Pharmaceuticals

CAMSIZER XT applications for the pharmaceutical industry

Application

Particle size analysis is a standard procedure in the pharmaceutical industry. Traditionally sieve analysis and laser diffraction have been used to characterize active ingredients and excipients. However, these methods suffer from different disadvantages. Sieving is time consuming, provides a limited amount of data points, the results are often user dependent and not very reproducible. Laser diffraction is a "black box" procedure, the results strongly depend on the evaluation model used. Comparability between different manufactuers or laboratories is therefore difficult to achieve. Image analysis with the CAMSIZER XT provides an alternative which overcomes most disadvantages of other sizing methods. The wide measurement range from 1µm to 3000µm allows the characterization of granulates and powders within less than 3 minutes. The operation is easy and the high throughput makes the CAMSIZER XT a perfect tool for routine analysis in quality control. However, the software offers a vast amount of possibilities in the data evaluation, making the instument suitable for R&D applications as well.

Typical sample material

The following materials can conveniently be analyzed with the CAMSIZER XT:

- Granulated material Powders
- Active pharmaceutical ingredients
- Excipients (Starch, Cellulose, Sugars etc...)
- Crystalline Material (e.g. citric acid)

Example: starch

Strach and starch derivatives are widely used excipients in the pharmaceutical industry. They are found in many solid oral dosage forms like tablets or capsules.

Our example shows the CAMSIZER XT measurement result of two different starch samples. The two samples are very similar in size, but show significant difference in particle shape (Fig. 1 and 2).

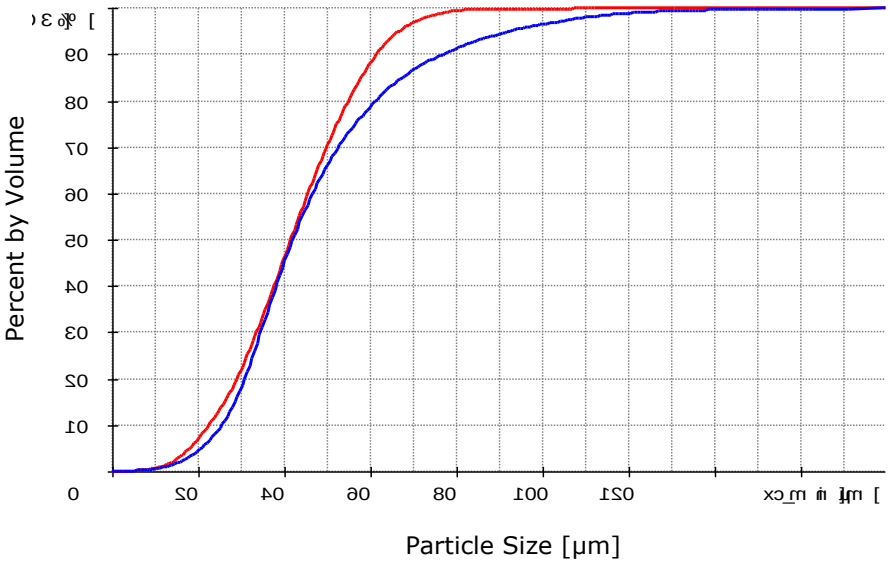

Fig. 1: Two starch samples, Sample 1 (red), Sample 2 (blue). CAMSIZER XT size measurement shows that the size distribution is quite similar, the d50 is exactly the same! The size definition is x-c-min (particle width), which gives a similar result as sieve analysis.

