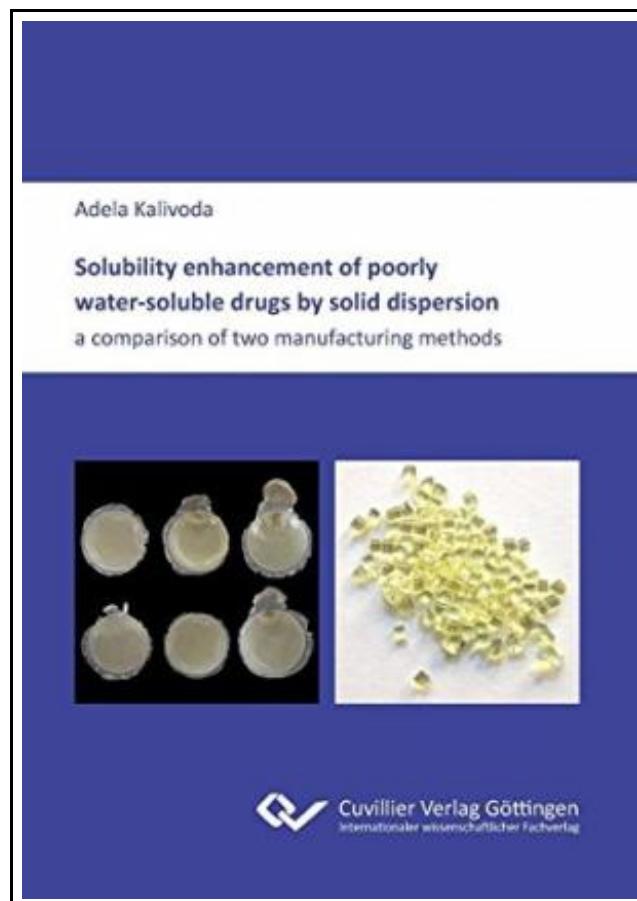


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Cuvillier Verlag Nov 2015, 2015. Taschenbuch. Book Condition: Neu. 211x149x17 mm. Neuware - Summary Solid dispersions are a promising approach for controlled release drug delivery systems as both the bioavailability enhancement of poorly water-soluble drugs as well as the sustained release of water-soluble drugs are possible to optimize their in vivo performance. Different methods for the manufacture of solid dispersion systems have been introduced in literature. In the present work, two methods are compared: hot-melt extrusion and ultrasound-assisted compaction technique. Various carrier systems and drugs with different physicochemical properties are applied to investigate the feasibility of the technologies for pharmaceutical formulation. The formulations are compared to the corresponding untreated physical blends of the components regarding their solid state structure and dissolution behavior to assess the effect of the manufacturing technique. Ultrasound-assisted compaction technique improves the initial dissolution rate of fenofibrate, a poorly water-soluble model drug. The crystalline API is partially converted into its amorphous state. As equivalent results can be achieved if the polymers are added directly to the dissolution medium, the dissolution enhancement is attributed to an improved wettability of the drug. A statistical design of experiments is employed to investigate the effect of the process parameters on the results. Difficulties are encountered in the determination of process parameters which result in an optimal outcome. The process is very sensitive to the smallest changes of settings, for example of the position of the sonotrode. Additionally, the delivery of ultrasound energy is inhomogeneous. There is no or only insufficient user control of these parameters available. Furthermore, the duration of ultrasound energy delivery which is identified as a crucial parameter cannot be set by the user. The variable factors ultrasound energy, pressure of the lower piston and pressure of the upper piston affect the defined responses in the opposite direction. Hence,...

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