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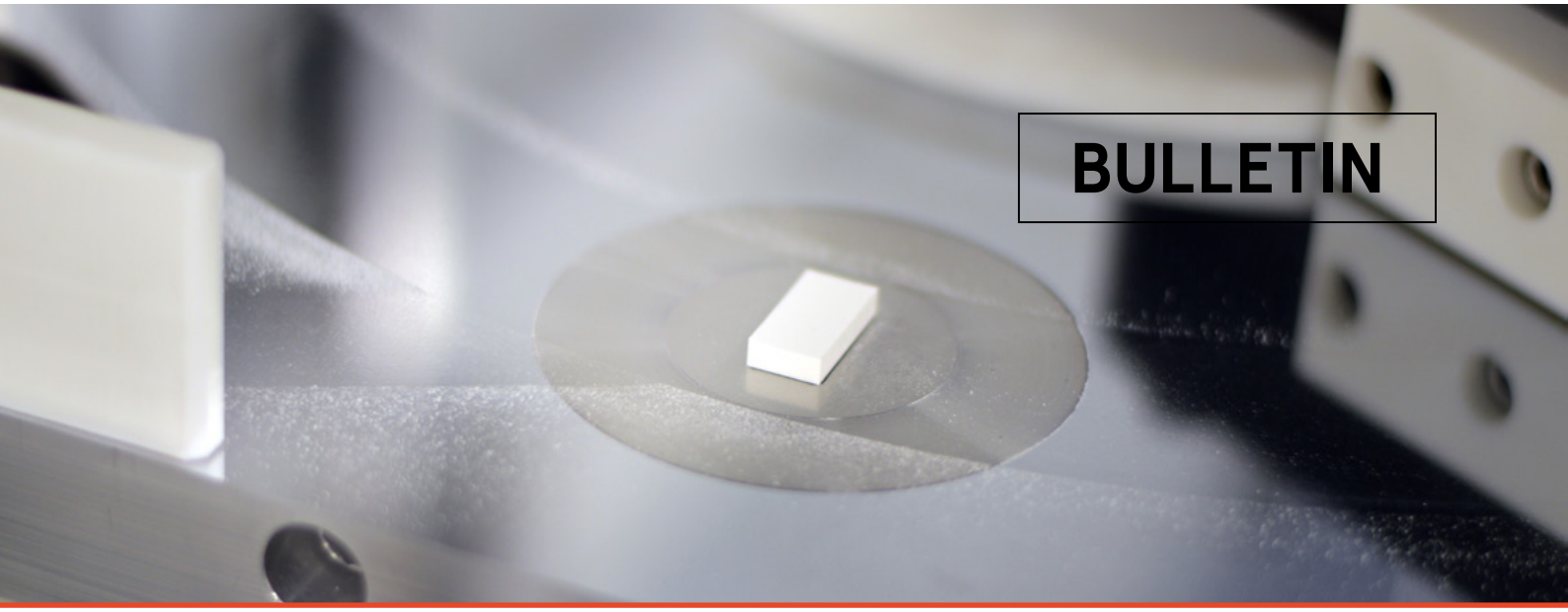

BULLETIN

MIMICKING DRY GRANULATION ON THE STYL'ONE EVO TO IMPROVE FLOWABILITY

Dry granulation is a commonly used process in the pharmaceutical industry. It provides several key advantages, including precise particle size control, improved flowability of powders, versatility in processing materials, increased bulk density for easier handling, and cost-effectiveness. The technique is particularly beneficial for handling moisture-sensitive active pharmaceutical ingredients (APIs). However, not all powder mixtures are suitable for dry granulation, as it may reduce compactibility or impede dissolution rates. Therefore, careful consideration of material properties and formulation requirements is essential when choosing the appropriate granulation approach in pharmaceutical manufacturing.

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Objectives

In this case study, MEDELPHARM Science Lab worked for a pharmaceutical company aiming at enhancing the flow properties of a mixture for capsule filling. The study's objective was to reduce the amount of fine particles ultimately improving flow and preventing clogging during the capsule filling process.

Our client, a pharmaceutical company, required to fill capsules with a specific powder formulation. Initially, the blend's particle size distribution was characterized, revealing a substantial presence of fine particles, with 72% of particles smaller than 63 microns. These fines lower the flowability and large PSD increases segregation risk.

