

# Comparative Performance Evaluation of the Westech FPD Impactor

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## Introduction

Multi-stage cascade impaction be it either Next Generation Impactor or Andersen Cascade Impactor (ACI) is the most widely used analytical technique for determination of the aerodynamic droplet size distribution of the aerosol produced from devices such as pMDIs and DPIs. Commissioned by AstraZeneca (AZ) R&D Charnwood in 2005, and designed and built by Mike Smurthwaite.



Westech Short-Stack Fine Particle Dose (FPD) impactor: based on the viable ACI with Petri dish sample collection

The Westech Fine Particle Dose (FPD) impactor is a simple 2-stage with filter impactor for determination of fine particle dose, and represents one design of a number of reduced stage impactors currently being developed as part of the abbreviated impactor measurement initiative (AIM).

## Study Aim

This poster describes a performance evaluation study designed to assess the performance of the FPD when compared with a 2-stage Andersen impactor (sACI) and a 6-stage (0 – 5) ACI control. In addition to this the effect of employing different collection plate/dish coating techniques on impactor performance were evaluated, namely-

- Simple coating of the collection plate/dish with a brij coating solution
- Addition of a brij soaked filter to the surface of the collection plate or dish
- Addition of a brij soaked mesh (ex Novi System Ltd) to the surface of the collection plate or dish

## Procedure

A single active pMDI formulation (ex. AstraZeneca) was used

To minimise can to can variations the same 3 pMDIs were used for all Impactor/coating variants studied

In accordance with the proprietary AZ method used as the basis for the study, the plates of the 6-stage ACI were uncoated.

The impactors were leak tested prior to sample collection

Sampling was undertaken using an airflow rate of 28.3 Litres/min.

The same AZ method was used to recover the API from the impactor, and quantified by High Performance Liquid Chromatography (HPLC).

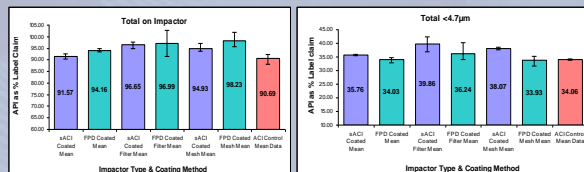
Total on Impactor (TOI), Fine Particle Dose, Individual stage and filter deposition were assessed for each Impactor/coating combination

## Results

Unless stated otherwise all following API data is expressed as % of nominal dose.

Error bars represent range of the data obtained (n=3)

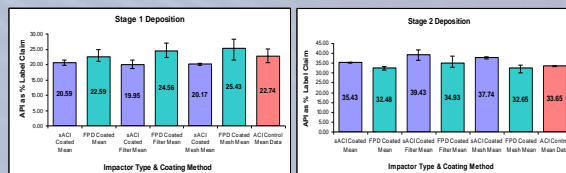
### Total on Impactor (TOI) and Fine Particle dose



For TOI, the sACI with brij-coated petri dishes compares best with the control ACI, the other variants yielding TOIs between 3.4% (brij coated FPD) – 7.8% (brij coated mesh FPD) higher than the control impactor.

For fine particle dose <4.7µm the brij coated sACI and FPD data correlated well with the control. Use of a brij coated ACI filter led to a slight increase in API fine particle dose, this effect being more pronounced with the sACI. Coated meshes in the sACI and FPD gave similar results to the coated filter.

### Upper & Lower Stage Deposition Profiles

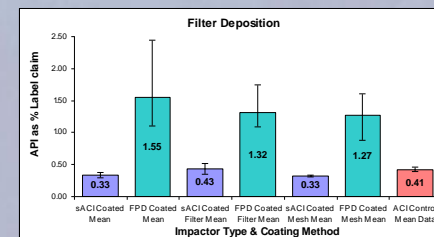


For the upper (9 – 4.7µm) stage, there was a tendency for the sACI to collect a lower proportion of the dose compared with the control and the FPD. Interestingly, it was found that in this study, the addition of a brij coated filter did not significantly affect the upper stages deposition on the sACI this is probably due to the lack of co-solvent in this formulation.

In terms of the lower (4.7 – 1.1 µm) stage, the FPD tended to collect a lower proportion of the dose compared to the control (-4.6%). The sACI fraction was 4.0% higher than the ACI control data. The addition of a brij coated filter led to an increase in drug deposition on this stage for both impactors, most notably with the sACI.

## Filter Deposition

The largest discrepancy seen between the impactors was in filter deposition. In this case the FPD filter deposition was found to be 3 times higher than that seen with both the sACI and the 6-stage ACI, and it was noted that this difference almost completely accounted for the difference seen between the FPD stage 2 and control. Using Brij coated filters in the collection dishes of the FPD instead of plain Brij coated dishes did not significantly affect the filter deposition of the device, thus indicating that particle re-entrainment is an unlikely explanation of this effect.



## Conclusion

- The Westech FPD, like the sACI, is capable of providing a rapid and reasonably accurate assessment of the respirable dose generated by a pMDI.
- Subtle differences in the sACI and FPD deposition patterns were observed compared with the ACI control, most notably that of filter deposition.
- The reason for the higher filter deposition observed with the FPD is unclear though unlikely to be the result of re-entrainment.
- In terms of API recovery, the coated meshes did not offer any significant advantages compared to coated filter papers. However they can be used quite satisfactorily and their robust mechanical properties may offer advantages in terms of re-usability thus cutting consumables cost.

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