
# BRC 100

## THE NEW DRY GRANULATOR

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# BRC 100 – the new dry granulator

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**Introduction**

Continuous dry granulation has been an established process in the pharmaceutical industry for decades. It is not only applied for moisture- and temperature-sensitive materials, but also for large volume or herbal products, respectively. In comparison with classical wet granulation techniques, a sophisticated drying system is not necessary. This avoids large investments for production equipment and space, and it requires only low manufacturing costs.

Furthermore the fast roller compaction process is also applicable for high material throughputs. This enables the production of different products and product batch sizes with one single machine [1]. The market already offers various dry granulators, which can be described by the arrangement of the two compaction rollers. They can be mounted horizontally, vertically or on an incline.

Depending on the supplier, the rollers differ in width, diameter and surface properties. Furthermore roller compactors are distinguished between fixed-gap and moveable-gap compactors, whereas the moveable roller compactors are state of the art. Only this processing type assures homogeneous ribbon porosity at constant compaction pressure. The granulation step where the ribbons are transferred into final granules is usually integrated in the roller compactor equipment and is performed in one or two steps [2, 3]. With this in mind, L.B. Bohle developed a new dry granulator with an electromechanical roller drive and massive roller shafts. Minimal time is needed to achieve a steady state during process start-up, and parallel gap is assured during the whole production time. The integrated PID loop control minimizes the gap deviations

during processing and enables constant granule porosities.

The granulation step is achieved using a conical sieve (Bohle Turbo Sieve 200, L.B. Bohle), which gently transforms the ribbons into final granules even at high material throughputs. Due to different sieve setups, the desired particle size distribution can be obtained. The aim of the following study is to show and prove the functionality of this sophisticated new dry granulator.

**Materials & Methods**

A powder mixture (1:1 ratio) consisting of lactose (Granulac 200, Meggle, Germany) and microcrystalline cellulose (Avicel PH 101, FMC, USA) was used for roller compaction. For lubrication, 0.5 % magnesium stearate (Pharma VEG, Baerlocher, Germany) was added.

The excipients were pre-mixed in a bin blender (PM 600, L.B. Bohle). The homogeneous blend was then roller compacted (BRC 100, L.B. Bohle) at different compaction forces and different sieve setups.

