

## IPAC-RS PUBLICATIONS

2000-2024

2024

**Limitations of metrics used in the regulation of aerodynamic particle size distributions (APSDs) of orally inhaled products (OIPs)** - An interview with Adrian Goodey of the IPAC-RS Cascade Impaction Working Group on reactions in the inhaler community to a series of published articles. *Inhalation*. February 2024. In press.

2023

**Laboratory Performance Testing of Aqueous Nasal Inhalation Products for Droplet/Particle Size Distribution: an Assessment from the International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC-RS)** | *AAPS PharmSciTech* (October 2023)

<https://link.springer.com/article/10.1208/s12249-023-02665-x>

**[IPAC-RS Summary of Global Regulatory Developments 2022](#)** (August 2023)

**Good Practices for the Laboratory Performance Testing of Aqueous Oral Inhaled Products (OIPs): An Assessment from the International Consortium on Regulation and Science (IPAC-RS).** Mitchell JP, Carter I, Christopher JD, Copley M, Doub WH, Goodey A, Gruenloh CJ, Larson BB, Lyapustina S, Patel RB, Stein SW, Lostritto R, Suman JD. *AAPS PharmSciTech*, (March 2023)

<https://link.springer.com/article/10.1208/s12249-023-02528-5>

**An Overview and Discussion of N-nitrosamine Considerations for Orally Inhaled Drug Products and Relevance to Other Dosage Forms.** Lee Nagao, Hera Shams Khan, Fabienne Despres-Gnis, Cheryl L. M. Stults, James Mullis, Niran Nugara, Atish Sen. *AAPS PharmSciTech* (January 2023)

<https://link.springer.com/article/10.1208/s12249-022-02491-7>

2022

**[IPAC-RS Year in Review 2022](#)**

**Spray Pattern and Plume Geometry Testing and Methodology: An IPAC-RS Working Group**

**Overview.** S. Baxter, B. Myatt, S. Stein, A. Parkinson, F. Chambers, B. Doub, et al. *AAPS PharmSciTech* 2022 Vol. 23 #145. DOI: 10.1208/s12249-022-02278-w <https://link.springer.com/article/10.1208/s12249-022-02278-w#citeas>

**Moving Forward from “Fine Particle Fraction: The Good and the Bad”.** Jolyon P. Mitchell, William Doub, J David Christopher, Christopher J. Gruenloh, Rajni B Patel, Mark Copley, Steven Tignor, Stephen W. Stein, Svetlana Lyapustina, and Steven P. Newman. *Journal of Aerosol Medicine and Pulmonary Drug Delivery*. 2022 vol 35. DOI: 10.1089/jamp.2022.0017 [Moving Forward from “Fine Particle Fraction: The Good and the Bad”](#) | [Journal of Aerosol Medicine and Pulmonary Drug Delivery \(liebertpub.com\)](http://Journal of Aerosol Medicine and Pulmonary Drug Delivery (liebertpub.com))

**[IPAC-RS Summary of Global Regulatory Developments 2021](#)** (April 2022)

**RDD-2022 – Perspectives on the Evolving Regulatory Landscape for Inhaled and Nasal Products.** S Prasad Peri, Ann Purrington, Svetlana Lyapustina, John Evans. *RDD* 2022

**2021****[IPAC-RS Year in Review 2021](#)**

**Performance of Multiple-Batch Approaches to Pharmacokinetic Bioequivalence Testing for Orally Inhaled Drug Products with Batch-to-Batch Variability.** Elise Burmeister Getz, Kevin J. Carroll, J. David Christopher, Beth Morgan, Scott Haughie, Alessandro Cavecchi, Christopher Wiggernhorn, Hayden Beresford, Helen Strickland & Svetlana Lyapustina. *AAPS PharmSciTech* volume 22, Article number: 225 (2021). <https://doi.org/10.1208/s12249-021-02063-1>

**Efficient data analysis (EDA): Size, mass and common sense.** William H. Doub, Adrian P. Goodey, Jolyon P. Mitchell, J. David Christopher and Ian Carter. *Inhalation Magazine*. August 2021  
<https://www.inhalationmag.com/>

**[IPAC-RS Summary of Global Regulatory Development 2020](#)** (May 2021)

**2020****[IPAC-RS Year in Review 2020](#)**

**Cascade Impactor Stage Groupings: Poor Decisions from Degraded Data.** A. Goodey, JP Mitchell, W Doub, JD Christopher. *Inhalation*, August 2020 <https://www.e-digitaleditions.com/i/1276475-inh0820/11?>

