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Novel *in situ* self-assembly nanoparticles for pediatric drug formulations

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Over 65% of current medications do not have commercially available pediatric formulations. Lack of pediatric formulations has led to the need to break tablets or open capsules for administration, risking reduced efficacy and adverse effects because of inaccurate dosing. Because of challenges and limitations on liquid dosage forms, flexible oral solid dosage forms are preferred for pediatric formulations. Recently, we discovered a novel platform nanotechnology to manufacture solid granules that produce in situ self-assembly nanoparticles (ISNPs) when introduced to water or other fluids (e.g. gastrointestinal fluid). The current ISNPs are lipid-based nanoparticles. We successfully applied the ISNP nanotechnology for ritonavir, lopinavir, a fixed-dose combination of lopinavir/ritonavir and a fixed-dose combination of four drugs. Drug-loaded ISNP granules achieved over 15% of drug loading, acceptable stability at room temperature and over 90% of drug entrapment efficiency. According to the evaluation using an electronic-tongue and dissolution, drug-loaded ISNP granules had similar taste to the placebo granules. Moreover, the pharmacokinetic studies showed that the ISNP granules improved drug bioavailability and biodistribution. The overall results demonstrated that the novel ISNP nanotechnology is a very promising platform to manufacture palatable, heat stable and flexible pediatric granules.

Biography

Xiaowei Dong has completed her PhD in Pharmaceutical Sciences from University of Kentucky and then joined Novartis Pharmaceutical Corporation working as a lead formulator for drug product development for about 4 years. In 2013, she joined UNT Health Science Center as an Assistant Professor in the Department of Pharmaceutical Sciences at the College of Pharmacy. Her research includes drug delivery and formulation development using nanotechnology and has special focus on pediatric formulation development.

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