

FDA Office of Generic Drugs Office of Research & Standards (ORS)
Journal Articles Published by External Collaborators and ORS Staff in Fiscal Year 2013

1. Chang RK, Raw A, Lionberger R, Yu L. Generic development of topical dermatologic products, Part II: quality by design for topical semisolid products, *AAPS J.* 2013;15(3):674-683.
2. Cruz CN, Tyner KM, Velazquez L, Hyams KC, Jacobs A, Shaw AB, Jiang W, Lionberger R, Hinderling P, Kong Y, Brown PC, Ghosh T, Strasinger C, Suarez-Sharp S, Henry D, Van Uitert M, Sadrieh N, Morefield E. CDER risk assessment exercise to evaluate potential risks from the use of nanomaterials in drug products, *AAPS J.* 2013;15(3):623-628.
3. Diaz FJ, et al. Random-effects linear modeling and sample size tables for two special cross-over designs of average bioequivalence studies: the 4-period, 2-sequence, 2 formulation and 6-period, 3-sequence, 3-formulation designs, *Clinical Pharmacokinetics.* 2013;52: 1033-1043.
4. Holbrook LT, Longest PW. Validating CFD predictions of highly localized aerosol deposition in airway models: In vitro data and effects of surface properties, *J Aerosol Sci.* 2013; 59: 6-21.
5. Lee SL, Raw A, Yu L, Lionberger R, Ya N, Verthelyi D, Rosenberg A, Kozlowski S, Webber K, Woodcock J. Scientific considerations in the review and approval of generic enoxaparin in the United States, *Nat Biotechnol.* 2013;31(3):220-226.
6. Lionberger R, Jiang W, Huang SM, Geba G. Confidence in generic drug substitution, *Clin Pharmacol Ther.* 2013;94(4):438-440.
7. Shukla C, Li J, Lionberger R, Bashaw ED. *Regulatory Aspects of Microdialysis: A United States Food and Drug Administration Perspective*, Springer. 2013; 67-80.
8. Walenga RL, Tian G, Longest PW. Development of characteristic upper tracheobronchial airway models for testing pharmaceutical aerosol delivery, *J Biomech Eng.* 2013; 135(9): 091010.
9. Weber B, Hochhaus G, Adams W, Lionberger R, Li B, Tsong Y, Lee SL. A Stability Analysis of a Modified Version of the Chi-Square Ratio Statistic: Implications for Equivalence Testing of Aerodynamic Particle Size Distribution, *AAPS J.* 2013;15(1):1-9.
10. Weber B, Lee SL, Lionberger R, Li BV, Tsong Y, Hochhaus G. A sensitivity analysis of the modified chi-square ratio statistic for equivalence testing of aerodynamic particle size distribution, *AAPS J.* 2013;15(2):465-476.
11. Zhang X, Zheng N, Lionberger RA, Yu LX. Innovative approaches for demonstration of bioequivalence: the US FDA perspective, *Ther Deliv.* 2013;4(6):725-740.