**Addressing the Need for Controls on Particle Bounce and Re-entrainment in the Cascade Impactor and for the Mitigation of Electrostatic Charge for Aerodynamic Particle Size Assessment of Orally Inhaled Products: An Assessment by the International Consortium on Regulation and Science (IPAC-RS)** William Doub, Stephen Stein, Jolyon Mitchell, Adrian Goodey. *AAPS PharmSciTech* 21, Article number: 239 (August 2020) <https://link.springer.com/article/10.1208/s12249-020-01720-1>

**Evaluation of the Sensitivity and Robustness of Modified Chi-Square Ratio Statistic for Cascade Impactor Equivalence Testing Through Monte Carlo Simulations.** Abhinav Kurumaddali, David Christopher, Helen Strickland, Beth Morgan, Christopher Wiggernhorn, Stephen Stein, Svetlana Lyapustina & Günther Hochhaus. *AAPS PharmSciTech*; vol. 21, Article number: 147 (May 2020)  
<https://link.springer.com/article/10.1208/s12249-020-01664-6>

**Posters at the Joint Virtual IPAC-RS RDD 2020 Symposium** (April 2020) <https://www.ipacrs.org/ipac-rs-symposium>

- [Patient-Centric Considerations for PTTT: Addressing Unintended Consequences in the Draft 2018 Guidance](#) by IPAC-RS Product Quality Demonstration Strategy Working Group, poster, 2020
- [Designs for a Robust Outcome in Pharmacokinetic Bioequivalence Testing of Orally-Inhaled Drug Products with Batch-to-Batch Variability](#) by IPAC-RS PK Batch-to-Batch Variability Working Group, poster, 2020
- [Update from the Cascade Impactor Working Group](#) by IPAC-RS Cascade Impactor Working Group, poster, 2020
- [Sharing Information Across the Globe: IPAC-RS Global Regulatory Review and Outreach \(GRRO\)](#) by GRRO Brazil, GRRO China, GRRO Europe and GRRO North America Working Groups, poster, 2020

- Common Use Error Matrix for pMDIs [https://ad5a4c28-0460-4e72-b7af-0f1ef44f9e41.filesusr.com/ugd/932589\\_4c077e96166847719bafa71785fec2de.pdf](https://ad5a4c28-0460-4e72-b7af-0f1ef44f9e41.filesusr.com/ugd/932589_4c077e96166847719bafa71785fec2de.pdf), Poster and Excel spreadsheet by IPAC-RS Devices WG, 2020

**The Liability of Fine Particle Dose (FPD). Can we rely on the fine particle dose metric alone for quality control?** Adrian P. Goodey, Jolyon P. Mitchell, William H. Doub & J. David Christopher. *Inhalation* magazine, <https://www.e-digitaleditions.com/i/1229406-inh0420/19> (April 2020).

**Reflections on Digital Health Tools for Respiratory Applications.** Andy Dundon, David Cipolla, Jolyon Mitchell, and Svetlana Lyapustina. *Journal of Aerosol Medicine and Pulmonary Drug Delivery* Published Online: 16 Mar 2020 <https://doi.org/10.1089/jamp.2020.1597>

## 2019

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**Performance of the Population Bioequivalence (PBE) Statistical Test with Impactor Sized Mass Data** *AAPS PharmSciTech* (2019) 20:296. DOI: 10.1208/s12249-019-1507-8

Stephanie Chen, Beth Morgan, Hayden Beresford, Elise Burmeister Getz, David Christopher, Göran Långström, Helen Strickland, Christopher Wiggenhorn, and Svetlana Lyapustina. <https://rdcu.be/bPqke> or <https://link.springer.com/content/pdf/10.1208%2Fs12249-019-1507-8.pdf>

**Overview of Brazilian Requirements for Therapeutic Equivalence of Orally Inhaled and Nasal Drug Products.** Marcia Silva, Helena Costa, Bruna Nardy, Lee Nagao, Gustavo Mendes Lima Santos. *AAPS PharmSciTech* August 2019, 20:235 <https://link.springer.com/article/10.1208/s12249-019-1415-y>

**Determination of Passive Dry Powder Inhaler Aerodynamic Particle Size Distribution by Multi-Stage Cascade Impactor: International Pharmaceutical Aerosol Consortium on Regulation & Science (IPAC-RS) Recommendations to Support Both Product Quality Control and Clinical Programs.** Jolyon P. Mitchell, Stephen W. Stein, William Doub, Adrian P. Goodey, J. David Christopher, Rajni B. Patel, Terrence P. Tougas, Svetlana Lyapustina. *AAPS PharmSciTech*. July 2019, 20:206 10.1208/s12249-019-1416-x <https://doi.org/10.1208/s12249-019-1416-x>

**Cascade Impactor Equivalence Testing: Comparison of the Performance of the modified Chi-Square Ratio Statistic (mCSRS) with the original CSRS and EMA's Average Bioequivalence Approach.** Abhinav Kurumaddali, David Christopher, Dennis Sandell, Helen Strickland, Beth Morgan, Juergen Bulitta, Christopher Wiggenhorn, Stephen Stein, Svetlana Lyapustina, Günther Hochhaus. doi:10.1208/s12249-019-1443-7 *AAPS PharmSciTech*; 2019;20:249; 1–17. <https://link.springer.com/article/10.1208%2Fs12249-019-1443-7>

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## 2018

**Plume Geometry Testing Relevance and Methodology: An IPAC-RS Survey.** Frank Chambers, Samiran De, Sherryl Baxter, Adrian Parkinson, Bill Doub, Iain Breakwell, Manfred Fischer, and Lee M. Nagao. *RDD 2018*, Volume 2, 2018: 437-442.

