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Nanonization of Active Pharmaceutical Ingredients (Part 2)

In part 1 of this article you were introduced to the business unit Grinding & Dispersing of the family-owned company NETZSCH. Besides the machine design there are other essential conditions for the successful comminution or dispersion of solids. These are the right formulation of the product suspension as well as the selection of the best grinding media and the optimal operating parameters of the mill.

The development of the formulation and the optimization of the operating parameters can be conducted in laboratory mills. In particular when it comes to the selection of the operating parameters of the mill NETZSCH-Feinmahltechnik GmbH can revert to a pool of experience of more than 6 decades. Illustration 2 shows the development of the particles size distribution of APIs during a grinding test on a laboratory bead mill. The customer aimed at a close particle size distribution with $x_{99,3} < 400$ nm. Moreover, the parameters had to be optimized to ensure that the product suspension would not exceed a defined maximal temperature during the comminution process.

Once the operating parameters have been optimized the results can be transferred to production-size mills. An essential parameter for the scale-up is the specific energy input, which states the energy input with reference to the product quantity produced. Illustration 3 shows the results of the scale-up from a laboratory agitator bead mill to a production-size mill.

The illustration clearly shows that the results of the laboratory test can be exactly transferred to the production-size plant.

Various nanonization strategies have emerged to increase the dissolution rates and bioavailability of numerous drugs that are poorly soluble in water. These strategies inlucde increasing the surface area to volume ratios of drug powders, changing the crystalline forms and designing novel nanomaterials that can act as carriers for controlled release. Nanonization can result in improved drug solubility and pharmacokinetics, and it might also decrease systemic side-effects.

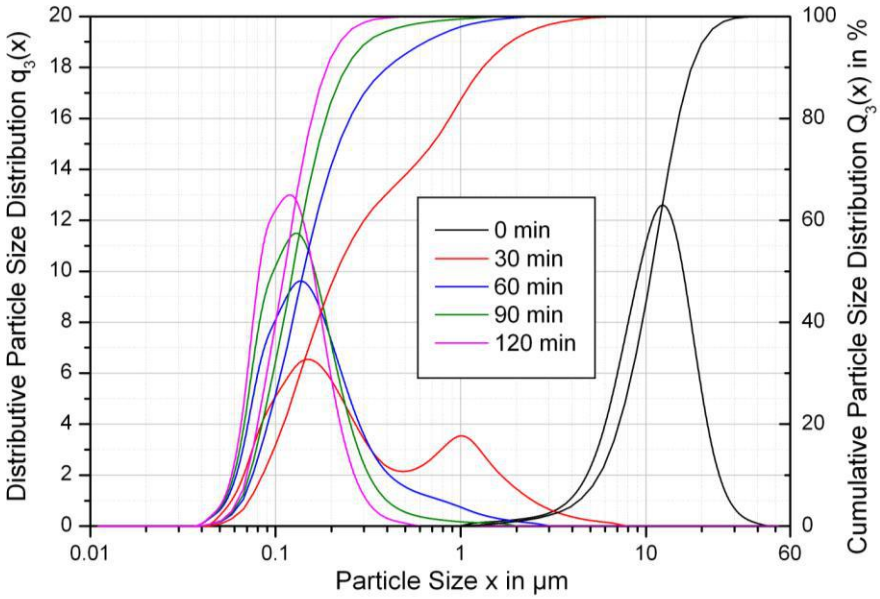

Illustration 1: **Development of the particle size distribution obtained during a grinding test in a laboratory bead**

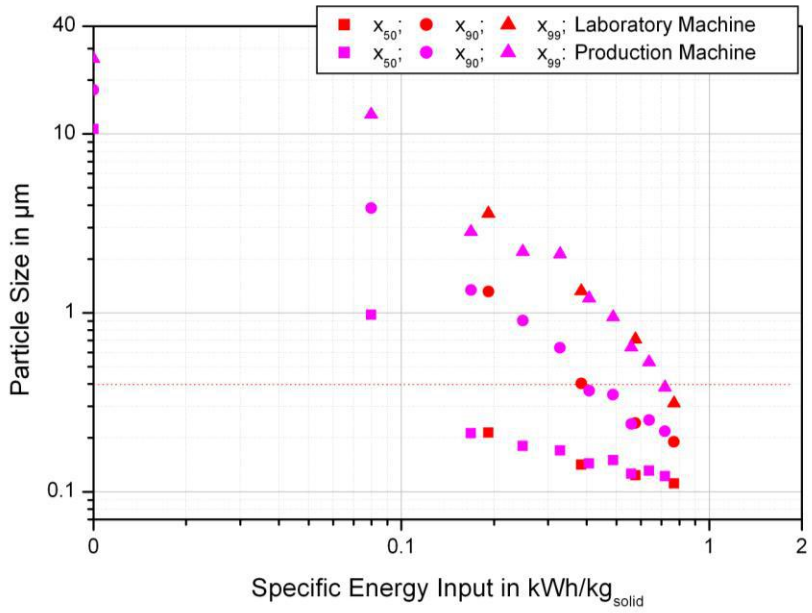

Illustration 2: **Results of the scale-up from a laboratory agitator bead mill to a production-size mill**