

EFFICIENT DATA ANALYSIS, ABBREVIATED IMPACTOR MEASUREMENTS, AERODYNAMIC PARTICLE SIZE DISTRIBUTIONS:

PUBLICATIONS AND PRESENTATIONS BY MEMBERS OF THE IPAC-RS CASCADE IMPACTION WORKING GROUP AND EPAG

2000-2011

Last updated: July 2011

Including output of collaborative efforts (e.g., through the Product Research Quality Institute) where IPAC-RS was the main driver and enabler

2011 – Manuscripts in Preparation

- **Orally Inhaled Products: Good Cascade Impaction Practices, AIM and EDA.** (Book). Terrence P Tougas, Jolyon P Mitchell, Svetlana Lyapustina, Editors. *Manuscript in preparation.*

2011 – Published

- **Non-impactor-Based Methods for Sizing of Aerosols Emitted from Orally Inhaled and Nasal Drug Products (OINDPs)** Jolyon Mitchell, Richard Bauer, Svetlana Lyapustina, Terrence Tougas, and Volker Glaab. *AAPS PharmSciTech 2011 DOI: 10.1208/s12249-011-9662-6*
<http://www.springerlink.com/openurl.asp?genre=article&id=doi:10.1208/s12249-011-9662-6>
- **[Efficient Data Analysis in Quality Assessment](#)**. Terrence P Tougas. *RDD Europe 2011 (2011), Vol 1, pp 209-214*
- **[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*
- **[Efficient Data Analysis for MDIs and DPIs: Failure Mode Effect Analysis](#)** Volker Glaab, Adrian Goodey, Svetlana Lyapustina, Jolyon P Mitchell. *RDD Europe 2011 (2011), Vol 1, pp 225-236*

- [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*
- **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 DOI: 10.1208/s12249-011-9590-5*
- **Detecting Differences in APSD: Efficient Data Analysis (EDA) vs. Stage Grouping.** David Christopher and Monisha Dey, on behalf of the IPAC-RS Cascade Impactor Working Group. *RDD Europe 2011*
- **Efficient Data Analysis in Quality Assessment.** Terrence P. Tougas, on behalf of the IPAC-RS Cascade Impactor Working Group. *RDD Europe 2011*
- **Efficient Data Analysis for MDIs and DPIs: Failure Mode Effect Analysis.** Volker Glaab, Adrian Goodey, Svetlana Lyapustina, Jolyon Mitchell, on behalf of the IPAC-RS Cascade Impactor Working Group. *RDD Europe 2011*
- **When Could Efficient Data Analysis (EDA) Fail? Theoretical Considerations** Jolyon P Mitchell, J. David Christopher, Terrence Tougas, Volker Glaab, and Svetlana Lyapustina, on behalf of IPAC-RS Cascade Impactor Working Group. *RDD Europe 2011*

2011 – Presentations & Posters at IPAC-RS 2011 Conference

<http://ipacrs.com/2011%20Conference.html>

[Overview of Effective Data Analysis – Terry Tougas](#)

Workshop #2: Abbreviated Impactor Measurements and Effective Data Analysis - Implementing a New Best Practice for OIP Aerosol Particle Size Analysis

- [Lifecycle Strategies for Using EDA, AIM and Full Resolution Impactor – Terry Tougas](#)
- [Control Strategies for APSD – Rajni Patel](#)
- [Equipment Options for AIM and Beyond – Jolyon Mitchell](#)
- [Precision and Accuracy of AIM – Dave Christopher and Rajni Patel](#)
- [Considerations for Applying EDA to an Existing Product - Helen Strickland](#)
- [Road to Adopting AIM/EDA as a Standard – Adrian Goodey](#)

Posters

[Application of the Abbreviated Impactor Measurement \(AIM\) concept: A Reduced Extraction Method for the Andersen Cascade Impactor](#)

