Poster Presentation

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Recrystallization behavior of amorphous and crystalline lactose from TSPDF

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Lactose is a disaccharide sugar of galactose and glucose that is most commonly associated with milk. Its importance to the food and animal product industry cannot be overstated, as it is involved in aspects as diverse as baking, confectionary, and infant products. The other major use of lactose is in the pharmaceutical industry. The mildly sweet and loosely bland flavor of lactose has lent to its use as a stabilizer and excipient in pharmaceutical products. Despite the wide range of applications for this material, there is still much to be studied. While it is known to exist in several crystalline forms and as two anomers, α and β, characterized by the flipping of a hydroxide group on the glucose ring, the amorphous form of lactose is less understood. Yet it is this amorphous form which may play a crucial role in the physicochemical stability of amorphous drug dispersions. In order to fully understand the structural changes which lactose undergoes when converted from a crystalline to amorphous material, total scattering experiments coupled with PDF analysis for structural identification of amorphous lactose of different origins were undertaken with the goal of understanding the recrystallization behavior of this versatile material. Samples measured included commercial forms of lactose, crystalline and amorphous, and amorphous forms obtained by melt quenching and lyophilization. Recrystallization was followed for the amorphous forms by measuring characteristic samples aged at 40 °C/75% RH, which is a standard condition for stressing pharmaceutical materials to extrapolate shelf-life. By fitting the PDF curves to a structural model of lactose, and refining with the characteristic function for a sphere of radius r, an estimate of the coherence length of atom-atom correlations for a give sample provides a measure of the growth progression, from single molecule to crystallite for the lactose samples. Coupled with data from NMR spectroscopy, TSPDF analysis is teasing out the nuances of the recrystallization behavior of lactose.

Keywords: pair distribution function, total scattering, amorphous