

Bibliography of Literature Related to EDA

[A Comparison of the Performance of Efficient Data Analysis Versus Fine Particle Dose as Metrics for the Quality Control of Aerodynamic Particle Size Distributions of Orally Inhaled Pharmaceuticals](#)

Terrence P. Tougas, Adrian P. Goodey, Gareth Hardwell, Jolyon Mitchell, Svetlana Lyapustina April 11, 2016. AAPS PharmSciTech, pp. 1-11.

- *Directly compares the ability of EDA and FPD to detect changes to in APSDs*
- *Comments on the superiority of EDA in this regard, and the inability of FPD to detect certain changes to APSD*

[Good Cascade Impactor Practices, AIM and EDA for Orally Inhaled Products](#)

Editors: Tougas, Terrence P., Mitchell, Jolyon P., Lyapustina, Svetlana A. (Eds.), 2013, Springer

- *Comprehensive volume on general good practices for CI testing*
- *Background information on aerosols and aerosol testing*
- *Discussion of potential failure modes and risk assessment of oral inhaled products*
- *Detailed discussion of performance characteristics of EDA and grouped stages with respect to their use in quality control*

[AIM and EDA of Aerodynamic Particle Size Data from Orally Inhaled Products](#)

Workshop at RDD Europe 2015, Nice, France, May 6, 2015. Available at: IPAC-RS website.

- *Overview of AIM and EDA concepts*
- *Review of studies characterizing performance of AIM and EDA*

[Product Lifecycle Approach to Cascade Impaction Measurements](#)

Terrence Tougas, Dave Christopher, Jolyon Mitchell, Svetlana Lyapustina, Michiel Van Oort, Richard Bauer, Volker Glaab AAPS PharmSciTech, 2011. 312-322.

- *Discussion of the types and purposes of particle size testing conducted through product lifecycle: i.e. research, development (process, product, clinical), commercialization*
- *AIM/EDA as an integral element of the control strategy/Quality Control*
- *Relationship of AIM/EDA to other forms of APSD testing*

[When Could Efficient Data Analysis \(EDA\) Fail? Theoretical Considerations](#)

Jolyon P Mitchell, J. David Christopher, Terrence P Tougas, Volker Glaab, Svetlana Lyapustina RDD Europe 2011, 2011. Vol 1, pp 237-246.

- *Risk assessment of EDA metrics with consideration of the physics/physical chemistry of aerosols*

Efficient Data Analysis for MDIs and DPIs: Failure Mode Effect Analysis

Volker Glaab, Adrian Goodey, Svetlana Lyapustina, Jolyon P Mitchell RDD Europe 2011, 2011. RDD Europe 2011. Volume 1, 2011: 225-236.

- *Examination of various factors (product and process) that may impact the APSD of an orally inhaled product. Includes risk assessment considering the ability of conventional stage groupings and EDA to detect various failure modes.*

Detecting Differences in APSD: Efficient Data Analysis (EDA) vs. Stage Grouping

J. David Christopher, Monisha Dey RDD Europe 2011, 2011. Vol 1, pp 215-224.

- *Comparison of the performance of EDA versus Stage Groupings on the basis of operating characteristics curves*

Efficient Data Analysis in Quality Assessment

Terrence P Tougas, Respiratory Drug Delivery, 2011. Vol 1, pp 209-214.

- *Overview of the application of EDA in the quality control environment.*

Abbreviated Impactor Measurement (AIM) and Efficient Data Analysis (EDA) concepts

Mitchell, Tougas, Christopher, Bauer, Church, Dey, Glaab, Goodey, Holmes, Iley, Lyapustina, Patel, Quiroz, Russell-Graham, Strickland, Svensson, Van Oort, Wu Inhalation Magazine, December 2010. pp. 8-12.

- *Overview of the application of AIM and EDA in the quality control environment.*

Generalized Simplified Approaches For MMAD Determination

David Christopher, Monisha Dey, Lana Lyapustina, Jolyon Mitchell, Terrence Tougas, Mike Van Oort, Helen Strickland, Bruce Wyka USP Pharmacopeial Forum, June 2010. 36(3), pp 812-823.

- *Proposal for alternative approach to estimating MMAD from CI data.*
- *Improves accuracy (vs. USP method) when assumption of log-normal APSD is not met.*
- *Includes several real case studies where accuracy improved by this approach*

Relative Precision of Inhaler Aerodynamic Particle Size Distribution (APSD) Metrics: Part 1

Jolyon P Mitchell, Mark W Nagel, Cathy C Doyle, Rubina S Ali, Valentina I Avvakoumova, J. David Christopher, Jorge Quiroz, Helen Strickland, Terrence Tougas, Svetlana Lyapustina, AAPS PharmSciTech, 2010.11(2):843 – 851.

- *Laboratory study comparing precision of AIM/EDA to full resolution Andersen Cascade Impactor*

[Relative precision of inhaler aerodynamic particle size distribution \(APSD\) metrics by full resolution and abbreviated andersen cascade impactors \(ACIs\): Part 2--investigation of bias in extra-fine mass fraction with AIM-HRT impactor.](#)

Jolyon P Mitchell, Mark W Nagel, Cathy C Doyle, Rubina S Ali, Valentina I Avvakoumova, J. David Christopher, Jorge Quiroz, Helen Strickland, Terrence Tougas, Svetlana Lyapustina, AAPS PharmSciTech. 2010 11(3):1115-8.

- *Laboratory study examining source of observed bias between AIM and full resolution ACI.*

[Improved Quality Control Metrics for Cascade Impaction Measurements of Orally Inhaled Drug Products \(OIPs\)](#)

Terrence P. Tougas, David Christopher, Jolyon P. Mitchell, Helen Strickland, Bruce Wyka, Mike Van Oort, and Svetlana Lyapustina, AAPS PharmSciTech. 2009 10(4):1276-85.

- *Defines the concept of EDA metrics.*
- *Examination of large body of CI results from eight products in IPAC-RS database comparing ability of EDA and stage groupings to detect shifts in particle sizes in orally inhaled pharmaceuticals*

[Cascade Impaction Tutorial Modules](#)

A series of educational videos are being prepared by the IPAC-RS Cascade Impaction Working Group. These tutorial aims to provide reference information and basic training in good cascade impactor practices, theory and practice of aerodynamic particle size testing of pharmaceutical aerosols, abbreviated impactor measurements (AIM), and efficient data analysis (EDA). Three of modules have been posted on the IPAC-RS website with several others under preparation.