Phenom™ use for pharmaceutical particle inspection

This application note illustrates how the Phenom™ can be used as an instrument for the rapid inspection and qualitative characterization of pharmaceutical particles.

The Phenom is a revolutionary tabletop SEM with magnifications up to 24,000x.
The Phenom's intuitive touch-screen controls and never-lost sample navigation features remove the difficulties associated with operating a traditional SEM. Pharmaceutical scientists no longer have to outsource SEM work. High resolution images of pharmaceutical particles can be obtained at the lab bench within seconds. The Phenom can help shorten drug development and validation cycles, enabling faster time-to-market for new drug products.

Particles

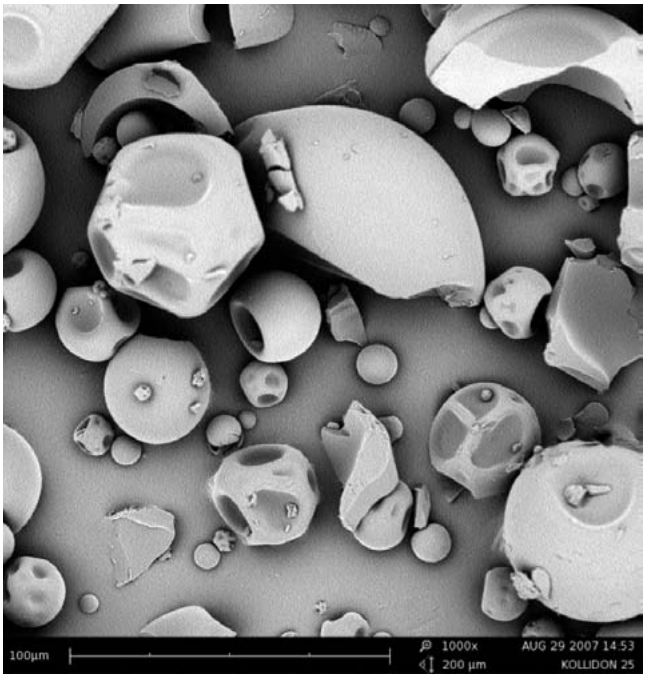
Production of a solid drug dosage form typically begins with the formation of an active pharmaceutical ingredient (API) into particles, generally within the range of 0.1 to 10 micrometers. Once the API is in particulate form it is blended with an excipient to form a larger particle called a granule in order to improve the flow and physiochemical properties with respect to the API.

The size, shape, and morphology of API and granule particles are important characteristics that can influence dissolution behaviour and drug bioavailability. Smaller particles with minimal size and shape variance provide faster and more predictable dissolution and absorption rates. Additionally, particle size and shape influence pharmaceutical production properties such as flow, compaction and dissolution.

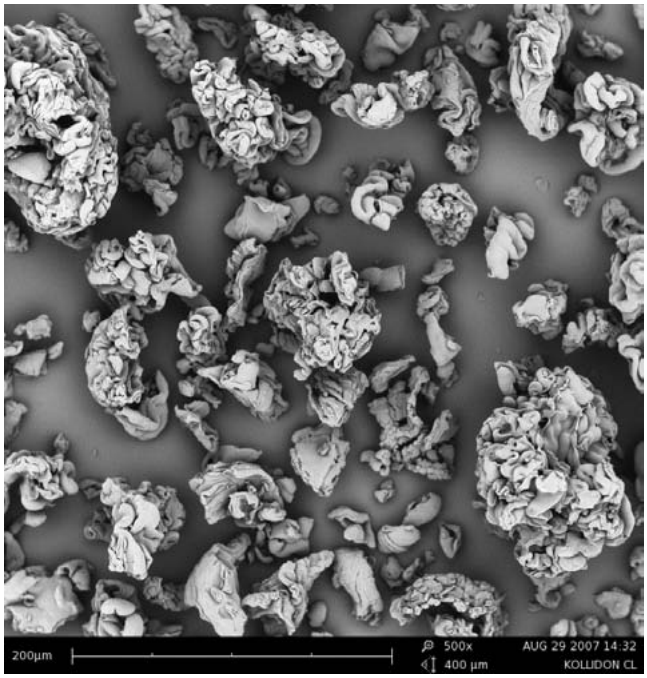
The Phenom can be used as an imaging tool at the development, formulation, and manufacturing stages of pharmaceutical product development.

The structure and surface morphology of two classes of Kollidon provide their unique properties. For example, Figure 1 illustrates the smooth surface and spherical shape that provides Kollidon 25 with good film-forming and dispersing action properties. Figure 2 provides excellent views of the sponge-like structure of Kollidon Cl which allows the particles to act as a disintegrant by absorbing water and swelling.

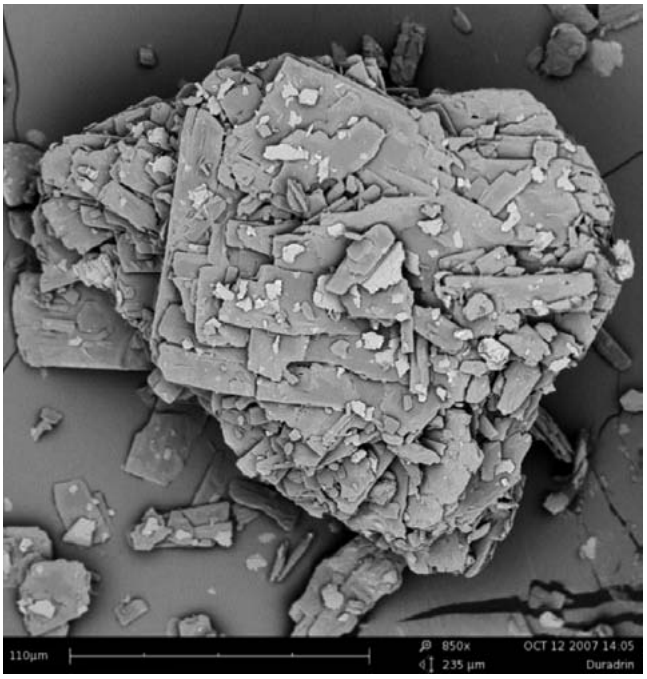
The Phenom allows visualization of broken particles, agglomerates, fines, and foreign particles. The powder samples shown in Figures 3 and 4 were affixed to carbon tape on a standard SEM stub before loading into the Phenom.



Kollidon 25 (Figure 1).



Kollidon C1 (Figure 2).



Powder sample (Figure 3).

Powder sample (Figure 4).

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