Recent Advances in Amorphous Drug Formulation

Thomas Rades[1]*
[1] Department of Pharmacy, Faculty of Health and Medical Sciences, University of Copenhagen, DENMARK
*E-mail address of the corresponding author: thomas.rades@sund.ku.dk

The low water solubility of many low molecular weight drugs continues to be a challenge in the development of oral drug formulations, since low water solubility can lead to low or variable bioavailability. Amongst the various enabeling formulations that are conceived to tackle this challenge, a very promising approach to increase not only the dissolution rate but also the apparent solubility of drugs, is the conversion of the crystalline drug material into an amorphous form. In this presentation, we will initially discuss the prerequisites for the drug material itself to be successfully converted into an amorphous form. The criteria amorphization ability, supersaturation propensity and physical stability will be defined and key experiments to address these critical quality attributes will be described. In the second part of the presentation, we will discuss different forms of amorphous drugs and co-amorphous systems with and without addition of polymer. Finally, we will address the question: Do amorphous systems also have a role in lipid based drug delivery?

Keywords: amorphous forms, co-amorphous systems, lipid systems, supersaturation, physical stability