DEVELOPMENT OF REGIME MAP FOR STEADY-STATE HIGH SHEAR WET TWIN-SCREW GRANULATION

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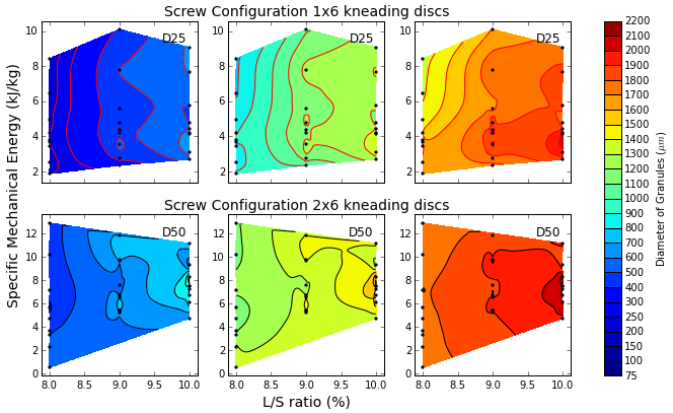
Twin-screw granulation is an emerging continuous granulation technique in the pharmaceutical industry. The flexibility in process settings such as the applied binder addition method, screw configuration, screw speed and material throughput allows the manipulation of size and shape properties of the granules. However, due to the fact that it is a rather new granulation technique, twin-screw granulation is not as well understood as batch-wise high shear wet granulation. Most of the twin-screw granulation studies are limited to a certain design and scale of the twin-screw granulator. In this study, in order to consolidate the understanding about the granulation process and to comprehend the applicability and limits of the process variables in a scale independent manner, the regime theory was applied. Scale dependence of parameters limits the ability of the study towards multiple-scale application. In this study, α-Lactose monohydrate was granulated with Polyvinylpyrrolidone (2.5%, w/w) as binder in the granulation liquid, with 1×6 and 2×6 kneading discs at 60° stagger angle in the screw configuration. The specific mechanical energy, which involves the combination of screw speed, material throughput and torque required for the rotation of the screws at the used process conditions, was correlated with the applied liquid-to-solid ratio. The study suggested that, although increasing liquid-to-solid ratio strongly drives the granule size distribution towards a large mean granule size, increasing the energy input to the system can be effectively used to lower the mean granule size and also narrow down the size distribution. Further experiments are desired in the near future such as evaluating other screw configurations, the effect of the stagger angle and other formulations with significantly different raw material properties.



Change in the granule size distribution for different screw configuration when liquid-to solid ratio and specific mechanical input are changed.