Yan He, J Pharm Drug Deliv Res 2016, 5:3(Suppl)
http://dx.doi.org/10.4172/2325-9604.C1.008

Amorphous solid dispersions: Utilization and challenges in drug discovery and development

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Amorphous solid dispersion (ASD) can accelerate a project by improving dissolution rate and solubility, offering dose escalation flexibility and excipient acceptance for toxicology studies, as well as providing adequate preclinical and clinical exposure. The prerequisite physicochemical properties for a compound to form a stable ASD are glass forming ability and low crystallization tendency, which can be assessed using computational tools and experimental methods. The experimental polymer excipient screening techniques are discussed. Improved technologies for polymer screening with minimal quantity of drug substance, and the scalability of ASD from bench to commercial are reviewed. Considerations of *in vitro* evaluations, preclinical animal selection, and the translation of the preclinical results to clinical studies are also discussed. Better understanding of how polymers improve the stability of the amorphous phase in the solid state and how ASD improves bioavailability have facilitated the applications of ASD ranging from discovery research to preclinical development and further to commercialization. With the understanding of how ASDs are currently used in the pharmaceutical industry and what challenges remain to be solved, ASD can be applied to solve drug formulation problems at given research and development stages.

Biography

Yan He has received her PhD degree in Pharmaceutical Sciences from the University of Arizona in 2005 with Dr. Samual H. Yalkowsy as her mentor. She has over ten years of experience working in industry. She is currently working as a Principle Research Investigator at Sanofi, USA. She has published nine papers in peer reviewed journals and the Handbook of aqueous solubility data in two versions. She has been serving as a Scientific Advisor to the *Journal of Pharmaceutical Sciences*.

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