

Solid displacement method to determine envelope density of roller compacted ribbons

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Achieving the same quality of intermediate product on a different roller compaction scale is crucial in scale-up project for production of a pharmaceutical formulation. The widely accepted notion for transferability of roller compaction processes lies in the intermediate's physical property which is ribbon envelope density. Through a pilot study on a small-scale roller compactor, it is possible to prepare multiple batches of granulate under different process parameters to select the most preferable batch for further processing. The ribbon densities of intermediate compacts for each batch differ due to process parameters set during compaction. The method presented in this work allows to determine envelope density of roller compacted ribbons by an accurate measurement of their envelope volume by utilizing solid volume displacement of glass microspheres. The data acquired by the application of this method are demonstrated for utilization in mathematical modelling to predict scale-up process parameters of a pharmaceutical mixture based on samples from pilot studies.