

Monitoring pharmaceutical products with tabletop SEM

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In the pharmaceutical industry, pharmaceutical dosage forms are getting increasingly important as a basis for making more effective drugs. In the successful development of a new dosage form, formulation development typically plays a crucial role in the introduction and application of state-of-the-art pharmaceutical technology. The manufacturability and/or bioavailability of many of these dosage forms regularly depend on the characteristics of the individual ingredients. It is for this reason, that it is extremely important that the bulk characteristics of so-called particulate systems such as powders and suspensions can be accurately monitored.



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Particle characterisation

On a regular basis these bulk characteristics are largely determined by the characteristics of the individual particles (e.g., morphology, surface texture, brittleness, etc.). It is safe to argue, that amongst the various particle characteristics their physical appearance is often most critical. Unfortunately, the latter is difficult to describe in absolute terms. This is even more true, since two particles are not likely to be exactly the same. For this reason, due to the complexity in the description of their physical appearance, the characteristics of a collection of particles are usually described on the basis of simplified descriptors which refer in some way to their size and the shape. Thereby, it gets easier to monitor the distribution in size and shape, and various analytical technologies have been made commercially available for that purpose.

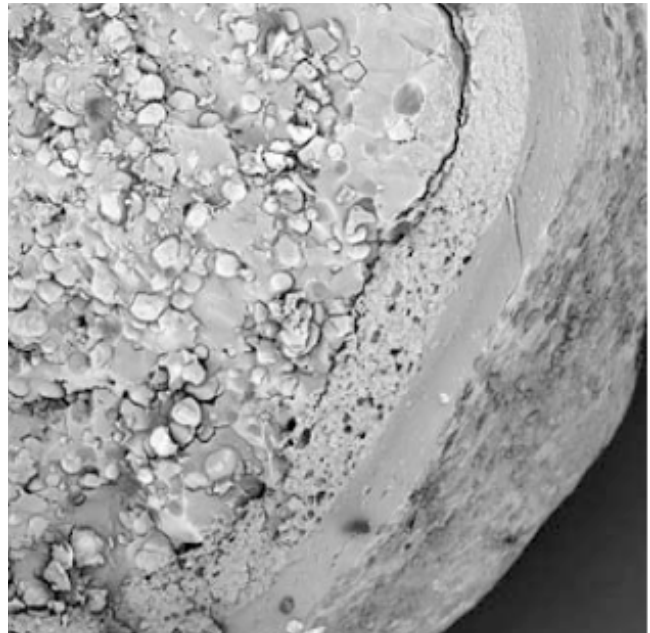
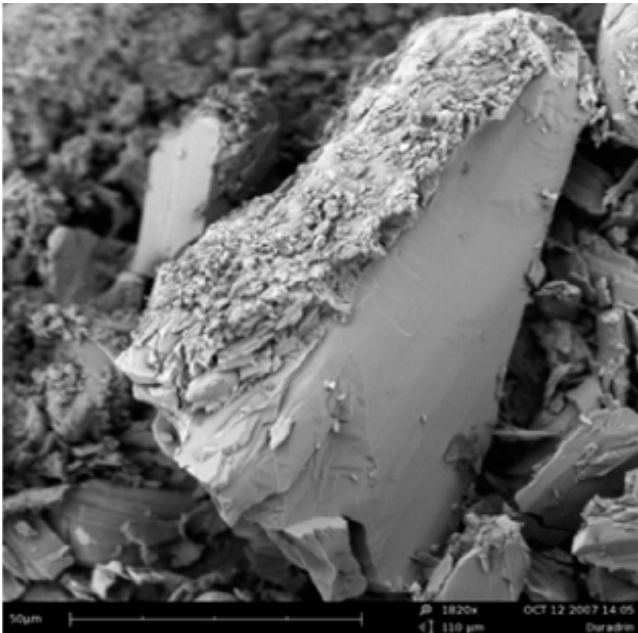
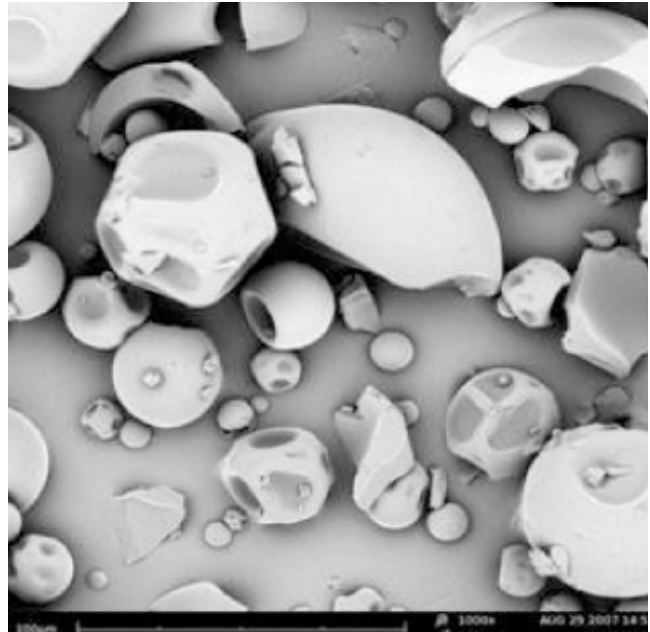
High resolution imaging

Despite the huge progress in technology meant for the quantitative size and shape evaluation of particulate systems, this can never fully describe the physical appearance of the product. Since the eye can see faster and also more things than ever can be described in a thousand words, analytical tools are required which allow one to evaluate on a more qualitative basis active substances, excipients, intermediate and end products.

Phenom proves to be an ideal tool for routine SEM imaging at J&J PRD Particle Characterisation Laboratory.



Since many evaluations and decisions need to be made on an immediate basis, the material scientist preferably needs a fast and reliable solution. It is here that the Phenom™ appears to be the ideal solution for monitoring pharmaceutical products in the micrometer and millimeter size range in less than a few minutes, and providing far higher resolution images than one can obtain with any optical microscope. First thing that really shows off seeing the instrument is it's wonderful design. But once one is working with it, the instrument is very robust, and extremely easy to use as well. With this piece of technology one is not dependent anymore of a skilled operator, neither does one need to invest in an expensive high end SEM apparatus. I can really say, that we not often had such a fast return of investment by implementing the Phenom in our particle characterization lab.



Some typical application images of pharmaceutical samples acquired with the Phenom.