Shari Sellers,
Jennifer Wylie,
Brent Donovan

[The EPAG Workshop on the Abbreviated Impactor Concept \(AIM\) in December 8th 2010 in Edinburgh, UK: Status, Key Results and Future Needs in Oral Inhaled Product \(OIP\) Testing](#)

Jolyon Mitchell
and Steve Nichols

[Principle Component Analysis as a tool for description of Aerodynamic Particle Size Distribution](#)

Alan Silcock,
Rachel Brody

2010

- **Extension of the Abbreviated Impactor Measurement (AIM) Concept to Incorporate Simultaneous Determination of Delivered Dose Uniformity with Efficient Data Analysis Metrics Pertinent to Aerodynamic Particle Size (AIM-DDU Apparatus).** Jolyon Mitchell, Terrence Tougas, J. David Christopher and Svetlana Lyapustina. DDL 21. 2010; *Journal of Aerosol Medicine and Pulmonary Drug Delivery*.
- **Abbreviated Impactor Measurement (AIM) and Efficient Data Analysis (EDA) concepts: A partnership for the assurance of Oral Inhaled Product (OIP) quality.** Mitchell, Tougas, Christopher, Bauer, Church, Dey, Glaab, Goodey, Holmes, Iley, Lyapustina, Patel, Quiroz, Russell-Graham, Strickland, Svensson, Van Oort, Wu. *Inhalation*, December 2010, pp. 8-12.
http://www.ecn5.com/ecn_images/customers/1983/publisher/1941/INH1210.pdf or
<http://inh1210.ecndigitaledition.com/magazine.aspx?eid=1941&e=71529243&b=312112>
- **Efficient Data Analysis (EDA) and Abbreviated Impactor Measurement (AIM) Concepts** T.P. Tougas, J.D. Christopher, J.P. Mitchell and S. Lyapustina. *Respiratory Drug Delivery 2010*. Orlando, Florida, USA, April 25-29 2010. RDD 2010, Vol 2 (2010): pp 599-604
- **Relative Precision Study 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 HRT-AIM 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 doi: 10.1208/s12249-010-9473-1
- **Relative Precision of Inhaler Aerodynamic Particle Size Distribution (APSD) Metrics by Full Resolution and Abbreviated Andersen Cascade Impactors (ACIs): 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. doi: 10.1208/s12249-010-9452-6

- **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* 36(3), pp 812–823. May – June 2010

2009

- **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, Svetlana Lyapustina. *AAPS PharmSciTech* 2009. DOI: 10.1208/s12249-009-9312-4 pp. 1276 – 1285 <http://www.springerlink.com/content/j316855116723866/>
- **Improved Accuracy of MMAD Determination Compared with USP Method.** T Tougas, D Christopher, M Dey, S Lyapustina, J Mitchell, and M Van Oort. *J Aerosol Med. Pulmonary Drug Delivery*. 22(2):181. 2009. DOI:10.1089/jamp.2008.00A3.
- **Evaluation Of An Approach For Characterizing Sources Of Variability In Cascade Impaction Particle Size Determinations.** T Tougas, D Christopher, S. Lyapustina, J Mitchell, J Quiroz, H Strickland, and B Wyka. *J Aerosol Med. Pulmonary Drug Delivery*. 22(2):181. 2009. DOI:10.1089/jamp.2008.00A3
- **Improved Methods For Detecting Differences In Aerosol Particle Size Distributions Of Orally Inhaled Drug Products.** T Tougas, D Christopher, S. Lyapustina, J Mitchell. *J Aerosol Med. Pulmonary Drug Delivery*. 22(2):169. 2009. DOI: 10.1089/jamp.2009.00A1.

