

The Influence of blend composition on the aerodynamic performance of a novel high resistance multi-dose device

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High resistance multi-dose inhaler devices are prescribed to Chronic Obstructive Pulmonary Disease (COPD) and asthma patients regardless of the severity of their disease, due to their easier handling and low peak inhalation flow (PIF) required.

The aim of this study was to investigate the influence of different blend composition on the aerodynamic performance of Aptar Prohaler[®] (Aptar Pharma, FR), a novel high resistance multi-dose inhaler.

Fluticasone propionate was blended (0.8% w/w) with lactose ($D_{v,50}$ 74 μm) to manufacture 8 different formulations comprising different percentages of fine lactose ($D_{v,50}$ 3 μm , 0 up to 5% w/w) and/or a force control agent (FCA). Strips were filled with 5 mg of formulation using Omnidose TT (Harro Höfliger, DE) and subsequently loaded into Prohaler[®]. Aerodynamic performance was tested employing a Next Generation Impactor (Copley Scientific, UK) at 39 L·min⁻¹ for 3.1 seconds. Data analysis was performed using R statistical software.

The presence of FCA significantly increased the Fine Particle Mass (FPM) as well as a higher fine lactose percentage. However, the latter was significant only in the formulations without FCA. Formulations with FCA showed the best performance (Fine Particle Fraction = 45%) overall. Mass Median Aerodynamic Diameter (MMAD) did not change significantly with an increased percentage of fine lactose. However, when FCA was used the lower MMAD was recorded (2.10 ± 0.15 μm).

The study highlighted that the use of a FCA, in a model blend formulation and in Prohaler[®] device, positively increased the FPM and produced a lower MMAD.