

Small Scale Mill for lab-scale roller compaction

Gerteis now offers the compact Small Scale Mill as an easy to use laboratory tool.



Small Scale Mill

Design and Features

Built for milling small amounts of a roller compacted pharmaceutical material, allowing pilot and test batches ranging from a few grams to 50gr to be milled in one pass. The Small Scale Mill reproduces the same milling steps as the company's renowned PACTOR® roller compaction machines with almost identical particle size distribution (PSD), making it a highly useful tool for developing dry granulates during first phase R&D.

Gerteis research studies indicated that existing laboratory scale or domestic mills were unable to reproduce the same PSD as full scale roller compactors. Therefore it developed the Small Scale Mill specifically to reproduce the grinding principles of the PACTOR® line.

Gerteis engineered the Small Scale Mill to be compact and simple, using manual operation for minimal footprint and low cost. The tool uses different screens with various apertures in order to vary and modify the particle size distribution of the achieved granules of the pharmaceutical formulation.

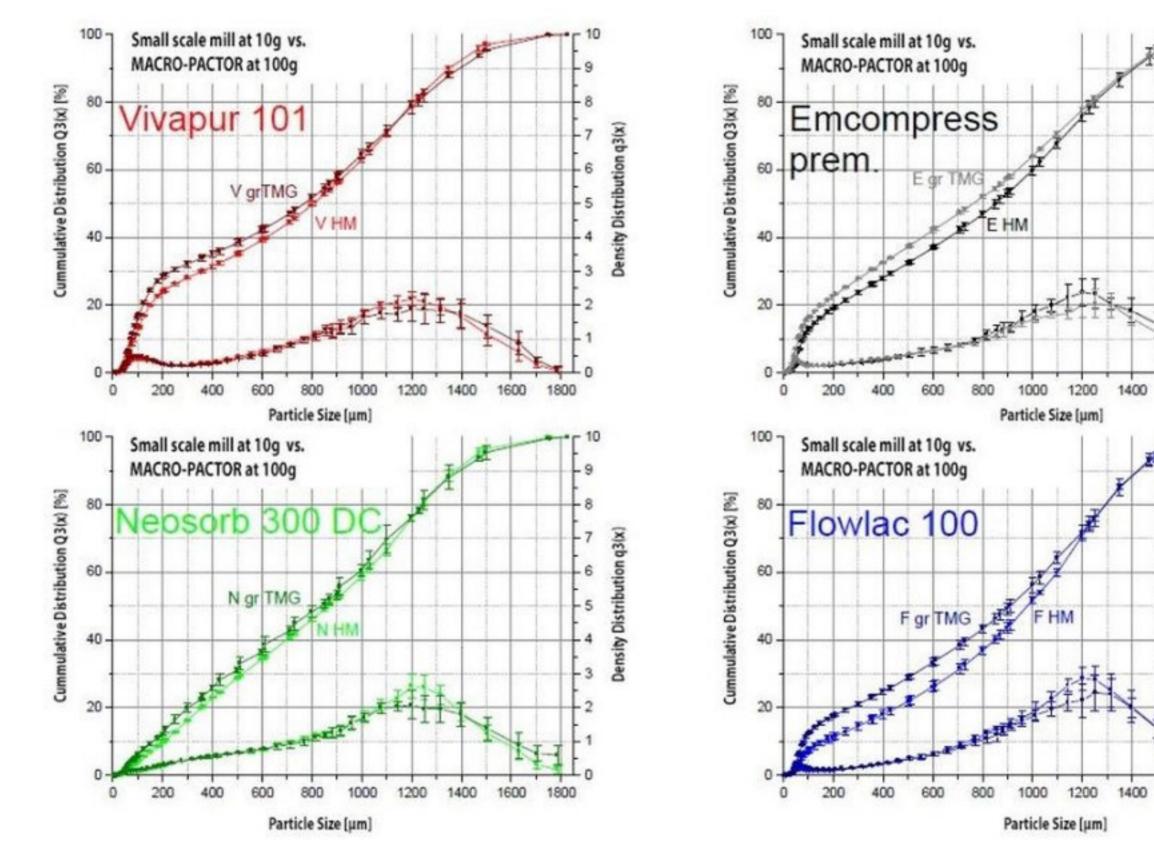
The various meshes and rasping screen are easily fitted and changed, allowing a very wide range of screening patterns to meet different specifications. The manually operated milling bars push material – either in roller compacted ribbon or tablet piece form - through the screens in the milling chamber, with fully processed granules collected in a drawer.

Density Distribution q3(x)

Density Distribution q3(x)

1600

The overall design emphasizes ease of use with fast and simple fitting and cleaning of all components. The materials used comply with all pharma regulatory guidelines.



PSD-curves comparison of four excipients

Performance

Gerteis has compared Small Scale Mill performance against the benchmark MACRO-PACTOR® production scale roller compactor using four different excipients; Vivapur® 101, Ecompress® prem, Neosorb® 300 DC and Flowlac® 100. In tests at the University of Bonn, each was milled with the Small Scale mill and the MACRO-PACTOR fitted with pocketed rotor.

The results for all tested excipients showed close PSD correlations between Small Scale Mill and MACRO-PACTOR®. All followed typical PSDs for dry granulates with a maximum 20 per cent proportion of <100 μ m 'fines'. Small differences between the two machines were observed for the strongest particle fraction (1000 μ m-1400 μ m), slightly tilting PSD for the Small Scale Mill towards coarser particles. The extent of this small deviation seems to depend on material and caused by those MACRO-PACTOR® features, such as granulator settings, that are not replicated by the manually operated Mill. Such process parameters will be optimized in scale-up and so can safely be ignored during development.

The Small Scale Mill shows very close PSD correlation with Gerteis production-scale roller

compactors, thereby providing an ideal tool for the research of milled granulates at lab scale.