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- **Capabilities of Aerodynamic Particle Size Distribution (APSD) Measurements Based on Analysis of a Blinded Database.** Terrence P. Tougas, David Christopher, Svetlana Lyapustina, Jolyon P. Mitchell, Rajni Patel. RDD-2008. Vol 1, pp.109–123. <http://rddonline.org/pub/article.asp?ArticleID=1133>
- **Minimizing Variability of Cascade Impaction Measurements in Inhalers and Nebulizers** M. Bonam, D. Christopher, D. Cipolla, B. Donovan, D. Goodwin, S. Holmes, S. Lyapustina, J. Mitchell, S. Nichols, G. Pettersson, C. Quale,

N. Rao, D. Singh, T. Tougas, M. Van Oort, B. Walther, B. Wyka. *AAPS PharmSciTech*. <http://www.springerlink.com/content/t22701k84w1665q4/> DOI 10.1208/s12249-008-9045-9 (February 2008)

2007

- **Comparison of Two Approaches for Treating Cascade Impaction Mass Balance Measurements** B. Wyka, T. Tougas, J. Mitchell; H. Strickland, D. Christopher and S. Lyapustina *J. Aerosol Med.* Vol.20, No. 3, pp 236-256 (2007). <http://www.liebertonline.com/doi/abs/10.1089/jam.2007.0609> Correction: *J. Aerosol Medicine and Pulmonary Drug Delivery*. March 1, 2008, 21(1): 155-156. <http://www.liebertonline.com/doi/pdfplus/10.1089/jamp.2007.0679>
- **Product Quality Research Institute Reports.** DeLuca PP, Lyapustina S. *AAPS PharmSciTech*. 2007; 8(1): Article 6. <http://www.aapspharmstech.org/view.asp?art=pt0801006> . (2007)
- **Product Quality Research Institute Evaluation of Cascade Impactor Profiles of Pharmaceutical Aerosols**
 - Part 1: Background for a Statistical Method.** Adams WP, Christopher D, Lee DS, Morgan B, Pan Z, Singh GJP, Tsong Y, Lyapustina S. *AAPS PharmSciTech*. 2007; 8(1): Article 4. DOI: 10.1208/pt0801004. <http://www.aapspharmstech.org/default/issueView.asp?vol=08&issue=01> or <http://www.aapspharmstech.org/view.asp?art=pt0801004>
 - Part 2 – Evaluation of a Method for Determining Equivalence** Christopher D, Adams WP, Lee DS, Morgan B, Pan Z, Singh GJP, Tsong Y, Lyapustina S.. *AAPS PharmSciTech*. 2007; 8(1): Article 5. DOI: 10.1208/pt0801005. <http://www.aapspharmstech.org/default/issueView.asp?vol=08&issue=01> . or <http://www.aapspharmstech.org/view.asp?art=pt0801005>
 - Part 3 - Final Report on a Statistical Procedure for Determining Equivalence.** Christopher D., Adams W., Amann A., Bertha C., Byron P. R., Doub W., Dunbar C., Hauck W., Lyapustina S., Mitchell J. P., Morgan B., Nichols S., Pan Z., Singh G. J. P., Tougas T., Tsong Y., Wolff R., and Wyka B. *AAPS PharmSciTech*.; 2007; 8(4): Article 90. DOI: 10.1208/pt0804090. <http://www.aapspharmstech.org/view.asp?art=pt0804090>
- **In Vitro/In Vivo Comparisons In Pulmonary Drug Delivery.** Newman, S.P. and Chan, H-K. *J. Aerosol Med.* 2007;20(2):211.
- **In Vitro and In Vivo Aspects of Cascade Impactor Tests and Inhaler Performance: A Review.** Mitchell J, Newman S, Chan H-K. *AAPS PharmSciTech*. 2007; 8(4):

Article 110. DOI: 10.1208/pt0804110 <http://www.aapspharmscitech.org/view.asp?art=pt0804110>
(2007)

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- **Aerodynamic Particle Size Distribution Profile Comparisons - Considerations for Assessing Statistical Properties of Profile Comparisons Tests.** D. Christopher, Z. Pan and S. Lyapustina. *Am. Pharm. Rev.* 8 (1): 68-72 (2005). An abbreviated version is available online at <http://www.americanpharmaceuticalreview.com/articleDetail.asp?SID=55B8044290274E448C5F90E7E4CC208B&ArticleID=236> (2005).

