

Off- and Inline Measurements of pharmaceutical granules

The release of the active ingredient is influenced by the particle size.

Definition of pharmaceutical granules:

Granules are wide spreaded in the pharma industry. They're a mix from different carrier substances, for example sugar, polysaccharide, polymer and cellulose. Thereby are size differents between 400 μm und 2,5 mm. Granules can be used in several forms, as gelatin covered capsules, direct medicine (globules) or compressed in pellet shape.

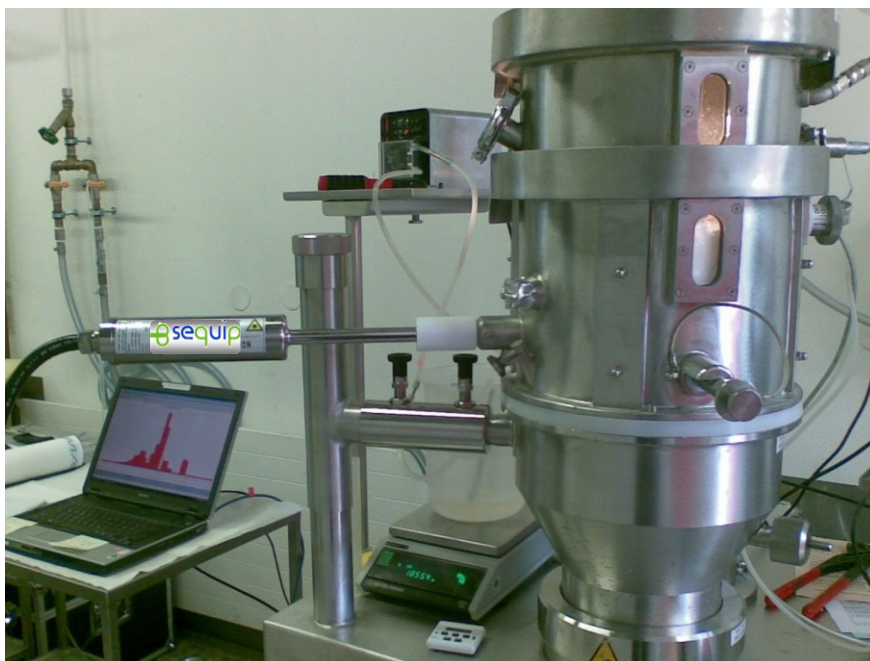
Production:

In the pharmacy, granules are produced in different ways. The fluidized bed- and the rotor-granulation are the usual processes. In this case the granules will be held in action, trough streaming air. In meantime the granules will be coated with additional substance, so they will be grew layer over layer, until the granules reach the desired size. Thereby the spray- and dry-phases change constantly. In later course of the process it's possible, also with fluidized bed-granulation, to coat the granules with active substance.

Guarantee of quality

Constant inspections, regarding the particle shape and -size, are essential to ensure a dependable release of the active substance. While these granules are a medical product, they must fit the highest standards, this can only be guaranteed if the quality-inspections fit this standard, too.

To fulfill these requirements, **Sequip** and **Occhio** present to you two excellent measurement applications, which allow you to inspect your granulation constantly.



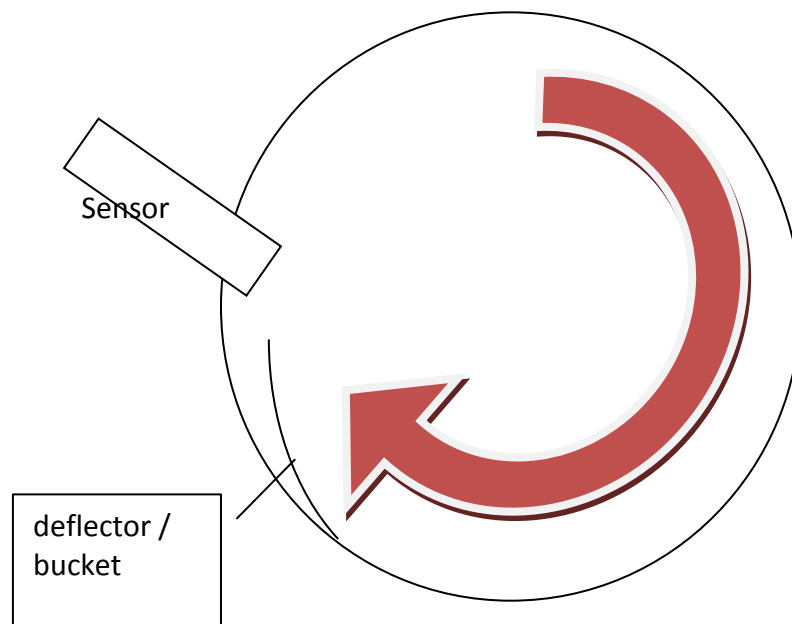
Inline process-application with a Sequip **PAT Sensor**

Inline Measurement principle: Insitu Sequip PAT Sensor

Sequip PAT Sensors enable the best and most dependable monitoring of this process. It's very important to identify the exact size-distribution, because only a densely distribution enables a controlled and repeatable release of the active substance.

