Addition of Leucine to Trehalose-Containing Microparticles Enhances Environmental Robustness against Moisture for Nasal Vaccination Applications

Zheng Wang, Hui Wang, Reinhard Vehring

Department of Mechanical Engineering, University of Alberta, Edmonton, Alberta, Canada

Nasal dosage forms, e.g. nasal dry powder vaccines, have attracted increasing research interest due to their needle-free administration and low storage and transportation requirements. High environmental robustness of dry powder vaccines is important to ensure efficacy is maintained when powders are exposed to humid environments during use. The purpose of this study was to investigate the environmental robustness of various two-component particle systems when exposed to high humidity environments. Trehalose/leucine, trehalose/pullulan, and trehalose/trileucine particle systems, as well as pure trehalose particles, were prepared using monodisperse spray drying. Particle size, morphology, crystallinity and powder dispersibility of the two-component particle systems were characterized and compared with those of the pure trehalose particles. The results show that trehalose/leucine formulations maintained a high emitted dose even after up to 60 min unprotected exposure to 90% relative humidity and 25°C, whereas almost no pure trehalose particles were emitted under these conditions. Protection for 10 min was achieved with as little as 10 % leucine in the formulation. In conclusion, leucine is an appropriate shell forming excipient to enhance the environmental robustness of nasal dry powder vaccines against moisture exposure.