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Systemic *in vitro* and *in vivo* evaluation of the feasibility of amorphous solid dispersion for a B-RAF (Rapidly Accelerated Fibrosarcoma) inhibitor

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It is well acknowledged that oral bioavailability of a drug candidate is often influenced by factors such as the permeability, physicochemical properties, and metabolism of the drug. Among the physicochemical properties, solubility and dissolution rate are considered critical factors affecting the oral bioavailability. For compound G-F, a potent and selective B-Raf inhibitor with poor solubility and solubility limited absorption at high doses, we evaluated a spray-dried amorphous dispersion (SDD) formulation to improve the solubility. A combination of theoretical solubility prediction and *in vitro* dissolution were used to predict the *in vivo* exposure of G-F. The predicted value was found to have good agreement with the *in vivo* exposure resulted from administering the crystalline and amorphous form of G-F to rats. In general, this combined approach demonstrated that the amorphous form of G-F offers an advantage over the crystalline form of G-F in terms of solubility; *in vitro* dissolution and *in vivo* absorption that were predictable and were consistent with literature. This systemic approach provides a great value for compound development.

Biography

Yingqing Ran has obtained her PhD in 2004 from University of Arizona, College of Pharmacy under Professor Samuel Yalkowsky. She is currently a Senior Scientist in Small Molecule Pharmaceutics Group. She has broad experience from drug discovery to development. She has published more than 25 papers in reputed journals.

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