

**FDA Office of Generic Drugs Office of Research & Standards (ORS)
Posters Presented by External Collaborators and ORS Staff in Fiscal Year 2017**

1. Andhariya JV, Shen J, Zou Y, Choi S, Qu W, Wang Y, Burgess DJ. Development of In Vitro-In Vivo Correlation of Parenteral Naltrexone Loaded Polymeric Microspheres, CRS 2017, Boston, MA, July 16-19, 2017.
2. Bao Q, Gu B, Price CF, Zou Y, Wang Y, Choi S, Burgess D. In Vitro Release Testing of Long-Acting Levonorgestrel Intrauterine System, CRS 2017, Boston, MA, July 16-19, 2017.
3. Bao Q, Newman B, Wang Y, Choi S, Burgess DJ. In Vitro - Ex Vivo Correlation of Drug Release from Semisolid Ophthalmic Ointments, AAPS 2017, San Diego, CA, November 12-15, 2017.
4. Birngruber T, Tiffner K, Kanfer I, Schimek D, Reisenegger P, Raml R, Augustin T, Sinner F. Validation of an In Vitro Release Test (IVRT) for Acyclovir Creams Including Apparatus and Laboratory Qualification, Controlled Release Society Annual Meeting, Boston, MA, July 16-19, 2017.
5. Bodenlenz M, Birngruber T, Tiffner K, Raml R, Tschapeller B, Augustin T, Schwagerle G, Korsatko S, Kanfer I, Raney SG, Sinner F. In Vivo Dermal Open Flow Microperfusion: Understanding and Controlling Sources of Variability to Evaluate Topical Bioequivalence, 2017 E2BRN Epidermal Barrier Network Meeting, Salzburg, Austria, September 27, 2017.
6. Choi S, Petrochenko P, Wu Y, Kozak D, Zheng J. Physicochemical Characterization of Tobradex and Tobradex ST under Physiological Conditions, ARVO 2017, Baltimore, MD, May, 2017.
7. Conti DS, Holt J, Sheth P, Sandell D, Hickey A, Saluja B. Effects Of Formulation Factors On The Aerosolization Performance Of Metered Dose Inhalers, FDA Science Forum, Silver Spring, MD, May 31-June 1, 2017.
8. Dahmane E, Gopalakrishnan M, Fang L, Gobburu J, Ivaturi V. Impact of Between-subject, Within-subject and Between-occasion Variability on Therapeutic Success for Narrow Therapeutic Index Drugs: a Bioequivalence Perspective, ASCPT, Washington, DC, March 15-18, 2017.
9. Helmuth M, Turenne M, Park J, Liu Q, Oguntimein O, Dutcher S, Balkrishnan R, Zee J, Smith A, Leichtman A. Immunosuppressant Costs for Medicare Part D and Kidney Transplant Recipients Since the Introduction of Generic Formulations in an Incident Kidney Transplant Population, 2017 American Transplant Congress, Chicago, IL, April 29-May 3, 2017.
10. Jiang W, Ansar S, Fong A, Mudalige T. Simultaneous Separation and Quantification of Free Drug and Liposome-Associated Drug by Capillary Electrophoresis with UV-Vis detection, 2017 ACS meeting, Washington, DC, August 20-24, 2017.
11. Jung N, Namjoshi SN, Mohammed YH, Grice JE, Raney SG, Roberts MS, Windbergs M. Visualizing the Penetration of Semisolid Topical Formulations in Excised Human Skin by Non-invasive Confocal Raman Microscopy, Controlled Release Society Annual Meeting, Boston, MA, July 16-19, 2017.
12. Jung N, Namjoshi SN, Mohammed YH, Grice JE, Roberts MS, Windbergs M. Analysis of skin penetration of semisolid topical formulations into excised human skin by confocal Raman microscopy, Function of Mammalian Skin Gordon Research Conference, Waterville Valley, NH, August 13-18, 2017.

