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CASE STUDY

Johnson & Johnson Pharmecutical Research and Development

Monitoring pharmaceutical products with Phenom Desktop SEM

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Pharmaceutical dosage forms are becoming 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.

Particle characterization

On a regular basis, 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 because 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 that refer in some way to their size and the shape. Thereby, it becomes easier to monitor the distribution in size and shape. Various analytical technologies have been made commercially available for this purpose.

High-resolution imaging

Despite the progress in technology 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 more things than ever can be described in a thousand words, analytical tools are required that allow one to evaluate on a more qualitative basis active substances, excipients, intermediate and end products. 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 Thermo Scientific[™] Phenom[™] Desktop SEM appears to be the ideal solution for monitoring pharmaceutical products in the micrometer and millimeter size range in less than a few minutes. Additionally, it provides far higher resolution images than one can obtain with any optical microscope.

The first thing that really catches the eye upon seeing the instrument is its wonderful design. But once one is working with it, the instrument is very robust and extremely easy to use. 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 on investment as we did by implementing the Phenom Desktop SEM in our particle characterization lab.



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Typical application images of pharmaceutical samples acquired with the Phenom Desktop $\ensuremath{\mathsf{SEM}}$



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