<https://www.rddonline.com/rdd/article.php?id=0&sid=103&ArticleID=2395&return=1>

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**Performance of the Population Bioequivalence (PBE) Statistical Test Using an IPAC-RS Database of Delivered Dose from Metered Dose Inhalers.** Beth Morgan, Stephanie Chen, David Christopher, Göran Långström, Christopher Wiggenhorn, Elise Burmeister Getz, Hayden Beresford, Thomas Hoffelder, Daniela Acerbi, Steven Andrews, Mark Berry, Monisha Dey, Joshi Keyur, Mary McKenry, Marisa Pertile, Helen Strickland, David Wilcox, Svetlana Lyapustina *AAPS PharmSciTech*. 2018 Apr;19(3):1410-1425. doi: 10.1208/s12249-017-0941-8. Epub 2018 Feb 12. <https://www.ncbi.nlm.nih.gov/pubmed/29435904>.

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**Highlights from the 2017 IPAC-RS/ISAM Joint Workshop “New Frontiers in Inhalation Technology”** Smyth Hugh D., Colthorpe Paul, George Maureen, Jansen Paul, Fuglsang Anders, Armstrong Katherine E., and Lyapustina Svetlana. *Journal of Aerosol Medicine and Pulmonary Drug Delivery*. November 2017, ahead of print. <https://doi.org/10.1089/jamp.2017.1425>

**Discriminating Ability of Abbreviated Impactor Measurement Approach (AIM) to Detect Changes in Mass Median Aerodynamic Diameter (MMAD) of an albuterol/salbutamol pMDI aerosol.** J. David Christopher, Rajni B. Patel, Jolyon P. Mitchell, Terrence P. Tougas, Adrian P. Goodey, Jorge Quiroz, Patrik U. Andersson, Svetlana Lyapustina. *AAPS PharmSciTech*, 2017. doi:10.1208/s12249-017-0814-1. Available for onscreen reading at <http://rdcu.be/thJT> OnlineFirst at <http://link.springer.com/article/10.1208/s12249-017-0814-1>

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**2016**

**The Application of Abbreviated Impactor Measurement and Efficient Data Analysis in the Lifecycle of an Orally Inhaled Product: A Roadmap.** Jolyon P Mitchell, Adrian P Goodey, Terrence Tougas, J David Christopher, Gareth Hardwell, Isabel Lopes, Svetlana Lyapustina. *USP 42 (6)*; 2016.

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**Patient Focus and Regulatory Considerations for Inhalation Device Design: Report from the 2015 IPAC-RS/ISAM Workshop** Nicolas Roche, Gerhard Scheuch, John N Pritchard, Cornelia Nopitsch-Mai, Deepika A. Lakhani, Bhawana Saluja, Janine Jamieson, Andrew Dundon, Roisin Wallace, Susan Holmes, David Cipolla, Myrna B. Dolovich, Samir A. Shah, and Svetlana Lyapustina. *Journal of Aerosol Medicine and Pulmonary Drug Delivery*. Vol. 30, No. 1, February 2017: 1-13. Online August 2016. doi:10.1089/jamp.2016.1326. <http://online.liebertpub.com/doi/abs/10.1089/jamp.2016.1326>

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**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.** Tougas TP, Goodey AP, Hardwell G, Mitchell J, Lyapustina S. *AAPS PharmSciTech*. Online 11 April 2016. pp 1-11, <http://link.springer.com/article/10.1208/s12249-016-0508-0>

**Risk Management for Materials and Components Used in Orally Inhaled and Nasal Drug Products.** Cheryl L. M. Stults, Gaby Reckzuegel, Arthur Bailey, Jonathan Petersen, Lisa Dick, Thomas Feinberg, Andrew Feilden, Sara Miller, James Connors, Lee M. Nagao, *Pharmaceutical Research*, January 2016. <http://link.springer.com/article/10.1007/s11095-015-1770-7>

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**Regulatory Considerations for Approval of Generic Inhalation Drug Products in the US, EU, Brazil, China, and India.** Sau L. Lee, Bhawana Saluja, Alfredo García-Arieta, Gustavo Mendes Lima Santos, Ying Li, Sarah Lu, Shuguang Hou, Juliet Rebello, Abhijit Vaidya, Jaideep Gogtay, Shrinivas Purandare, Svetlana Lyapustina. *The AAPS Journal volume 17, pages1285–1304 (2015)* <https://link.springer.com/article/10.1208/s12248-015-9787-8>

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*Respiratory Drug Delivery* 2012. Volume 3, 2012: 731-736.

