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Influence of hot melt extrusion processing parameters on the properties of a pharmaceutical formulation

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Hot melt extrusion (HME) is an old technology that has been recently adapted to be used in the pharmaceutical industry. HME is a continuous process that is widely used to produce a solid dispersion matrix. The aim of this dissertation is to evaluate different factors that will affect the pharmaceutical formulation properties that are produced using HME. For HME, there are different variables that will affect the product quality such as processing parameters, material selection, material ratio and the presence of gas or moisture. One aim of this study is to find the most significant factor that affects the product properties using the simplest design of experiment. Material selection and the ratio between the materials will be extensively evaluated using carbamazepine as a model drug. Moisture content and gas introduced during the process will be assessed to illustrate the best method to remove them. Process parameters show a significant effect on the product quality. Polymer selection and the ratio between the polymers show a great impact on drug dissolution and stability studies. Effective degassing has successfully enhanced the overly product quality features such as dissolution, shape, drug content and stability.

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