Pseudopolymorphism of Active Pharmaceutical Ingredients (APIs): A Case Study of L-Phenylalanine

Jie LU*, Zhen LI & Jing WANG

National Engineering Laboratory for Cereal Fermentation Technology, School of Chemical & Material Engineering, Jiangnan University, Wuxi 214122, China

SUMMARY. The solid-state characterization, dimorphic nature, solubility and solvent-mediated transformation of the anhydrous form and the monohydrate form of L-phenylalanine have been firstly conducted in detail. The results have shown that, the two forms are enantiotropically related, and the transformation rate can be prohibited by increasing temperature and reducing water content in the solvent mixtures. These results will contribute to a better understanding about the pseudopolymorphic systems for pharmaceutical industry.

KEY WORDS: Active pharmaceutical ingredients, Characterization, Phenylalanine, Pseudopolymorphism, transformation.

* Author to whom correspondence should be addressed. E-mail: lujie6742@sina.com