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.

Jambhekar, S. S. and P. J. Breen (2013). "Drug dissolution: Significance of physicochemical properties and physiological conditions." *Drug Discov Today* 18(23–24):1173–1184.

Oral bioavailability of a drug is determined by a number of properties, including drug dissolution rate, solubility, intestinal permeability, and presystemic metabolism. Frequently, the rate limiting step in drug absorption from the GI tract is drug release and drug dissolution from the dosage form. Therapeutic agents with aqueous solubilities less than 100 μg/mL often present dissolution limitations to absorption. Physicochemical, formulation-related and physiological factors can all influence drug dissolution. In this review, the authors will discuss the important physicochemical properties of a drug and physiological conditions in the GI tract that play an important part in drug dissolution and absorption processes and, consequently, the bioavailability of a drug.

Parrott, N. et al. (2009). "Predicting pharmacokinetics of drugs using physiologically based modeling—application to food effects." *AAPS J* 11(1):45–53.

Our knowledge of the major mechanisms underlying the effect of food on drug absorption allows reliable qualitative prediction based on biopharmaceutical properties, which can be assessed during the preclinical phase of drug discovery. Furthermore, several recent examples have shown that physiologically based absorption models incorporating biorelevant drug solubility measurements can provide quite accurate quantitative prediction of food effect. However, many molecules currently in development have distinctly suboptimal biopharmaceutical properties, making the quantitative prediction of food effect for different formulations from in vitro data very challenging. If such drugs reach clinical development and show undesirable variability when dosed with food, improved formulation can help to reduce the food effect and carefully designed in vivo studies in dogs can be a useful guide to clinical formulation development. Even so, such in vivo studies provide limited throughput for screening, and food effects seen in dog cannot always be directly translated to human. This paper describes how physiologically based absorption modeling can play a role in the prediction of food effect by integrating the data generated during preclinical and clinical research and development. Such data include physicochemical and in vitro drug properties, biorelevant solubility and dissolution, and in vivo preclinical and clinical pharmacokinetic data. Some background to current physiological absorption models of human and dog is given, and refinements to models of in vivo drug solubility and dissolution are described. These are illustrated with examples using GastroPlus to simulate the food effect in dog and human for different formulations of two marketed drugs.