OP-22

DOI: 10.14232/syrptbrs.2023.44

Dry powder inhaler of a miniprotein decoy for SARS-CoV-2 infection inhibition

Stefania Glieca[1], Angelo Bolchi[2], Elisabetta Levati[2], Davide Cavazzini[2], Valentina Garrapa[3], Barbara Montanini[2], Francesca Buttini[1]

[1] Department of Food and Drug, University of Parma, Parma, Italy
[2] Department of Chemical, Life and Environmental Sustainability Sciences, University of Parma, Parma, Italy
[3] Preclinics GmbH, Potsdam, Germany

A novel approach that has been proposed for the treatment of SARS-CoV-2 infection is the use of a small protein which interacts with the receptor binding domain (RBD) of the spike protein, avoiding the virus entry into the human cells, thus preventing the multiorgan failure induced by the virus [1]. The aim of this project was the development and characterization of a dry powder inhaler containing the LCB1 small protein.

A quality by design approach has been applied for the formulation of the spray dried powder, investigating the effect of the critical material attributes and process parameters on the quality of the powder. The LCB1 was expressed as described in literature [2], and then was spray dried using a mini Spray Dryer B-290.

The lead powder, composed by 5.7% of LCB1, 15% of L-leucine, 78.3% of trehalose and 1% of buffer salts provided an emitted fraction (the fraction of the powder leaving the device after aerosolization) of 86.6% and a respirable fraction (the fraction of the powder with an aerodynamic diameter less than 5 µm) of 50.6%, parameters obtained using a Next Generation Impactor. In addition, it was evaluated whether the protein maintained its conformation, and ability to interact with the RBD. For this purpose, SDS-page, SEC and ELISA assay were employed, and they revealed no differences between the protein in the powder and the native one.

In conclusion, the process parameters adopted, combined with the addition of trehalose, favoured the respirability and structural integrity of LCB1 inhalation powder.

References:

1. Case J. et al, Cell host & microbe, 29(7), 1151–1161.e5
2. Cao L. et al, Science, 370: 426-431. (2020).