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- **Statistical Techniques Used in Simulation of Cascade Impactor Particle Size Distribution Profiles.** Z. Pan, J. D. Christopher, S. Lyapustina and E. Chou. *Respiratory Drug Delivery IX*, (VCU/DHI, ISBN 1-930114-65-6) Vol. III, 669-672 (2004).

2003

- **Considerations for the Development and Practice of Cascade Impaction Testing Including a Mass Balance Failure Investigation Tree.** D. Christopher, P. Curry, W. Doub, K. Furnkranz, M. Lavery, K. Lin, S. Lyapustina, J. Mitchell, B. Rogers, H. Strickland, T. Tougas, Y. Tsong, B. Wyka. *J. Aer Med* 16 (3): 235-247 (2003). <http://www.liebertonline.com/doi/abs/10.1089/089426803769017604>
- **Letter to the Editor.** *J Aerosol Medicine*. Jolyon P. Mitchell. December 1, 2003, 16(4): 433-433. doi:10.1089/089426803772455686. <http://www.liebertonline.com/doi/abs/10.1089/089426803772455686>

2000

- **Initial Assessment of the ITFG/IPAC Aerodynamic Particle Size Distribution Database by the CMC Specifications Technical Team of the ITFG/IPAC Collaboration Submitted to FDA** http://ipacrs.com/PDFs/Initial_Assess_of_Particle.PDF and http://www.fda.gov/ohrms/dockets/ac/00/techrepro/3609_rpt2.pdf (2000)



Supporting Publications from the European Pharmaceutical Aerosol Group (EPAG)

2011

[European Pharmaceutical Aerosol Group \(EPAG\): Summary of Abbreviated Impactor Measurement \(AIM\) Workshop - December 2010.](#) Jolyon P Mitchell, Steven C Nichols
RDD Europe 2011 (2011), Vol 2, pp 469-472

2010

AIM Workshop at Drug Delivery to the Lungs-21, The Aerosol Society, Edinburgh, UK. Copies of the presentations together with an audio file of the entire workshop can be downloaded from the EPAG website (<http://www.epag.co.uk/>):

- **Overview of AIM-EDA** J. Mitchell and M. Copley
- **Further Evaluation of the Fast Screening Impactor for determining Fine Particle Fraction of Dry Powder Inhalers** D. Russell-Graham, Cooper, B Stobbs, E McAulay, H Bogard, V Heath & E Monsallier
- **Assessment of Abbreviated Impactor Measurement (AIM) Methods for Nebulizer Characterization** M Tservistas, M Uhlig and J Mitchell
- **Measuring the fine particle dose using inter-stage filters in the NGI - An overview of two methods** M Svensson and E Berg
- **Comparison of Next Generation Impactor and Fast Screening Impactor for determining Fine Particle Fraction of Dry Powder Inhalers** F Després-Gnis and G Williams
- **Application of Fast Screening Impactors as a Screening Tool for pMDI and Nebulizers** G Sheng and W Watanabe
- **FSI vs NGI: comparison and evaluation** P Rogueda, B Morrical and Y D Chew

- **The Abbreviated Impactor Measurement (AIM) Concept: Experimental Aspects and Compendial Needs for Apparatuses** S C Nichols (Moderator)

2009

Drug Delivery to the Lungs-20, The Aerosol Society, Edinburgh, UK.

- **Evaluation of the Fast-Screening Impactor for determining Fine Particle Fraction of Dry Powder Inhalers** B Stobbs, E McAulay, H Bogard and E Monsallier can be downloaded at: http://www.ddl-conference.org.uk/index.php?q=previous_conferences by members of the Aerosol Society

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