Formulation of a combined dry powder inhalation therapy for cystic fibrosis

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Cystic fibrosis (CF) is a common lung disease, caused by a gene mutation (CFTR). It leads to abnormal mucus accumulation, chronic airway infection, inflammation, progressive lung damage and death. Therefore, there is no cure for CF, but a range of treatment can help control symptoms, reduce complications, and improve the quality of life of patient. Through the pulmonary administration route, inhalation therapy is widely used for the treatment of local pulmonary disorders. The dry powder inhalers (DPIs) are the most used and stable form of drug administration via lung.

Since the Cystic Fibrosis Foundation recommends mucolytic, antibiotic, and anti-inflammatory agents, in the same sequence for inhaled medications; our project is developing a novel DPI containing a combined therapy of mannitol, levofloxacin and/or ketoprofen by controlled release. The aim of this combination is to achieve the patient convenience with the highest drug effectiveness at the same time.

The combination powder will be produced by spray dryer and under controlled conditions to obtain nanoparticles with same particle size distribution. Laser scattering, FT-IR, XRPD, DSC, SEM and aerodynamic particle size analysis are the investigation methods for the particle characterization. Quality by design (QbD) approach will be used to predict the final quality of the products.

It is expected to design a novel promising inhaled combined therapy for cystic fibrosis with; I. improved aerodynamic properties, II. a high release profile, III. an increased local deposition in the lung cell, and IV. a long-term stability.