

A novel thermodynamic strategy for predicting influence of relative humidity on stability of amorphous solid dispersions

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Abstract

In this work, the influence of polymeric excipients and relative humidity (RH) on stability of amorphous solid dispersions (ASDs) was investigated. Irbesartan and oxaprozin of BCS II were selected as model active pharmaceutical ingredients (APIs). PVP and PVP/VA were chosen as model excipients. The water sorption and the physical stability of amorphous solid dispersions stored at constant temperature and humidity were measured. The thermodynamic phase diagrams were constructed using Perturbed-Chain Statistical Associating Fluid Theory (PC-SAFT) and Gordon-Taylor equation. The results showed that the hygroscopicity of PVP-containing was stronger than PVP/VA-containing. The water sorption was found to significantly decrease the API solubility in the polymer as well as the glass-transition temperature of the formulation. The solubility of irbesartan and oxaprozin in PVP and PVP/VA were further predicted at 25 °C with PC-SAFT. It could guide the design of amorphous solid dispersions and selection of storage conditions.

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