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**Challenges and Concerns with Development of an In Vitro Dissolution Test for Orally Inhaled Products (OIPs).** Trevor Riley; David Christopher; Jan Arp; Andrea Casazza; Agnes Colombani; Andrew Cooper; Monisha Dey, Janet Maas; Jolyon Mitchell; Maria Reiners; Nastaran Sigari; Terrence Tougas; Svetlana Lyapustina; *AAPS PharmSciTech: Volume 13, Issue 3 (2012), Pages 978-989.* DOI 10.1208/s12249-012-9822-3 <http://www.springerlink.com/openurl.asp?genre=article&id=doi:10.1208/s12249-012-9822-3>

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**Initial Assessment of the ITFG/IPAC Dose Content Uniformity Database by the CMC Specifications Technical Team of the ITFG/IPAC Collaboration. Submitted to FDA (2000)** [original location [http://www.fda.gov/ohrms/dockets/ac/00/techrepro/3609\\_rpt1.pdf](http://www.fda.gov/ohrms/dockets/ac/00/techrepro/3609_rpt1.pdf)] now at [https://wayback.archive-it.org/7993/20170405182405/https://www.fda.gov/ohrms/dockets/ac/00/techrepro/3609\\_rpt1.pdf](https://wayback.archive-it.org/7993/20170405182405/https://www.fda.gov/ohrms/dockets/ac/00/techrepro/3609_rpt1.pdf)

**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 (2000)** [original location: [http://www.fda.gov/ohrms/dockets/ac/00/techrepro/3609\\_rpt2.pdf](http://www.fda.gov/ohrms/dockets/ac/00/techrepro/3609_rpt2.pdf)] Current location: [https://wayback.archive-it.org/7993/20170405182408/https://www.fda.gov/ohrms/dockets/ac/00/techrepro/3609\\_rpt2.pdf](https://wayback.archive-it.org/7993/20170405182408/https://www.fda.gov/ohrms/dockets/ac/00/techrepro/3609_rpt2.pdf) (last visited on December 6, 2019)

- The Federal Register notice for the 1998 Draft FDA Guidance for MDIs/DPIs: <https://www.gpo.gov/fdsys/pkg/FR-1998-11-19/pdf/98-30938.pdf>. That guidance can be found at:
  - <https://wayback.archive-it.org/7993/20170403220934/https://www.fda.gov/ucm/groups/fdagov-public/documents/document/ucm070573.pdf>
  - [https://wayback.archive-it.org/7993/20170405182634/https://www.fda.gov/ohrms/dockets/ac/00/backgrd/3634b1c\\_sectiond.pdf](https://wayback.archive-it.org/7993/20170405182634/https://www.fda.gov/ohrms/dockets/ac/00/backgrd/3634b1c_sectiond.pdf)
  - <https://wayback.archive-it.org/7993/20170404224939/https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070573.pdf>
  - <https://wayback.archive-it.org/7993/20170405182102/https://www.fda.gov/ohrms/dockets/ac/00/backgrd/3609b1j.pdf>
- The 2018 revised draft FDA Guidance for MDIs/DPIs is posted at <https://www.regulations.gov/docket?D=FDA-2018-D-1098>

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*Note 1:* Access to AAPS publications is free for AAPS members. In addition, for AAPS PharmSciTech articles published in 2000-2016, access is free at <https://www.ncbi.nlm.nih.gov/pmc/journals/793/>

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*Note 2:* Links to IPAC-RS articles published in Inhalation and archived there:

- [An introduction to the International Pharmaceutical Aerosol Consortium on Regulation and Science \(IPAC-RS\), October 2011](#)
- [An IPAC-RS update: A practitioner's perspective on human factors, October 2012](#)
- [An IPAC-RS update: Delivery Systems, L&E and GRRO, August 2013](#)
- [Inhaler adherence is everyone's responsibility: Conclusions of the IPAC-RS Patient Concordance Initiative, December 2013](#)
- [An IPAC-RS update: Events and GRRO, Cascade Impaction and Device working groups, December 2014](#)
- [IPAC-RS: 15 years of research, advocacy and consensus building, February 2016](#)

- [Abbreviated impactor measurement \(AIM\) and efficient data analysis \(EDA\) concepts: Current questions and future considerations, February 2016](#)
- [An update on the activities of IPAC-RS, December 2017](#)

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