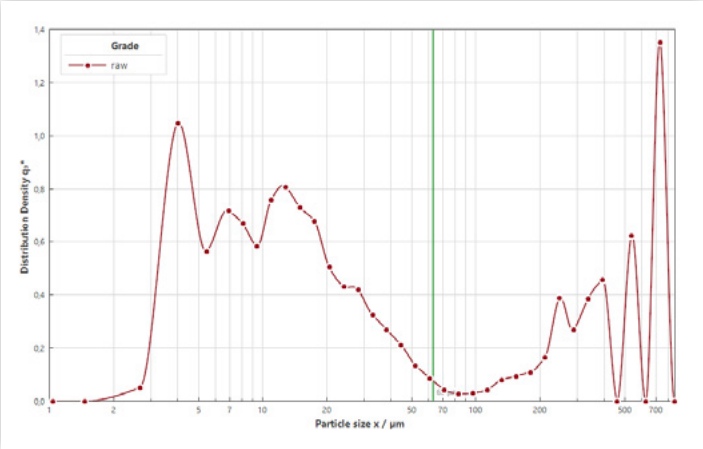
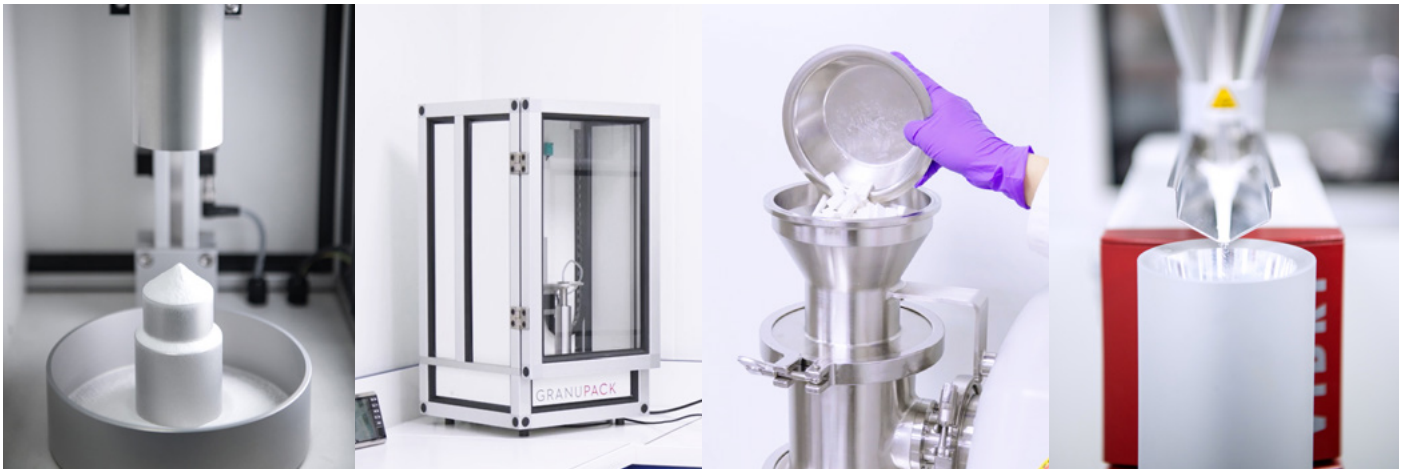


Figure 1
Particle size distribution of initial blend

Methodology

To address this issue, MEDELPHARM adopted a systematic approach using the RoCo module for dry granulation mimicking. Various specific compaction forces, including low, medium, and high, were applied to investigate their impact on flowability properties with the use of small amount of powder to ensure optimal flow in reduced time.

After dry granulation, the ribbons were further processed using the Quadro SLS™ with a conical head, operating at 3 500 RPM as recommended for conical milling. Compactibility tests were not performed in this case, as the primary focus was to fill capsules. Particle size and shape were characterized using QICPIC, and flow measurements were conducted using GranuHeap and GranuPack. Bulk and tapped densities were used to compute the Carr Index and Haussner Ratio. Angle of repose was also used to characterize the flowability.



From left to right: GranuHeap, GranuPack, Quadro Scalable Lab System ™, QICPIC

Results

The specific compaction force had a significant impact on the spread of the particicle size distribution. Granulation substantially reduced the number of fine particles and the risk of segregation. It was observed that 10 kN/cm was sufficient for achieving good flow.