13. Kedia K, Zheng X, Zhou M, Ansong C, Baker ES, Cort JR. Mass Spectrometry Profiling of Pentosan Polysulfate Sodium (PPS), 65th ASMA Conference on Mass Spectrometry and Allied Topics, Indianapolis, IN, April 08, 2017.
14. Kimbell JS, Schroeter JD, Tian G, Walenga R, Babiskin A, Delvadia RR. Estimating size-specific numbers of active pharmaceutical ingredient particles in the regional deposition of a nasal spray, International Society for Aerosols in Medicine Conference, Santa Fe, NM, June 3-7, 2017.
15. Koo B, Qin B, Jiu Y, Wu, Y, Choi S, Kozak D, Zheng J. Characterizing How Size Distribution and Concentration Affect Echogenicity of Ultrasound Contrast Agent Products: Scientific Considerations for an In Vitro Bioequivalence Approach, AAPS 2017, San Diego, CA, November 12, 2017.
16. Kozak D, Petrochenko P, Wu Y, Absar M, Zheng J, Choi S. Scientific Considerations for In Vitro Bioequivalence Studies of Generic Cyclosporine Ophthalmic Emulsions, ARVO 2017, Baltimore, MD, May, 2017.
17. Liu Q, Smith A, Park J, Oguntimein O, Dutcher S, Bello G, Helmuth M, Turenne M, Balkrishnan R, Fava M, Sharma P, Beil C, Leichtman A, Zee J. The Adoption of Generic Immunosuppressant Medications Among Kidney and Liver Transplant Recipients Using the Colorado All Payer Claims Database, 2017 American Transplant Congress, Chicago, IL, April 29-May 3, 2017.
18. Manna S, Petrochenko P, Wu Y, Dong Y, Koo B, Chen L, Ren K, Oktem B, Choi S, Xu X, Kozak D, Wang Y, Zheng J. Physicochemical Characterization and In Vitro Drug Release Testing of a Multivesicular Liposomal Bupivacaine Formulation, American Chemical Society National Meeting, Washington, DC, August 20-24, 2017.
19. Manna S, Petrochenko P, Wu, Y, Koo B, Ren K, Chen L, Dong Y, Xu X, Choi S, Kozak D, Wang Y, Zheng J. Assessing In Vitro Drug Release from Multivesicular Liposome: Comparison of Reverse Dialysis and Rotary Shaking Methods, AAPS 2017, San Diego, CA, November 12, 2017.
20. Mohammed YH, Namjoshi SN, Jung N, Talaprolu K, Grice JE, Windbergs M, Benson HA, Raney SG, Roberts MS. A Novel Method to Selectively Differentiate Between the Loss of Water and Other Volatiles from Topical Semisolid Products, Controlled Release Society Annual Meeting, Boston, MA, July 16-19, 2017.
21. Mohammed YH, Namjoshi SN, Jung N, Talaprolu K, Grice JE, Windbergs M, Benson HA, Raney SG, Roberts MS. The Impact of Topical Semisolid Product Microstructure and Metamorphosis on Bioavailability and Bioequivalence, Controlled Release Society Annual Meeting, Boston, MA, July 16-19, 2017.
22. Mullin J, van Osdol W, Lukacova V, Woltosz WS, Bolger MB. Simulation of in vitro Dissolution and Degradation of Orntide-loaded PLGA Microspheres, CRS 2017, Boston, MA, July 16-19, 2017.
23. Myung JH, Elliott LC, Stavis S, Zheng J, Kozak D. New Tools to Improve Complex Drug Regulation: Establishing simple and cost-efficient techniques for nanoparticle counting, TechConnect 2017, Washington, DC, May 14, 2017.
24. Myung JH, Zheng J, Kozak D. Assessing High-Resolution Single Nanoparticle Counting Techniques to Improve the Regulatory Science of Complex Drug Products, AAPS 2017, San Diego, CA, November 12, 2017.
25. Patere S, Newmay B, Choi S, Wang Y, Jay M, Lu X. Impact of Process and Quality Control on the Physicochemical Properties of Tobramycin, CRS 2017, Boston, MA, July 16-19, 2017.