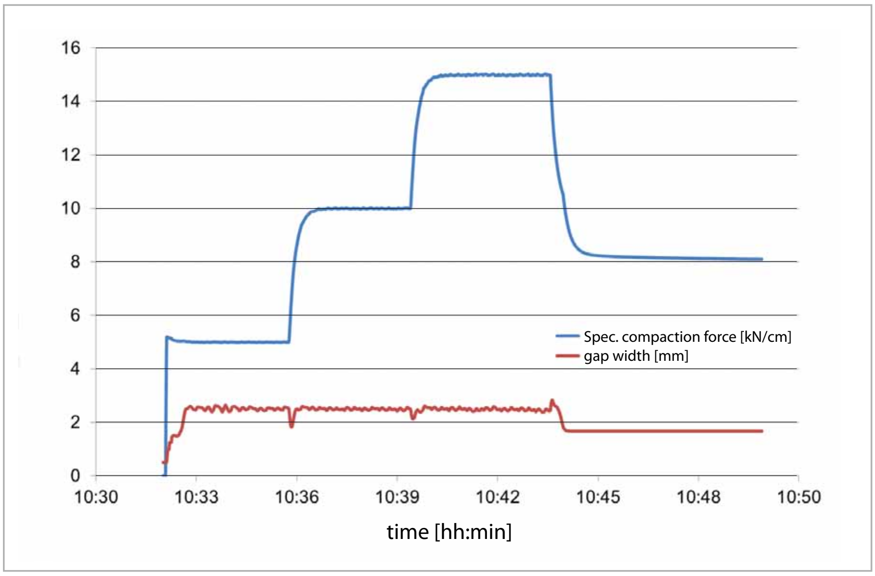


Figure 1: Gap width over time at increasing compaction force values

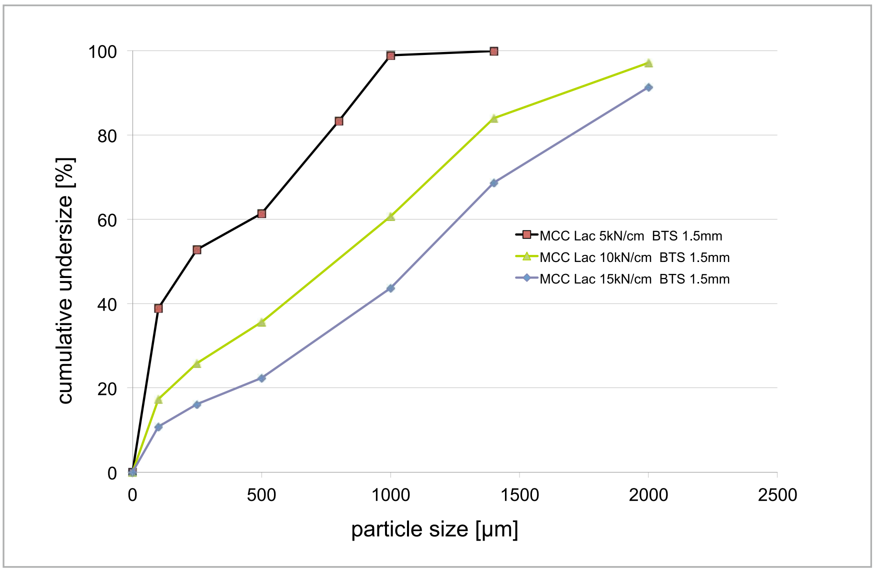


Figure 2: Compaction force impact on granule particle size

A smooth master roll and a grooved slave roll of 100 mm width were used for the compaction trials. Sampling was performed after the process start-up when steady state was reached. Final granules were manually sub sampled and analyzed in duplicate by mechanical sieving (Haver EML 200 digital, Haver&Boecker, Germany).

### Compaction force

The impact of the compaction force on the final granule particle size was analyzed at 2 rpm roller speed, 300 rpm for the 1.5 mm rasp sieve and a gap width of 2.5 mm. The process began with activated PID loop control for the feeding system. Steady state was achieved within 40 seconds with a constant specific compaction force and a constant gap width (Figure 1). Thus, a minimal material loss could be detected due to the quick loop control.
During processing, the compaction force was increased step wisely whereas the next force level was quickly achieved within seconds. Deviations of the specific compaction force were below ±0.1 kN/cm and ±0.1 mm for the gap respectively. Thus, both parameters could be considered constant during the whole processing.

Granule particle size increased with higher compaction force levels [4]. After granulation through a 1.5 mm rasp sieve, the amount of fines (particle size <100 µm) ranged from 39 % for the granules compacted at 5 kN/cm down to 11 % for granules prepared at 15 kN/cm compaction force (Figure 2). Compaction at such a high force level led to a higher amount of coarse granules (larger than 2000 µm). Therefore, a smaller screen size between 1.0 and 1.5 mm is recommended in order to minimize this large granule fraction.

### Gap width

Material throughput during roller compaction can be increased with a larger gap width. It was reported in literature that a larger gap width at constant compaction force level leads to finer granules [4]. This effect could not be observed when compacting the powder mixture at 10 kN/cm (Figure 3). At 2 rpm roller speed and 300 rpm sieve speed (1.5 mm rasp sieve), comparable granule particle size distributions were obtained although the gap width was increased from 1.5 mm up to 3.5 mm. A homogeneous application of the compaction force over the whole roller width could be one reason for the similar granule size. Thus, material throughput could be easily increased without a change in granule properties.

### Sieve setup

The applied compaction force mainly affects granule particle size. Secondly the setup of the integrated granulation unit (Bohle Turbo Sieve 200) determines the final particle size distribution. With increasing screen size, coarser granules are obtained (Figure 4).

The rasp sieves with 1.5 and 2.0 mm screen size led to similar granule particle size distributions at 300 rpm sieve speed. In comparison the 1.0 mm rasp sieve led to finer granules with higher amount of fines. Finally all three screen types led to acceptable amounts of fines due to the gentle cutting behaviour of the rasp sieve during granulation. The choice of the right screen size makes it possible to influence the final

