Poster 20

Combined application of novel physical chemical tools to bring greater understanding of lipid controlled release multiparticulate systems aimed towards a once-daily medication for pediatric patients

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Purpose

To better understand annealing kinetics and phase behavior of a modified release melt spray congeal multiparticulate formulation using a fundamental physical chemistry approach.

Methods

USP dissolution, new flow-NMR dissolution, PXRD, q1NMR, Raman, and SEM

Results

Dissolution performance is a representative in-process control for annealing kinetics and closely links to other physical-chemical techniques.

Conclusion

Learnings from this work allow us to identify key properties of lipids that are less prone to the observed annealing changes of glyceryl behenate based modified release melt spray congeal systems. This greater understanding is aimed at developing a modified release melt spray congeal platform that requires little to no annealing to achieve the target dissolution profile and results in a physically stable (i.e. no change in dissolution) over the shelf life of the product.

Keywords: formulation, modified release, multiparticulate, pediatric, dissolution