Melt Rheology of Selected Pharmaceutical Polymers for Hot Melt Extrusion

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Hot melt extrusion (HME) is a process with increasing importance fast for the pharmaceutical industry. The importance is due to the fact that HME is a robust production process for solid dispersions. products comprise These active pharmaceutical ingredient (API), carrier polymer and additives and are an approach to tackle current drug development challenges, such as the improvement of bioavailability of poorly water soluble APIs or modified API release.

In process design, it is necessary to understand the thermoplastic melt flow behavior. For instance, the extrusion die is designed based on viscosity data for a given formulation, so that the requested target throughput can be reached without exceeding the maximum extrusion pressure. However, in the openly accessible literature very little is published concerning the flow behavior of polymers relevant to pharmaceutical HME. Therefore, the aim of this study is to characterize the rheological properties of selected polymers to provide data for process equipment design.

The measurements were carried out using a rotational rheometer in oscillatory mode. A vacuum compression molding device was used for sample preparation. All analyzed samples showed shear thinning behavior and decreasing viscosity with increasing

temperature. The measurements showed excellent reproducibility as the standard deviation between repetitions is lower than 3%.