

Accepted Manuscript

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Sonia Al-Qadi, Pablo Taboada, Carmen Remuñán-López

PII: S0378-5173(18)30627-6
DOI: <https://doi.org/10.1016/j.ijpharm.2018.08.049>
Reference: IJP 17735

To appear in: *International Journal of Pharmaceutics*

Received Date: 1 April 2018
Revised Date: 12 August 2018
Accepted Date: 24 August 2018

Please cite this article as: S. Al-Qadi, P. Taboada, C. Remuñán-López, Micro/nanostructured inhalable formulation based on polysaccharides: Effect of a thermoprotectant on powder properties and protein integrity, *International Journal of Pharmaceutics* (2018), doi: <https://doi.org/10.1016/j.ijpharm.2018.08.049>

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Micro/nanostructured inhalable formulation based on polysaccharides: Effect of a thermoprotectant on powder properties and protein integrity

Sonia Al-Qadi^a, Pablo Taboada^b, Carmen Remuñán-López^{a,*}

^aNanobiofar Group, Department of Pharmacology, Pharmacy and Pharmaceutical Technology, Faculty of Pharmacy, University of Santiago de Compostela, Campus Vida, E-15782-Santiago de Compostela, Spain.

^bColloids and Polymers Physics Group, Department of Condensed Matter Physics, Faculty of Physics, University of Santiago de Compostela, Campus Vida, E-15782-Santiago de Compostela, Spain.

Sonia Al-Qadi's e-mail address: hannaq1996@gmail.com

Pablo Taboada's e-mail address: pablo.taboada@usc.es

*Corresponding author: C. Remuñán-López - Tel.: +34881815045; fax: +34981547148; E-mail address: mdelcarmen.remunan@usc.es

Abstract

Combined micro- and nanosystems are appealing for pulmonary protein delivery, fulfilling the specific physiological requirements for efficient outcomes *in-vivo*. However, fabrication of protein formulations may impose stresses perturbing protein conformational stability and, hence, biological activity. Herein, a protein, insulin (INS), was nanoencapsulated inside chitosan nanoparticles (CS NPs) by ionic gelation. By spray drying, the resultant protein-loaded NPs were further encapsulated with a thermoprotectant into powders bearing adequate aerodynamic properties for lung delivery. Structural modifications and interactions of the protein/carrier system were investigated following processing, with special emphasis on protein integrity. Accordingly, physicochemical, elemental, structural and thermal experiments were performed. The analyses revealed the localization of a proportion of the protein on the NPs' surface following nanoencapsulation, and the involved molecular interactions between the NPs and thermoprotectant after microencapsulation. Protein integrity was conserved throughout the preparation processes. This highlights the non-invasiveness of the fabrication techniques, particularly spray drying, for preparing micro-nanosystems for effective administration of inhalable macromolecules.

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