



VIII. Symposium of Young Researchers on Pharmaceutical Technology, Biotechnology and Regulatory Science

28–30 January, 2026 – Szeged, Hungary

OP-22

DOI: [10.14232/syrptbrs.2026.47](https://doi.org/10.14232/syrptbrs.2026.47)

The effect of critical process parameters on the final product during high-shear granulation of mesoporous silica microparticles

Flórián Benkő, Nóra Zacsik, Katalin Kristó, Tamás Sovány

Institute of Pharmaceutical Technology and Regulatory Affairs, University of Szeged, Szeged, Hungary



Mesoporous silica is widely used as a carrier in pharmaceutical solid dosage forms due to its high specific surface area, large pore volume, and excellent adsorption capacity. However, its poor powder flowability—caused by irregular particle shape, small particle size, and low bulk density—create challenges during both batch and continuous manufacturing. Wet granulation can improve these properties, but it can reduce drug-loading capacity by decreasing surface area by blocking pores. This study aimed to develop a binder-free high shear granulation process and to evaluate the influence of key process parameters on granule quality.

Mesoporous silica (Neusilin FH1) and microcrystalline cellulose (Comprecel 101) were used as raw materials, with purified water as granulation liquid. Granulation was performed using a high shear granulator. A full factorial 2^2 experimental design with a center point was applied to assess the effects of impeller speed and liquid dosing speed. The prepared granules were dried, sieved, and characterized for particle size, size distribution, particle morphology, yield percentage, flow properties, crushing strength, moisture content, and compressibility.

The results showed significant differences between batches. Granulation successfully improved powder flowability compared to raw materials. The higher impeller speed combined with the lower dosing speed produced granules with an increased crushing strength. Improvements in particle size distribution and yield were also observed in selected batches. The improvement in sphericity is consistent with the powder flow characteristics.

In conclusion, mesoporous silica can be effectively granulated using purified water alone, indicating that binders are unnecessary under optimized conditions. The developed method significantly improves flowability while maintaining functionality, offering a promising approach for processing mesoporous silica in pharmaceutical applications.

Acknowledgment

Project no TKP2021-EGA-32 has been implemented with the support provided by the Ministry of Culture and Innovation of Hungary from the National Research, Development and Innovation Fund, financed under the TKP2021-EGA funding scheme.