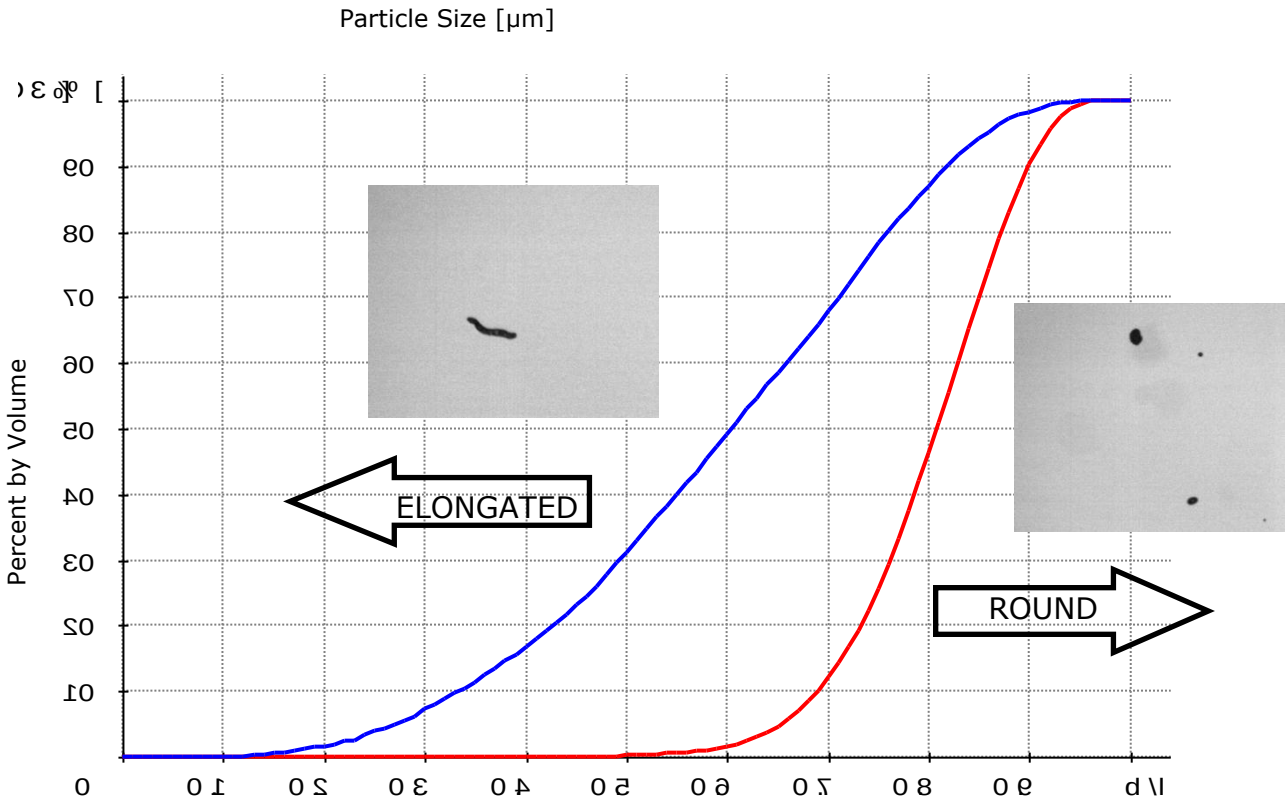

Fig. 2: The same two starch s Particle Shape (Aspect Ratio) width/length, aspect ratio). Sample 1 has compact, round particles which is reflected by high values of b/l. Sample 2 has significantly lower aspect ratio. The images clearly show that sample 2 is fibrous material.

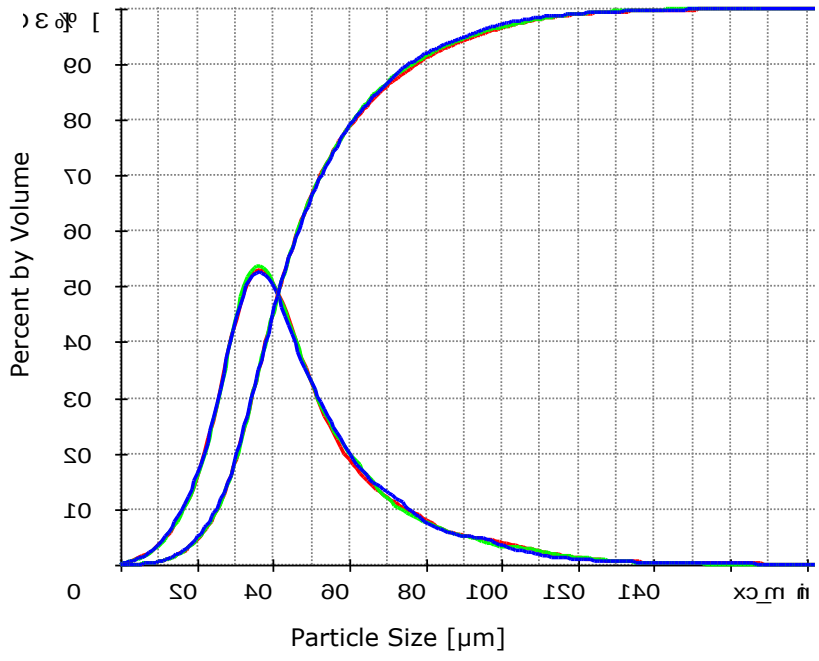

Fig. 3: Three consecutive measurements of sample 5. The repeatability is excellent. This shows the reliability of the CAMSIZER XT measurements.