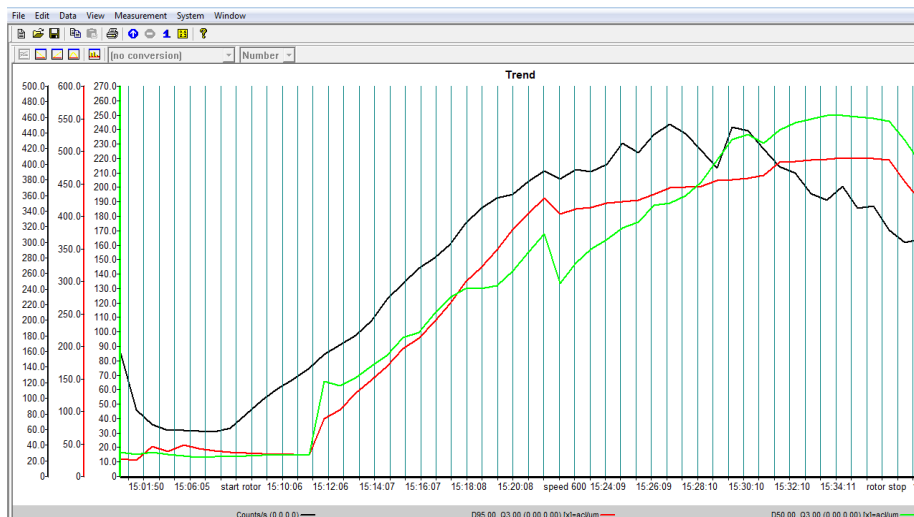
Ordinary sieve classes often just don't fit the required standards to enable an exact assumption or calculation of the releasing-rate.

The shape, especially the roundness is very important to characterize the quality of the particles. Particles with low or none roundness disturb, in fact of their low trickle-ability, the production process, furthermore they fit, in neither case, the required quality standards



Application of a Sequip PAT Sensor while measuring during the granulation

Owing to the excellent measurement qualities of the **Sequip PAT Sensor**, the growing process can be monitored and controlled in the current granulation process.



Usual Trend of a granulation

Offline measurement principle: Occhio Zephyr System

The patented measurement application of the Occhio **Zephyr** System – monochromatic lighting as a adaptive measurement unit – improves and optimizes, with digital image processing based on diffraction-free light, the particle analytics.

Trough this technique it is possible to measure a large grain spectrum (20 μm to 20 mm) with a very high precision and without the need of any Measurement- or Hardware-setup. The sample will be supplied to the measure field over a

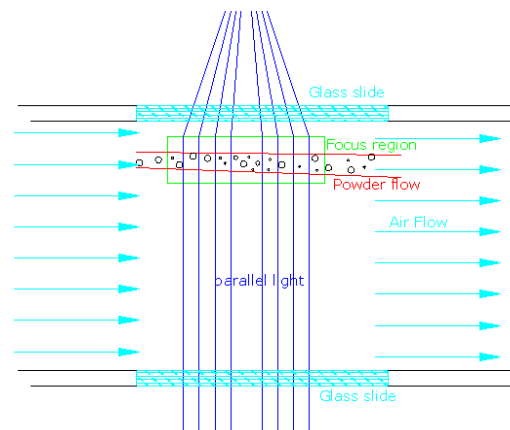
conveying chute so all particles will reach the disperses-area, where they will be adjusted trough an airstream.

Cameras with high resolution detect the adjusted particles, which will be made visible through a blue light illumination. In meantime all desired grain-shapes and –sizes will be detected, furthermore the measurement is contact-free and in real time.



All advantages in summary:

- Repeat- and dependable measurements of particle shape and –size
- High resulted size classes
- Automatic calibration
- Fast measurement



References

- University of Düsseldorf
- Company Boehringer in Biberach

If you have further more questions, please visit our websites:

www.occhio.be
www.sequip.de