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Small molecule enabling formulation development: A super-saturation perspective

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Over 90% of small molecule NMEs are poor water soluble and super-saturation drug delivery systems, i.e. amorphous solid dispersions, nano-suspensions and lipid based drug delivery systems, are the main strategy to enhance bioavailability. Super-saturation can also be included due to pH change during GI transition for both free form and pharmaceutical salt. Super-saturation can also increase flux rate by creating higher API concentration gradient in the GI tract. Therefore, it is critical to obtain a good understanding of the kinetics of super-saturation process both *in vitro* and *in vivo*. As super-saturation can occur rapidly and it can be very sensitive to pH, hydrodynamics, a real-time concentration monitoring, multi-channel and miniaturized setup was used to investigate the kinetics of super-saturation. The results were also compared with HPLC analysis for validation purpose. The *in vitro* data was also used to model and simulate super-saturation process by GastroPlus to further understand the impact of super-saturation on biopharmaceutics. Case studies of how super-saturation studies can help with formulation design to enhance bioavailability in different situations were given. Finally, the future direction of super-saturation investigations and applications was also shared.

Biography

Likun Wnag has obtained his Bachelor's degree in Biomedical Devices and PhD in Industry Pharmacy with focus on PAT, imaging, pelletization and coating process. He has joined Johnson & Johnson Pharmaceutical Research & Development (Belgium Site) in 2011 and acts as Scientist to develop and manage automated screening platforms for early development. In 2014, he became Senior Scientist and Preformation Group Leader for automated screening and early development. In 2015, he joined Jiangsu Hengrui Medical co., as NanJing R&D Site Director and returned to China.

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