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Invited Speaker Abstract

Amorphous stabilization using proteins as excipients

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Abstract: Poor aqueous solubility is a pressing problem especially for oral drug delivery. Amorphous drug delivery systems present one of the most promising approaches to overcome this challenge. The inherent physical instability of pure amorphous drugs usually requires the addition of stabilizing excipients. Here, polymeric materials have been widely explored in combination with the poorly soluble drugs resulting in so called polymeric amorphous solid dispersions (ASDs). Whilst some products using the ASD technology have reached the market, the technology is often limited by low drug loadings (≤30wt%) or insufficient solubility enhancement. Recently, proteins as excipients have been introduced as amorphous stabilizers and solubility enhancers in protein based amorphous formulations, so called Dispersomes®. In particular, whey proteins enabled the formulation of physically stable Dispersomes® at drug loadings of ≥50wt%, with improved dissolution, solubility and bioavailability compared to polymeric ASDs and the crystalline drug. The presentation will give an overview on the state-of-the-art of the Disperosme® technology.

Keywords: Poor solubility, amorphous, whey proteins, Dispersome®