Delivery of Respimat Soft Mist Inhaler from a Valved Holding Chamber

**RATIONALE**

- The Soft Mist Inhaler (SMI) platform is used to deliver inhaled medications to treat different disease conditions and patient populations. Valved Holding Chambers (VHCs) are also used to treat the same patient populations.
- Questions have arisen regarding the applicability of the SMI+VHC particularly in pediatric and geriatric patients.
- This laboratory investigation was undertaken to assist practitioners with information regarding potential drug delivery from the SMI+VHC.

**MATERIALS AND METHODS**

- Evaluated with: *Excellence By Design 1* V. Kushnarev, M. Nagel, C. Doyle, J. Suggett

**RESULTS**

- Measurements of Fine Particle Mass (FPM, 0.54-3.99 µm aerodynamic diameter) were made by means of a chilled Next Generation Pharmaceutical Impactor equipped with USP inlet operated at 30 L/min.
- Assay for active ingredients recovered from components of the apparatus was undertaken by HPLC.

**CONCLUSIONS**

- The differences in FPM between the SMI and SMI + VHC were within the typical magnitude of method variability and likely to be clinically insignificant.
- Healthcare providers can have assurance that the use of the SMI with *AeroChamber Plus Flow-Vu* AVHC should deliver a similar FPM of medication compared to the SMI alone.

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**Fine Particle Mass (0.54-3.99 µm)**

<table>
<thead>
<tr>
<th>SMI TYPE</th>
<th>Respimat SMI Alone (µg)</th>
<th>AeroChamber Plus Flow-Vu AVHC (µg)</th>
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</thead>
<tbody>
<tr>
<td>Spiriva</td>
<td>1.8 ± 0.1</td>
<td>1.4 ± 0.1</td>
</tr>
<tr>
<td>Inspiolto</td>
<td>2.0 ± 0.1/2.0 ± 0.1</td>
<td>1.7 ± 0.3/1.4 ± 0.2</td>
</tr>
<tr>
<td>Combivent</td>
<td>11.4 ± 0.9/61.7 ± 2.5</td>
<td>11.7 ± 0.8/84.8 ± 5.0</td>
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</tbody>
</table>

**Fine Particle Mass (0.5-3.99 µm)**

- *Inspiolto* Respimat SMI
- *Spiriva* Respimat SMI
- *Combivent* Respimat SMI

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*Excellence By Design 1* V. Kushnarev, M. Nagel, C. Doyle, J. Suggett
