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A quantitative analysis of drug migration during granule drying

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Highlights

- We study the effect of drug migration in granules during the drying state.
- We provide a more quantitative understanding of the drug migration.
- We understand the most important factors that govern the kinetics of drug migration.

Abstract

This study investigates the extent of drug (active) migration in granules made via high shear wet granulation subject to factors such as the viscosity of the binder solution, particle size of the excipient and granule porosity. Due to the complexity of a qualitative comparison between granules having different sizes, shape and porosities, a quantification technique that is independent of these differences was developed. The radial distribution function (RDF), developed as part of this effort, quantifies the spatial distribution of the active ingredient in granules produced under different processing conditions.

A two component system with potassium chloride (KCl) as the water-soluble model active and microcrystalline cellulose (MCC) was studied at 20% (w/w) active load. In order to eliminate any non-homogeneity due to segregation and difference in wettability of the two compounds, the soluble active ingredient was dissolved in the granulating vehicle and then sprayed on the powder bed to carry out granulation. The extent of drug migration and structure of the dry granules was analysed using X-ray microtomography (μ -CT).

The extent of capillary migration in the resulting granules was analysed by the dividing the μ -CT images into conical sections and quantifying the distribution of the active across these

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