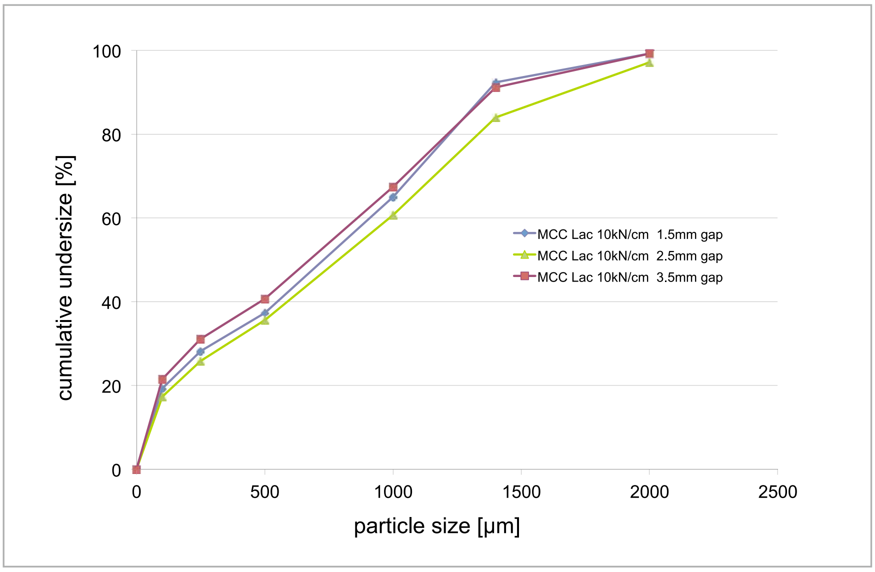


Figure 3: Influence of gap width on granule particle size

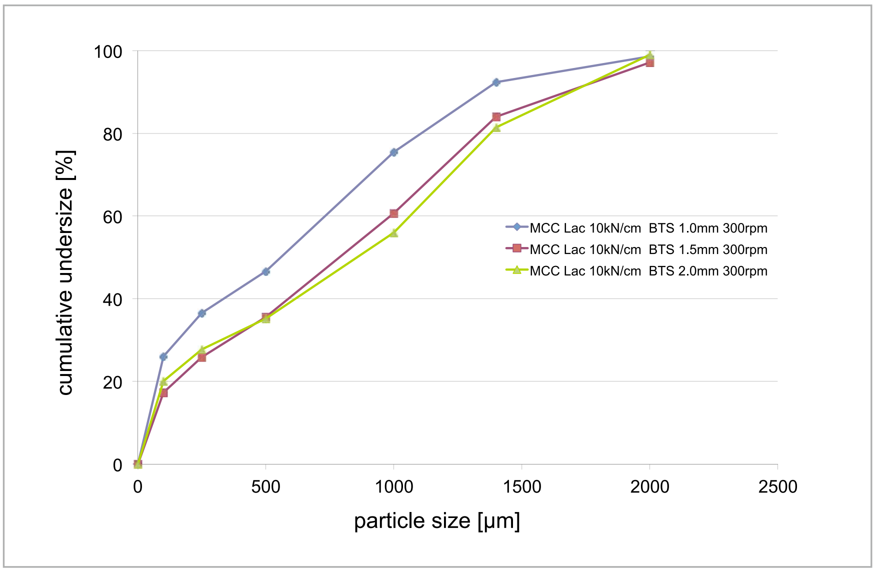


Figure 4: Impact of screen size on granule particle size distribution

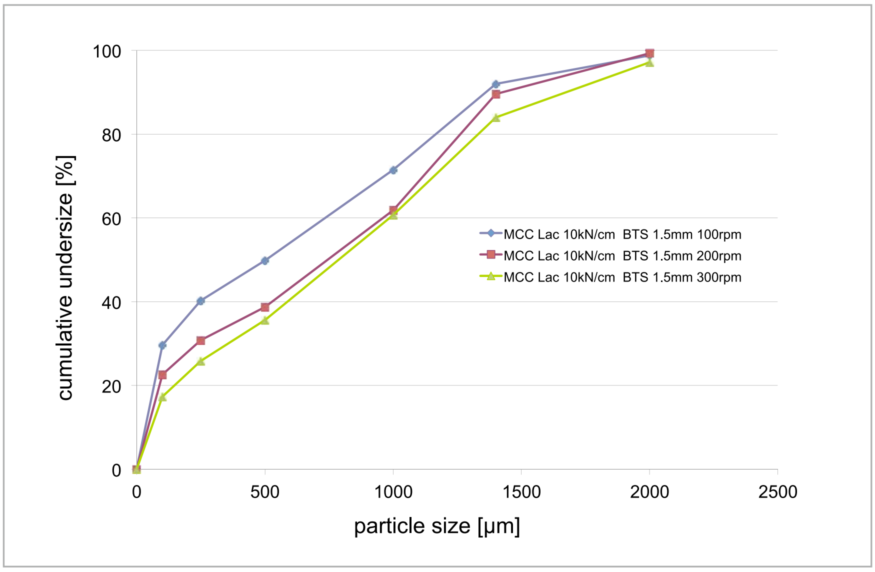


Figure 5: Interrelation between sieve speed and granule particle size distribution

granule particle size distribution. A further possibility to vary the sieve setup is the alteration of the sieve rotor speed. In contrast to classical rotating sieve systems conical sieves offer a high material throughput already at low sieve speed values. To evaluate the sieve speed impact on final granule size, compaction was performed at 10 kN/cm specific compaction force, 2 rpm roller speed and increasing sieve speed values for one screen size (1.5 mm rasp sieve). With higher sieve speed the amount of fines decreased (Figure 5).

This can be explained by the fact that, with higher rotor speed, the ribbons need less time to pass the screen. Less friction occurs during granulation and leads to lower amount of fines. Therefore, altering the sieve speed is another possibility to adjust the desired particle size distribution of the final granules. .

## Conclusion

The case study proves the functionality of the new BRC 100 roller compactor. It was possible to precisely produce a representative placebo granule formulation with negligible material waste during the process start-up. Furthermore, it shows that a suitable sieve setup offers the possibility to achieve a desired granule size by altering screen size and sieve speed.


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