Example: Active ingredient

Many active ingredients used in the pharmaceutical industry are highly agglomerated powders. Handling these materials in the laboratory is difficult, especially when it comes to particle size analysis. Sieving is not a very meaningful type of analysis if the particles do not separate to pass the apertures. Air-jet sieving might be a solution for some materials, but many substances will still be too sticky (Fig. 4). The CAMSIZER XT offers a powerful dispersion system that disrupts agglomerates using a venturi nozzle. The dispersion pressure can be adjusted from 20kPa to 460kPa.

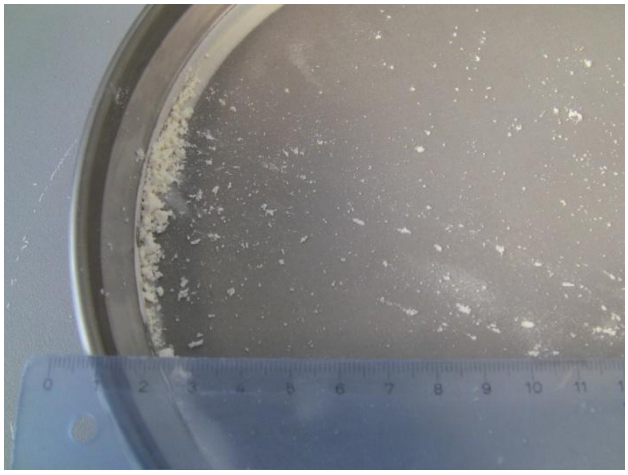

Fig. 4: Active ingredient particles on a 50 µm sieve after air-jet sieving. The particles stick to the wall of the sieve due to static charge. Agglomerates are clearly visible.

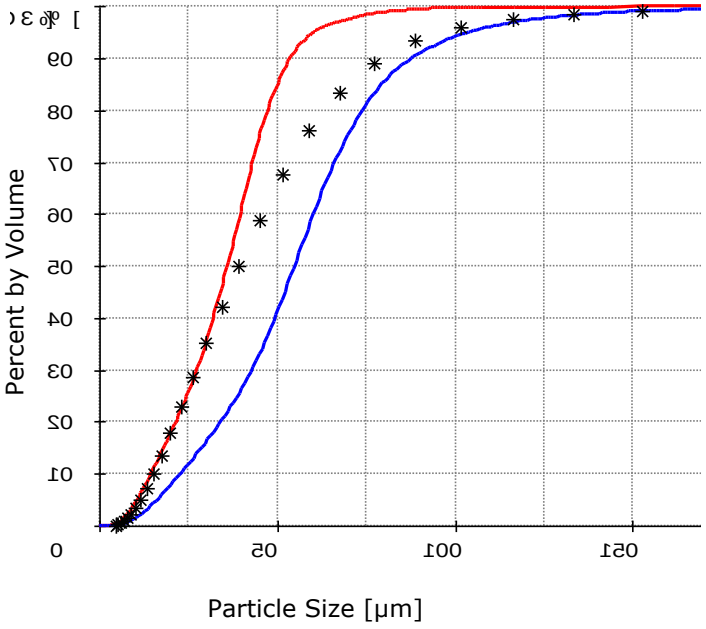

Fig. 5: Active ingredient sample, CAMSIZER XT result, RED: size definition x-c-min (particle width), BLUE: size definition x-Fe-max (particle length). BLACK: laser diffraction result. CAMSIZER XT and Laser analyzers can disperse the particles better than sieving, but laser data do not discriminate between length and width. The image analysis data therefore provided more detailed information about the sample.

CAMSIZER XT® - Benefits at a glance

- faster results
- less manpower required
- Dry measurement with air-jet dispersion 20-460kPa, free-fall option
- More reliable results than sieving due to better dispersion
- higher resolution than sieving or laser diffraction
- high sample throughput
- excellent reproducibility
- larger sample quantities provide better statistics
- more objective, independent of operator
- no abrasion, non-destructive measurement
- higher sensitivity for oversize particles than laser diffraction
- shape analysis: length and diameter of particles
- easy to use
- low maintenance, robust design
- Measurement time typically 2-5 minutes
- Full compliance with 21CFR part 11