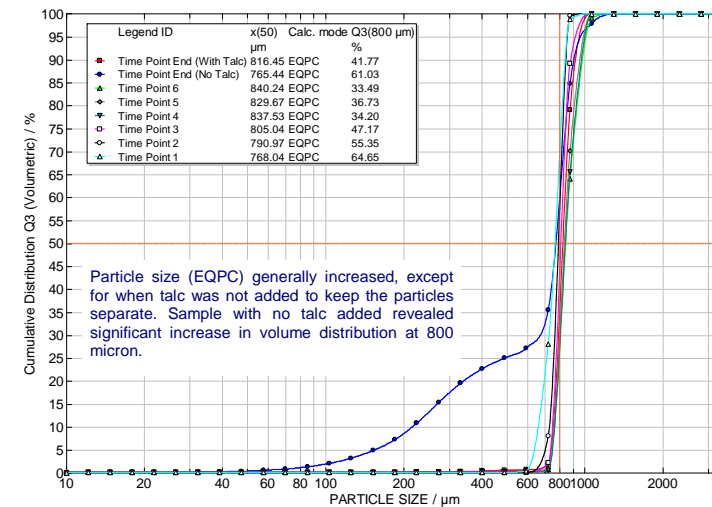
The sphericity is defined by the formula below:

$$S = P_{EQPC} / P_{real} = 2 \times (\pi \times A)^{0.5} / P_{real}$$

The result is a value between 0 and 1. The smaller the value, the more irregular is the shape of the particle. This results from the fact that an irregular shape causes an increase of the perimeter.

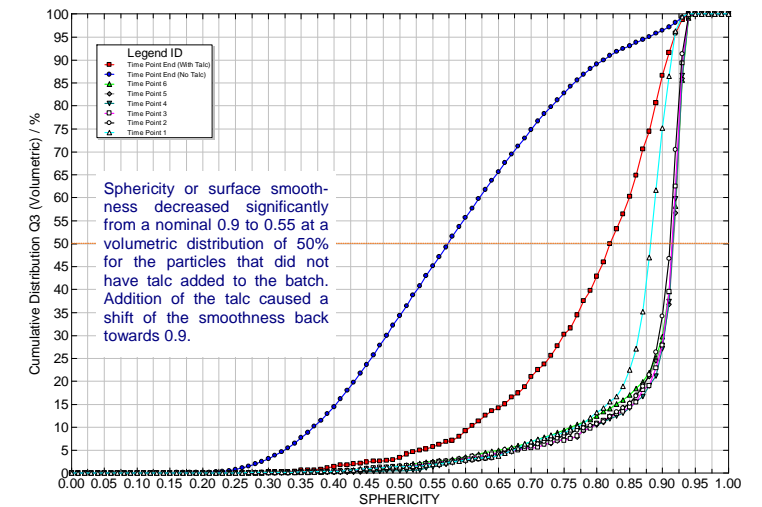
## RESULTS

### Particle Size

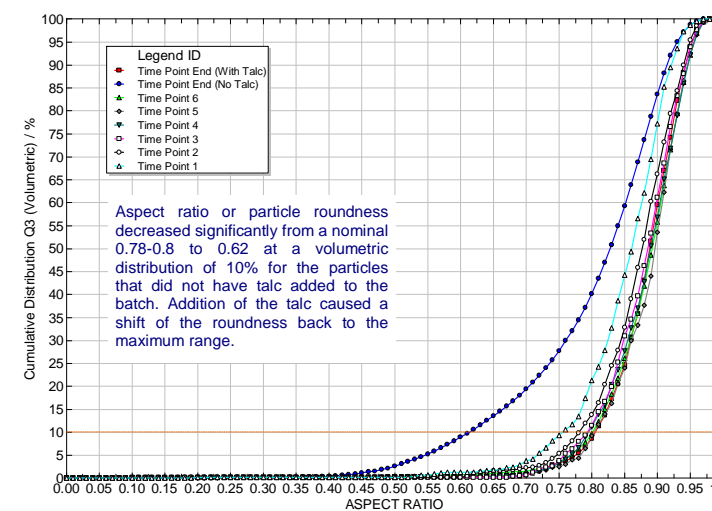


Particle size (EQPC) generally increased, except for when talc was not added to keep the particles separate. Sample with no talc added revealed significant increase in volume distribution at 800 micron.

### Sphericity



### Aspect Ratio



### Particle Image Analysis

>800 micron and Aspect Ratio <0.7

Typical Images



Numerous Agglomerates

EQPC = 1160-1300 μm

Aspect Ratio = 0.49-0.53

Talc Added



No Agglomerates  
 Discrete Particles

EQPC = 847 μm

Aspect Ratio = 0.696

## CONCLUSIONS

Graphical imaging technology can provide a "picture" of changes in a process. Coupled with analyzing the effects of individual processing steps, the results of graphical imaging can indicate process deviations and what caused the deviation.

