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Thesis Abstract (1995)

FUNCTIONALITY TESTING USED TO RATIONALLY ASSESS PERFORMANCE OF A MODEL RESPIRATORY SOLUTION OR SUSPENSION IN A NEBULIZER

There are currently no USP performance standards for nebulizers and their associated respiratory solutions. This research sought to establish reliable methodologies for comparing total aerosolized output (TO), output rate (OR) and fine droplet fraction (FDF) between an air-jet and an ultrasonic nebulizer. The nebulized output of an aqueous 0.08 % w/v fluorescein solution was collected in a total output collection device and four inertial samplers over 0.5, 2 and 5 minutes. Increases in airflow rate to the air-jet nebulizer resulted in significant increases in output rate and variability. However, no practical increases in fine droplet fraction for the air-jet nebulizer were observed. The determination of fine droplet fraction from an ultrasonic nebulizer was found to be prone to sampler overloading. Results among the impactors showed similar trends, but the data was not interchangeable.

Using the validated methods established for characterizing a respiratory solution, a model suspension containing 0.1 % w/v fluorescein (to estimate droplet deposition) and known quantities of 1, 3 and 6 μm latex spheres (representing insoluble drug particles) was aerosolized from an air-jet and an ultrasonic nebulizer to determine if differences in the aerosolization mechanism affected droplet and sphere deposition. Nebulized output was collected in a modified Andersen impactor. Samples were analyzed spectrophotometrically and by a Coulter Counter to estimate droplet and sphere deposition, respectively. Theoretical mathematical predictions were compared to experimental findings. Significant differences between nebulizers were observed. In the ultrasonic nebulizer, 99% of the spheres were not aerosolized, which the model did not predict. However, the results more closely followed the model for the air-jet nebulizer, since a substantial fraction of the spheres appeared in the aerosolized output. Any attempt to regulate nebulizer performance standards should consider that dissolved drug or droplet deposition patterns do not necessarily reflect those of undissolved drug particles.

This research highlighted several justifications for reliably evaluating nebulizer output characteristics. The presented methods provide a rational basis to evaluate performance of nebulizers and their associated respiratory solutions or suspensions.

Education Summary

- July 1991 - 1995, Graduated with Ph.D. in Pharmaceutical Sciences, University of Maryland.
- July 1986 - May 1991, B.S., Pharmacy, Philadelphia College of Pharmacy and Science.
- Licensed Pharmacist.

Employment Summary

- 1998 - Present, [Schering Plough Research Corporation](#), Respiratory Formulations Group, Kenilworth, NJ.
- 1996 -1998, Organon Inc., Pharmaceutical Development

Publications

- **Susan L. Tiano** and Richard N. Dalby. Comparison of a respiratory suspension aerosolized by an air jet and ultrasonic nebulizer. *Pharmaceutical Development and Technology*, 1 (3), 261-268 (1996).
- Richard N. Dalby and **Susan L. Tiano**. Pitfalls and opportunities in the inertial sizing and output testing of nebulizers. *Pharmaceutical Technology*, 17 (9), 144-156 (1993).

Abstracts

- **Susan L. Tiano** and Richard N. Dalby. Deposition modeling of a nebulized respiratory suspension in a cascade impactor. American Association of Pharmaceutical Scientists National Meeting, *Pharmaceutical Research*, 12 (9), S181 (1995).
- **Susan L. Tiano** and Richard N. Dalby. Aerosolization of a model respiratory suspension from an air-blast and ultrasonic nebulizer. American Association of Pharmaceutical Scientists Eastern Regional Meeting, New Brunswick, NJ (1995).
- **Susan L. Tiano** and Richard N. Dalby. Comparison of two sampling methods for assessing nebulizer output. American Association of Pharmaceutical Scientists National Meeting, *Pharmaceutical Research*, 11 (10), S139, October 1994.
- **Susan L. Tiano** and Richard N. Dalby. Rational comparison of nebulizer performance. 141st A.Ph.A. Annual Meeting in Seattle, WA, March 1994.
- **Susan L. Tiano** and Richard N. Dalby. Nebulizers and respiratory solutions: testing in three inertial impactors. American Association of Pharmaceutical Scientists National Meeting, *Pharmaceutical Research*, 10 (10), S142, (1993).

Book Chapters

- Richard N. Dalby, Anthony J. Hickey and **Susan L. Tiano**. Medical Devices For The Delivery Of Therapeutic Aerosols To The Lungs. In *Inhalation Aerosol Handbook* (ISBN 0-8247-9702-7), Anthony J. Hickey, Editor, Marcel Dekker, New York, NY (1996).
- Richard N. Dalby and **Susan L. Tiano**. Rational Testing Methods for Nebulizers and Respiratory Solutions. In *Respiratory Drug Delivery IV* (ISBN 0-935184-61-9), Peter R. Byron, Richard N. Dalby and Stephen J. Farr, Editors, Interpharm Press, Buffalo Grove, IL (1994).

Honors and Awards

- Rho-Chi Honor Society Member
- United States Pharmacopeia Division of Standards Fellow, 1994 -1996

Professional Affiliations

- American Association of Pharmaceutical Scientists (AAPS)
- ITFG/IPAC-RS CMC Tests and Methods Technical Team
- NJ Pharmaceutical Association for Science and Technology
- Philadelphia Pharmaceutical Forum

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