

Title	Peptide Stability In Spray Dried Powders For Inhalation
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Abstract	<p>Purpose. Investigate the effect of spray drying, crystallinity, and water content on the physical stability of salmon calcitonin (sCT) in a dry powder for inhalation. Methods. sCT was spray dried in a Büchi 190, with and without mannitol. Powders were stored for five days at 0, 29, 51, 58, 69, and 84% relative humidity at 25° C. The crystallinity (by XRPD and Raman spectroscopy), water content (by Karl-Fischer titration), secondary structure (by FT-IR) and aggregation (by RP- and SEC-HPLC) were determined. In addition the water sorption isotherms (by DVS) and reactivity to water vapor (by isothermal calorimetry) were measured for all powders. Results. The spray-drying process had no effect on sCT aggregation and all powders remained stable during the course of the study, when stored at RH <29%. The initial mannitol crystallinity in the dry powders was proportional to the amount of mannitol. A greater degree of mixing between amorphous mannitol and sCT at lower mannitol concentrations is suggested by the observed differences in surface concentration. Moisture-induced crystallization of mannitol occurred at RH >51%, and was most significant for powders that have low mannitol content (<30%). Under these conditions, it appeared that all powders contain crystalline mannitol only, and that sCT aggregation and β-sheet content increased significantly. sCT degradation in 30% mannitol formulations was comparable to 100% sCT and significantly greater than formulations containing 70% mannitol. Conclusion. Spray drying did not have an effect on the stability of sCT. sCT degradation in dry powders for inhalation can be minimized if stored in a low humidity environment. When stored at high humidity, sCT degradation appeared to be decreased by dilution with crystalline or amorphous mannitol. No trend was found between the stability of sCT and water content when the powder content was corrected for crystallization.</p>

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