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An investigation into the stability and aqueous solubility of amorphous solid dispersions of BCS class II drugs

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Amorphous solid dispersions have shown the potential to offer higher apparent solubility and bioavailability of BCS class II drugs. Drug stability, drug-polymer miscibility and drug supersaturation are the fundamental requirements for the successful design and development of such systems. The main objectives of this work are to study amorphous drug crystallization kinetics, assess a theoretical approach for the estimation of drug stability, drug-polymer interaction and miscibility on the basis of Flory-Huggins (F-H) theory and the role of polymer in maintaining drug supersaturation in dissolution media. Firstly, the relevance of fragility and glass forming ability to recrystallization of amorphous drugs is assessed. Secondly, the non-isothermal crystallization kinetics of model systems was also analysed by statistically fitting the crystallization data to 15 different kinetic models and the relevance of model-free kinetic approach has been established. Thirdly, a comprehensive investigation of binary and ternary F-H theory of amorphous solid dispersions of model drugs and polymers was conducted using modulated differential scanning calorimeter, dynamic vapour sorption and X-ray diffraction. The simplified relationship between F-H interaction parameter and temperature was established. This enables us to generate free energy of mixing curves at different temperature and finally the spinodal curve. Furthermore, a three-component F-H model was employed to analyse the moisture sorption behaviour of solid dispersions. It is also used to estimate the F-H interaction parameter of drug and polymer in the presence of moisture since it does not require *a priori* knowledge about binary interaction parameters between drug and polymer. Finally, the role of polymers in generating and maintaining drug supersaturation in dissolution media has also been investigated. Thus, this research work involves a multidisciplinary approach to establish crystallization tendency/kinetics and F-H theory as stability predictors for amorphous drug formulations.

Biography

Shrawan Baghel is currently doing PhD in "Novel technologies and optimized formulations for delivery of solid dispersion of BCS class II drugs" at Pharmaceutical and Molecular Biotechnology Research Center (PMBRC), Waterford Institute of Technology. He is the winner of Science Foundation Ireland scholarship for this project in collaboration with Synthesis and Solid State Pharmaceutical Centre. The main aim of this project is to gain an insight into the mechanistic and molecular aspects of solid disperison prepared by spray drying, hot melt extrusion and supercritical fluid process using DSC, XRD and NMR.

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