Comparative Performance Evaluation of the AeroChamber Max® Anti-Static Valved Holding Chamber with AeroChamber Plus® Using Symbicort Rapihaler® pMDI

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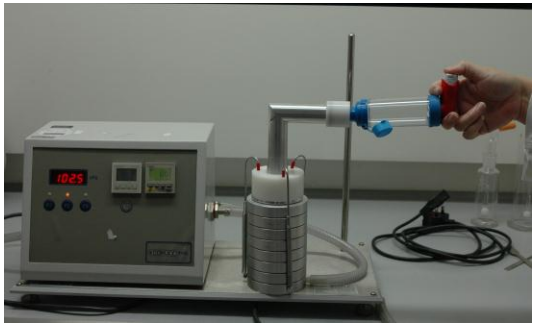
INTRODUCTION

Symbicort Rapihaler is a pressurised metered dose inhaler (pMDI) that contains the glucocorticosteroid budesonide (BUD) and the rapid and long-acting b2 –agonist formoterol (as formoterol fumarate dihydrate - FFD). It is intended for use in adults and children with persistent asthma and in the regular treatment of adult patients with moderate to severe chronic obstructive pulmonary disease (COPD). Two strengths of Symbicort Rapihaler have been developed: 80/4.5 μg and 160/4.5 μg ex-actuator.

The electrostatic properties of the material used in the construction of the holding chamber can have a profound effect of the performance of the device in terms of Delivered Dose and Fine Particle Dose (FPD). The aim of this study was to compare the performance of a new Trudell Medical International VHC with improved anti-static properties (AeroChamber Max™) with their currently available device (AeroChamber plus) when used with Symbicort Rapihaler

INSTRUMENTATION



- Andersen Cascade Impactor (ACI) operated at 28.3 L/min
- Copley TPK-S Airflow and Delay Timer
- Symbicort Rapihaler pMDI
- AeroChamber Plus Plastic VHC (Ex. Trudell Medical International)
- AeroChamber Max Plastic VHC (Ex. Trudell Medical International)

* Both HC variants were pre-washed in detergent before use

METHODS

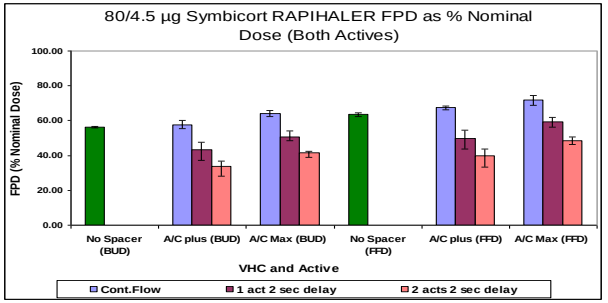
The performance of the VHC's was assessed using Symbicort RAPIHALER. The effect of different dose regimens on Delivered Dose and Particle Size Distribution by ACI were investigated.

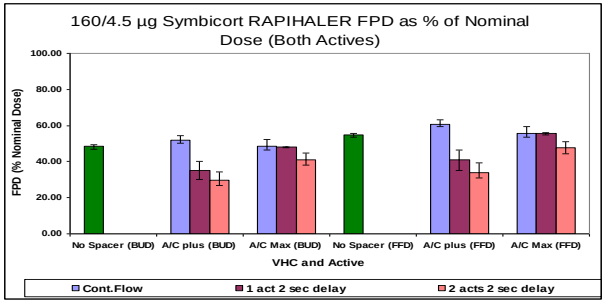
The dose regimens investigated were as follows –

- Single actuation of the pMDI into the VHC connected to the Impactor/Filter to which a continuous airflow is applied
- Single actuation of the pMDI with VHC connected to the Impactor/Filter with a 2 second delay between actuation and collection (1act, 2 sec delay)
- 2 actuations together with 2 seconds delay before collection on the ACI (2 acts, 2 sec delay)

RESULTS AND DISCUSSION

The following graphs illustrate FPD expressed as % of nominal dose for both active drugs. Both product strengths are shown





** Error Bars represent data range*

- *The FPD delivered from Symbicort RAPIHALER/VHC combination is equivalent to that delivered by the pMDI alone when delay between actuation and administration is minimised.*
- *No significant difference in the FPD profiles of both actives*
- *The Aerochamber Max is provides an improved FPD when a delay between actuation and administration is encountered*
- *The Importance of the dose regime on pMDI/VHC performance is demonstrated, and that multiple actuation and delays before administration should be avoided*

CONCLUSION

- **This in vitro study demonstrates that both AeroChamber Max and AeroChamber plus can be used effectively with Symbicort RAPIHALER**
- **That when used in keeping with manufacturers guidance notes the performance of the Rapihaler/VHC combination is equivalent to the pMDI alone when delay between actuation and administration is kept to a minimum**
- **AeroChamber Max is more robust when delays between actuation and administration are encountered this probably due to the anti-static properties of the construction materials**

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