26. Paul P, Yoon S, Kim N, Trunfio N, Handelman G, Kim J. Population Pharmacokinetic/Pharmacodynamic (PKPD) Modeling for Long Acting Injectable(LAI) Products and Statistical Analysis for Bioequivalence(BE) Assessment,6th Annual Biomanufacturing Summit, Boston, MA, May 22-23, 2017.
27. Paula P, Handelman G, Kim J, Yoon S. Qualitative Analysis of Generic and Reference LAI Drug PK Profiles Using Multivariate Score Space,6th Annual Biomanufacturing Summit, Boston, MA, May 22-23, 2017.
28. Qian J, Hansen R, Surry D, Howard J, Kiptanui Z, and Harris I. Association Between Increasing Generic Drug Use and Medicare Prescription Plan Star Ratings,33rd ICPE: International Conference on Pharmacoepidemiology & Therapeutic Risk Management, Montreal, Canada, August 26-30, 2017.
29. Qu H, Wang J, Wu Y, Zheng J, Yellela K, Absar M, Choi S, Ashraf M, Cruz C, Xu X. Determination of Globule Size Distribution of Cyclosporine Ophthalmic Emulsions using Asymmetric Flow Field Flow Fractionation, CRS 2017, Boston, MA, July 16-19, 2017.
30. Schroeter J, Kimbell J, Walenga R, Babiskin A, Delvadia R. A CFD-PBPK model to simulate nasal absorption and systemic bioavailability of intranasal fluticasone propionate, International Society for Aerosols in Medicine Conference, Santa Fe, NM, June 3-7, 2017.
31. Shin SH, Yu M, Thomas S, Hammell DC, Hassan HE, Stinchcomb AL, Ghosh P, Sam SG. Evaluation of Level A In Vitro In Vivo Correlations (IVIVC) for Nicotine and Fentanyl Transdermal Delivery Systems, Barrier Function of the Mammalian Skin (GRS), Waterville Valley, NH, August 12, 2017.
32. Shin SH, Yu M, Thomas S, Hammell DC, Hassan HE, Stinchcomb AL. Level A In Vitro/InVivo Correlations(IVIVC) for Nicotine and Fentanyl Transdermal Delivery Systems with Transient Heat Exposure, Evaluate dusing Multiple Approaches, GSK meeting, Philadelphia, PA, September 06, 2017.
33. Shukla S, Thomas S, Hammell D, Bunge A, Hassan A, Stinchcomb AL. In Vivo Evaluation of Lidocaine Bioavailability from Two Topical Patch Products by Pharmacokinetic and Skin (Tape) Stripping Analyses, Gordon Research Conference, Waterville Valley, NH, August 13-18, 2017.
34. Strand A, Cribari K. A User-Friendly Platform To Simulate And Assess Generic Drug Pharmacokinetics, CSU CURC, Fort Collins, CO, April 26, 2017.
35. Suh MS, Kastellorizios M, Zou Y, Wang Y, Choi S, and Burgess DJ. Formation and Microstructural Changes in In Situ Forming Implants: In Vitro and In Vivo, CRS 2017, Boston, MA, July 16-19, 2017.
36. Thomas S, Hammell DC, Hassan HE, Stinchcomb AL, Ghosh P, Sam SG. In Vitro Evaluation of a Buprenorphine Transdermal Delivery System with Transient Heat Exposure and the Correlation of In Vitro Results with Existing In Vivo Results, Barrier Function of the Mammalian Skin (GRS), Waterville Valley, NH, August 12, 2017.
37. Wittum R, Wang J, Mohammed Y, Namjoshi S, Grice JE, Ghosh P, Raney SG, Roberts MS, Nägel A, Wittum G. In-silico investigation of the skin penetration profile of creams containing acyclovir and penetration enhancers, Gordon Research Conference on the Barrier Function of Mammalian Skin, Waterville Valley, NH, August 13-18, 2017.

38. Wu Y, Petrochenko P, Koo B, Manna S, Myung JH, Choi S, Kozak D, Zheng J. Distinguish Coexistence of Nanoemulsion and Liposome in Propofol by Cryogenic Transmission Electron Microscopy, Microscopy and Microanalysis 2017 Annual Meeting, St. Louis, MO, August 6-10, 2017.
39. Wu Y, Petrochenko P, Liu J, Manna S, Koo B, Myung JH, Chen L, Choi S, Kozak D, Zheng J. Evaluating Complex Emulsion and Liposome Morphology in Propofol Drug Products with High Resolution Cryogenic Electron Microscopy, AAPS 2017, San Diego, CA, November 12, 2017.
40. Yang J, Chitranshi P, Zeng K, Keire D, Trehy M, Jiang W, Zhang D, Jiang X, Verthelyi D, Vidavsky IG. Rapid Screening of Peptide Impurities in Calcitonin-Salmon Nasal Spray Using Data-Dependent LC-MS-MS and Data-Independent LC-MS, 65th American Society for Mass Spectrometry (ASMS) Conference on Mass Spectrometry and Allied Topics, Indianapolis, IN, June 4-8, 2017.
41. Zhang X, Ghosh P, Rane SG, Hammell DC, Hassan HE, Stinchcomb A. Characterization of the Cutaneous Pharmacokinetics of Three Metronidazole Topical Drug Products, Gordon Research Conference, Waterville Valley, NH, August 13-18, 2017.
42. Zou L, Zhang X, Ni Z, Tsakalozou E, Giacomini KM. Excipients Inhibit Human Organic Anion Transporting Peptide 2B1 (OATP2B1)-Mediated Intestinal Uptake Of Levothyroxine, ASCPT, Washington, DC, March 15-18, 2017.