

Pharmaceutical Granules

Drug release rate depends on particle size

What are pharmaceutical granules?

Granules, which contain a mixture of medical agents and various carrier substances like polymers, sugar, cellulose or polysaccharides, are widely used in the pharmaceutical industry. The size of these granule beads ranges approx. from 400 μm to 2.5 mm

The granules are used in different pharmaceutical forms: directly filled in a dispenser (Globuli) or processed and filled e.g. into gelatine coated capsules or pressed into soluble tablets



Production Process



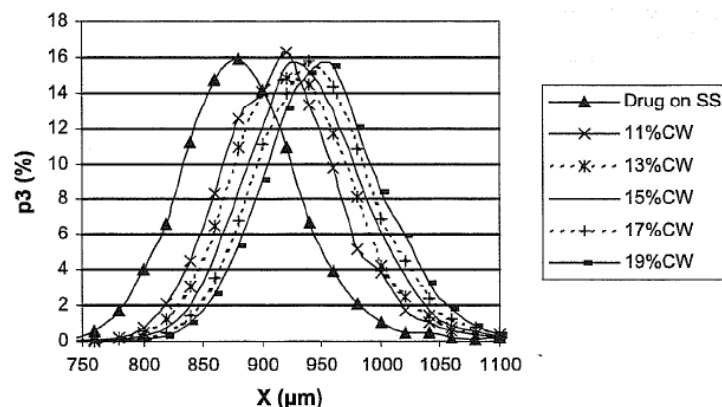
Pharmaceutical granules can be produced in different ways. Fluidised bed granulation or rotor granulation are the most common methods. The granules are kept in motion, either by rotation or by air blown into a chamber. New material is being sprayed upon the particles and they grow layer-by-layer in a process of repeated spraying and drying. Later in the manufacturing process, the granules may be coated with active pharmaceutical agents, also in a fluidised bed setup.

Quality Assurance

During the production process of pharmaceutical granules both size and shape analysis of the globules are important for a reliable release rate of the drug. The finished product needs to reach highly demanding quality standards which makes quality control a crucial step in the production process. With the help of the CAMSIZER these processes can be controlled reliably.

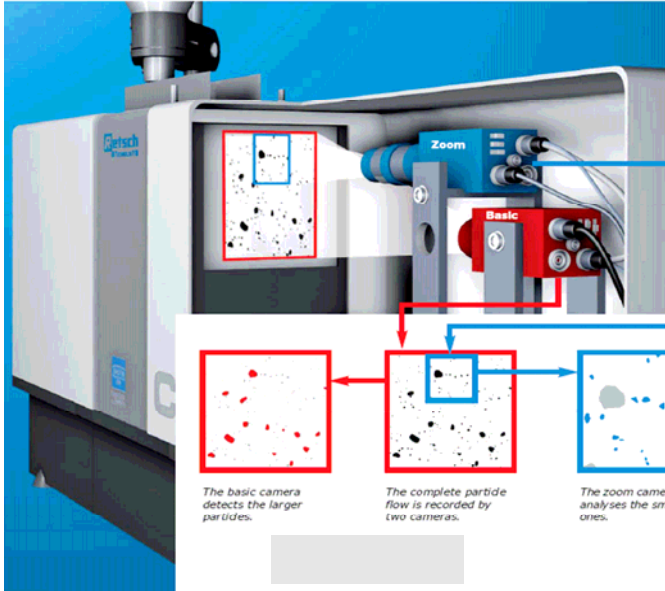
The accurate knowledge of the size distribution is crucial, because only a narrow size distribution guarantees an accurately controlled and repeatable release rate of the active agent. Common sieve classes are often too wide for a proper estimation or calculation of the release rate. Shape, especially roundness, is also very important for determining the quality of the globules. Non-round granules do not meet the required quality standards and also disturb the production process due to their reduced pourability.

Due to the excellent resolution of the CAMSIZER, the successive growth during granulation can also be monitored. The diagram on the right compares the size measurements of uncoated sugar spheres and five successive 2% polymer coat weight increments.



Benefits at a glance

- Reliable and reproducible measurement of both particle size and shape
- High resolution of particle size classes
- Fast measurement
- Easy to calibrate

Measuring Principle

The patented measuring setup of the CAMSIZER – two digital cameras as an adaptive measuring unit – improves and optimises particle analysis by digital image processing. Therefore, it is possible to measure a wide range of particles from 30 µm to 30 mm with extreme accuracy, **without having to switch measuring ranges or make adjustments**. The sample is fed in from the feed channel so that all particles fall through the measurement field. During the measurement procedure the two digital cameras (CCD) perform different tasks. The basic camera (CCD-B) records large particles, the

zoom camera (CCD-Z) records the small ones. The contact-free optical measurement is carried out in real time and simultaneously obtains all the required information about particle size and particle shape. A modularly configurable online version of the instrument has been developed to allow automated measurements to be conducted continuously.

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