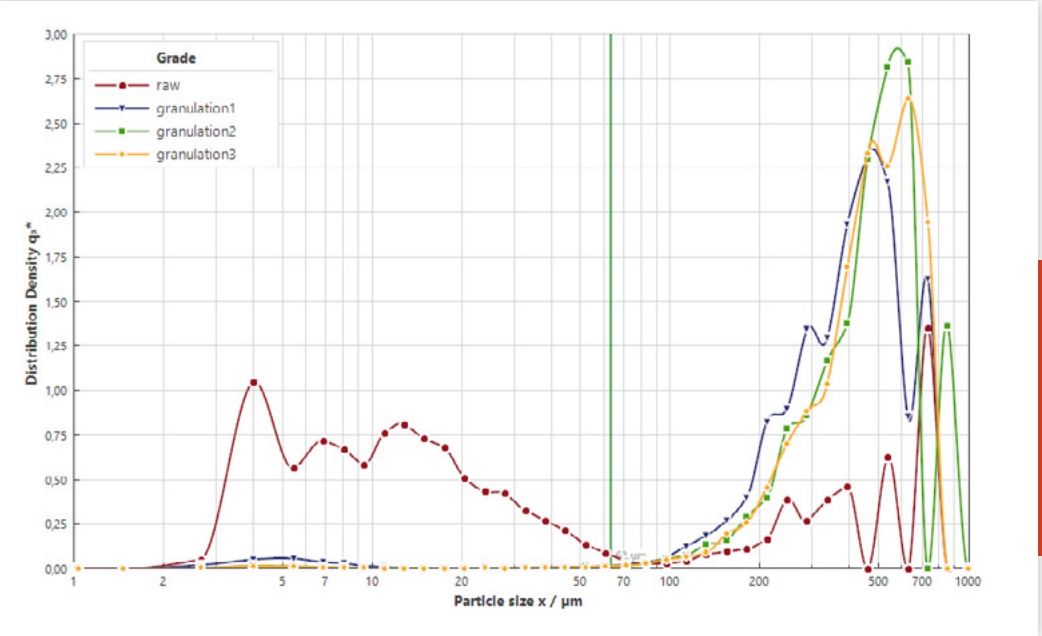


Figure 2
Particle size distribution of initial blend and after dry granulation

Detailed analysis revealed that the Carr index and angle of repose consistently decreased with each specific compaction force, indicating improved flow properties.

This trend held regardless of the specific force applied, emphasizing the effectiveness of dry granulation in enhancing flowability.

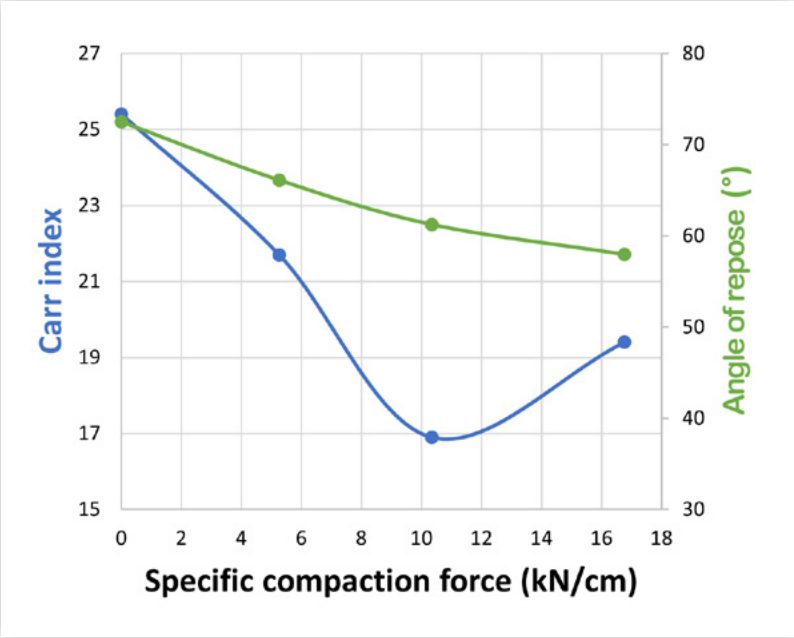


Figure 2
Carr index and angle of repose as a function of specific compaction force (kN/cm)

Conclusion

In conclusion, this case study demonstrates the successful optimization of flowability properties for capsule filling in the pharmaceutical industry. By employing dry granulation with specific compaction forces, we effectively reduced fine particle content and improved flowability with no more than 100g of material. This approach not only met the client's requirements but also provided valuable insights into the relationship between compaction force and flowability properties.

- **Future considerations**

To complete the project's story, it is recommended to inquire whether the client conducted dissolution studies to assess the impact of granule properties on the overall performance of the capsule-filled product. This additional information would provide a comprehensive understanding of the project's outcomes and potential implications for future endeavors in pharmaceutical manufacturing.

STYL'One Evo key benefits

- **Versatile**
- **Standard tooling**
- **Material sparing methodology for dry granulation mimicking**
- **Simulation of any roller compactor**
- **Easy to clean – easy to handle**
- **Quick product and tooling changeover**
- **User-friendly HMI for fast experiment setup and results**

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