

# Shailaja Somaraju, Ph.D.

## Thesis Abstract (1999)

### OPTIMIZING PULMONARY DRUG DELIVERY USING SPACER DEVICES IN CONJUNCTION WITH PRESSURIZED METERED DOSE INHALERS

Spacers are commonly prescribed for use with pressurized metered dose inhalers (pMDIs), in the hope of increasing the total drug dose inhaled by a patient. The effect of spacer geometry, size, design and mode of use on the quality of aerosol output was critically examined to assess the validity of typical in-vitro test protocols used by spacer manufacturers to document spacer performance. (1) A pilot clinical study showed that patients induced delays between actuation and the onset of inhalation, even after extensive training on AeroChamber, ACE and OptiHaler spacers. Total dose output from these spacers was reduced substantially when such delays were simulated in-vitro. (2) AeroChamber and OptiChamber (differently sized spacers with mouthpiece valves) were tested with Ventolin, Beclomethasone and Intal to determine total dose output (TDO) and fine particle dose (FPD). OptiChamber yielded a higher TDO and FPD, which was less sensitive to actuation-inhalation delays than AeroChamber. Spacer size and valve design were found to affect performance. (3) Spacers 2 to 8 inches long, with internal diameters of 1 to 2.5 inches were tested with Ventolin and Intal. For Ventolin, the 2.5 inch spacer gave the highest TDO and FPD of all the lengths tested. Length had a minimal effect. Drug output from Intal was affected by both spacer length and width. (4) Sites of maximum drug loss within these spacers were determined by building equivalently sized spacers from interlocking rings. Ventolin deposition was concentrated 1 to 2 inches from the actuator spray nozzle, while almost uniform Intal distribution was observed along the spacer length. (2) and (3) suggest that all spacer-pMDI combinations may not function equivalently. Determining spacer performance under ideal in-vitro conditions, and ignoring patient use scenarios can potentially over estimate spacer efficiency. All valved spacers do not perform identically and larger spacers do not all always enhance dose delivery. There are significant differences in meaningful performance parameters of marketed spacers deemed equivalent by the United States Food and Drug Administration. Spacer performance with one inhaler may not be indicative of all inhaled medications.

### Education Summary

- July 1992 - Dec. 1999, Graduated with Ph.D. in Pharmaceutical Sciences, University of Maryland.
- July 1989 - July 1990, Virginia Polytechnic Institute and State University, Blacksburg, Virginia, Special Student, Chemistry.
- Sept. 1986 - July 1989, St. Frances College for Women, Osmania University, India, B.S., Chemistry.

### Employment Summary

- July 2000 - Present, [NextBreath LLC](#), Director of Pulmonary Drug Delivery.
- Feb. 2000 - June 2002, University Pharmaceuticals of Maryland, Baltimore, Maryland.
- Consultant for three drug delivery companies while in Graduate School.

### Publications

- Dalby, R. N., **Somaraju, S.**, Chavan, V. and Jarvis, D., Evaluation of aerosol drug output from the OptiChamber spacer: Comparison to the AeroChamber in a model system, *Journal of Asthma*, 35(2), 173 -177 (1998).

- **Somaraju, S.**, Dalby, R. N. and Pierpont M., Liquefied Propellant Density - Measurement and Utility, *Pharmaceutical Technology*, 21(10), (1997).
- **Somaraju, S.**, Suman, J., Dalby, R.N. and Stridick, W., Semi-automated spray pattern testing of nasal sprays, *Pharmaceutical Technology*, 21(5), (1997).

### Abstracts and Presentations

- Dalby, R. N., Demarest, D., Hollenbeck, R.G., Leslie, J., Redmon, M.P., Wald, S.A., Chavan, V., Jarvis, D., Jashnani, R.N., Leakittikul, D., **Somaraju, S.** and Suman, J., In-vitro metered dose inhaler performance: An accelerated stability study of metered dose inhalers. *Pharmaceutical Research*, 14(11), S136, September 1997. Presented at AAPS Annual Convention 1997, Boston, MA.
- Jashnani, R. N., Chavan V., Dalby, R.N., Jarvis, D., Leakittikul, D., Leslie, J., Mistry, B., Redmon, M.P., **Somaraju, S.** and Wong, L., Comparison of two particles sizing methods for an accelerated stability study of metered dose inhalers. *Pharmaceutical Research*, 14 (11), S146, September 1997. Presented at AAPS Annual Convention 1997, Boston, MA.
- **Somaraju, S.** and Dalby, R.N., The effect of spacer length and diameter on the emitted dose and fine particle dose from metered dose inhalers. *Pharmaceutical Research*, 14(11), S144, September 1997. Presented at AAPS Annual Convention, 1997, Boston, MA.
- Dalby, R.N., **Somaraju, S.**, Fuchs, R. and Stridick, W., A novel semi-automated method for determination of spray pattern from metered dose nasal pumps. *Pharmaceutical Research*, 13(9), S175, September 1996. Presented at AAPS Annual Convention 1997, Seattle, WA.
- Dalby, R. N., Ziegler, L., **Somaraju, S.**, Tsoukleris, M. and Teeter, J., The effect of time delays between inhaler actuation and onset of inhalation on the dose of albuterol exiting OptiHaler, AeroChamber, and Aerosol Cloud Enhancer (ACE) spacers. Presented at the Respiratory Drug Delivery V Symposium, Phoenix, AZ.
- **Somaraju, S.**, Dalby. R. N. and Pierpont, M, Liquefied propellant density - Measurement and utility. *Pharmaceutical Research*, 12(9), S182, September 1995. Presented at AAPS Annual Convention 1996, Miami Beach, FL.

### Honors and Awards

- Rho-Chi Honor Society Member
- Best Scientific Poster Award at University of Maryland Annual Research Day, May 1996 and May 1998

### Professional Affiliations

- American Association of Pharmaceutical Scientists (AAPS)
- Pharmaceutical Graduate Student Association
- Kappa Psi Professional Pharmaceutical Fraternity

Stay in touch at [ssomaraju@hotmail.com](mailto:ssomaraju@hotmail.com)