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COMPARISON OF SWIRLING AIRFLOW FLUIDIZED BED GRANULATION AND TOP-SPRAY FLUIDIZED BED GRANULATION WITH HIGH AND LOW BINDING SOLUTION SPRAY RATES

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ABSTRACT

The use of swirling airflow in fluidized bed granulation has not been explored. Hence, the aim of this study was to investigate the granulation process employing swirling airflow, in comparison with the better known top-spray fluidized bed granulation. FlexStream, a recently introduced side-spray granulation system that employs swirling airflow in a fluidized bed system, was used in this study. It was found that granules prepared using the FlexStream at high binding solution spray rate (FGH) had smaller mass median diameter than granules prepared using the top-spray fluidized bed at either high (TGH) or low (TGL) binding solution spray rate. Furthermore, FGH produced granules with narrower size distribution when compared to either TGH or TGL. FGH was found to produce minimal amount of fines but had slightly elevated amount of lumps when compared to TGL. It was also found that FlexStream at low binding solution spray rate (FGL), equivalent to the level used for TGL, failed to produce satisfactory granules. This finding indicates that the FlexStream required high granulation binder spray rates, due in part, to the higher drying efficiency. High speed granulation was superior to low speed granulation as it reduced the amount of fines as well as shortened the granulation processing time. FGH was superior to TGH, as the amount of granules in the size range of 250 – 710 μm (i.e. useful product yield) was the highest. Results from FT4 powder rheometer showed that FGH and TGH had similar flow properties, and these were superior to FGL and TGL. Drug content analysis also showed that FGH was capable of achieving high content uniformity in granules of different size ranges. The FlexStream fluidized bed granulation was clearly efficient and capable of high speed fluidized bed granulation.

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