

IPAC-RS PUBLICATIONS

2000-2023

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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*, 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*. [An Overview and Discussion of N-nitrosamine Considerations for Orally Inhaled Drug Products and Relevance to Other Dosage Forms | SpringerLink](https://link.springer.com/article/10.1208/s12249-022-02491-7), <https://link.springer.com/article/10.1208/s12249-022-02491-7>

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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 \(liebertpub.com\)](https://doi.org/10.1089/jamp.2022.0017)

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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 Wiggenhorn, 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/>

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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 Wiggenhorn, 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, Poster and Excel spreadsheet by IPAC-RS Devices WG, 2020

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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>

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Charles Ireland, Oscar Liu, Svetlana Lyapustina, John O'Neill, Nate Patterson, Michelle Quinlan, Dennis

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- 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/7993/20170404224939/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>

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/>

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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