PROCESSING CHANGES MONITORED DURING SPHERONIZATION AND POWDER LAYERING VIA USE OF A GRAPHICAL IMAGING TOOL

Shawn Engels [1], Brian Jensen [1], Timothy J .Smith[1], Allen Pieper [2]
[1] Vector Corporation, Marion, IA USA
[2] Sympatec, Lawrenceville, NJ USA

PURPOSE

To study the particle size and shape changes during rotor spheronization of starch and lactose and powder layering of ibuprofen onto sugar cores .

METHODS

Two different processes, spherical granulation and active powder layering, were run on a Vector Corporation GXR-35 rotary fluid bed. For the spherical granulation, a powder blend containing 1 kg of Lactose 312 (Foremost Farms) and 1 kg of B820 Corn Starch (Grain Processing Corporation) was loaded into the GXR-35. The blend was granulated using a binding solution of 10% PVP K-30 in water. Samples were taken at applied binder levels of 0g, 100g, 200g, 300g, 400g, 500g and after drying.

For the active powder layering, 1 KG of 25/30 mesh NP's were loaded into the GXR-35. 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. Samples were taken at powder addition levels of 0g, 100g, 200g, 300g, 400g, 500g and after the RS-30D was applied.

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

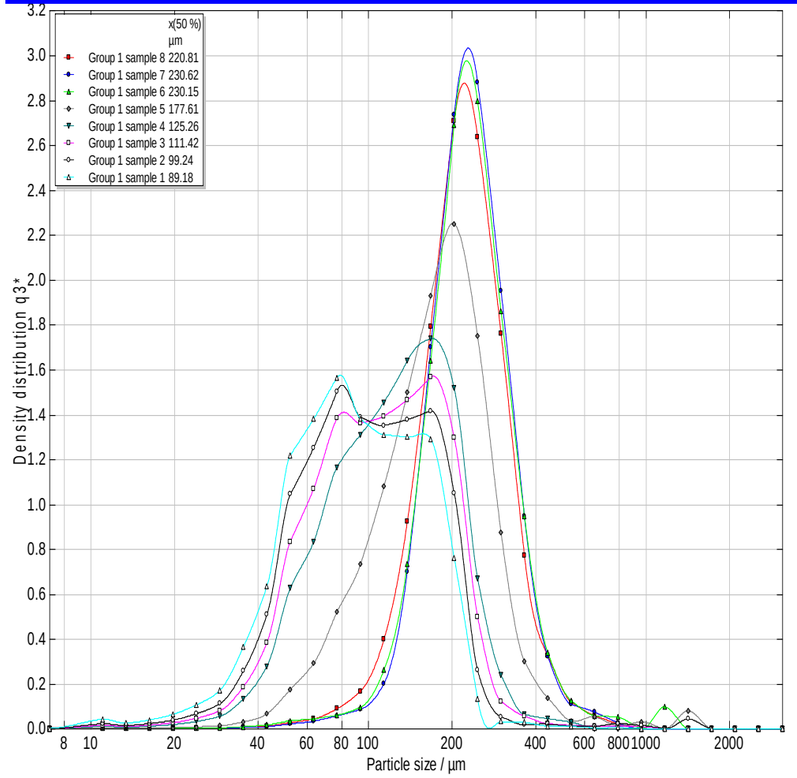
EQUIPMENT

Vector Corporation Granurex GXR-35

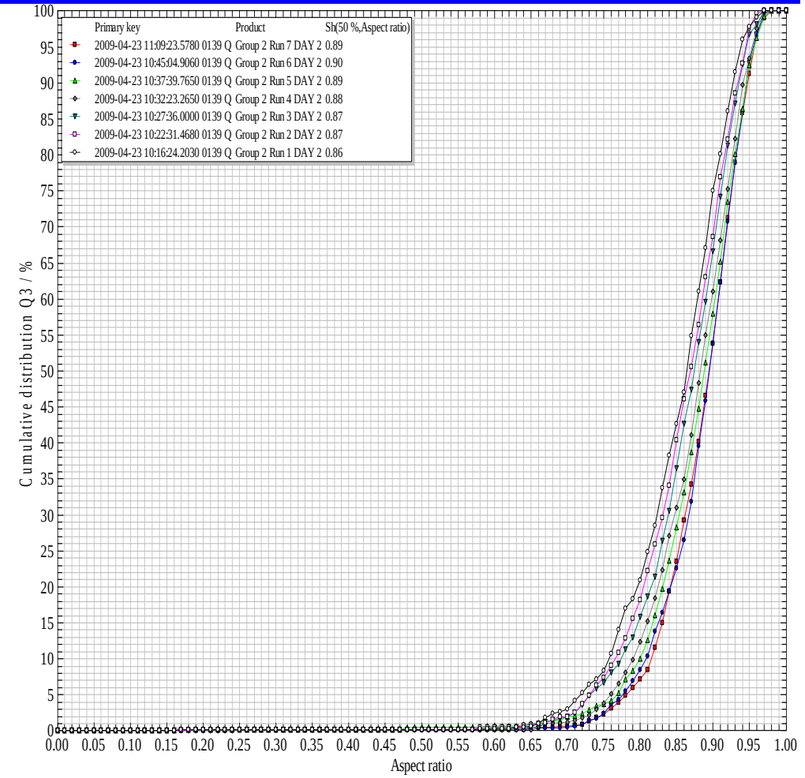
Sympatec QICPIC

RESULTS

PROCESS DATA



Spherical Granulation Particle Size Chart



Powder Layering Aspect Ratio Chart

The granules produced from the spherical granulation trial showed an increase in particle size (89 - 230 micron) and aspect ratio or roundness (0.73 - 0.76) throughout the trial, with the largest, most round particles being observed in the last sample. Sphericity or smoothness slightly decreased throughout the process (0.87 - 0.84), showing that the agglomerated particles had less surface smoothness than the raw material.

The beads from the active powder layering showed increases in particle size (760 - 850 micron), aspect ratio (0.86 - 0.89) and sphericity (0.89 - 0.92) throughout the process, with the smoothest, roundest and largest beads being observed in the final sample.

CONCLUSIONS

Changes in particle characteristics such as sphericity, aspect ratio and particle size can be effectively tracked throughout the process by utilizing graphical imaging technology. This technology can be a useful tool for the processing of multi-particulate systems.