

**FDA Office of Generic Drugs Office of Research & Standards (ORS)
Posters Presented by External Collaborators and ORS Staff in Fiscal Year 2015**

1. Abdallah I, Hammell D, Hassan H, Stinchcomb AL. Preformulation Analysis And Product Stability Of Norelgestromin/Ethinyl Estradiol Intravenous Infusion, AAPS 2015, Orlando, FL, October 28, 2015.
2. Alattof A, Amidon GL. Fasted State Motility-Dependent Transit and Dissolution of Ibuprofen, AAPS 2015, Orlando, FL, October 25-29, 2015.
3. Andhariya JV, Shen J, Qu W, Wang Y, Choi S, Burgess DJ. Stability Tests of Risperidone-Loaded PLGA Microspheres, AAPS 2015, Orlando, FL, October 25, 2015.
4. Angamuthu M, Murthy SN. Evaluation Of Water Activity (Aw) As A Critical Quality Attribute Of Topical Dosage Forms, AAPS 2015, Orlando, FL, October 25-29, 2015.
5. Babiskin A, Kim H, Fang L, Lapteva L, Jiang W, Lionberger R. Use of partial AUC to demonstrate bioequivalence of generic methylphenidate extended-release products using physiologically based absorption modeling and simulation, ASCPT, New Orleans, LA, March 15, 2015.
6. Bai J, Babiskin A, Zhang X, Lionberger R, Abernethy D, Burckart G, Mulberg A, Sinha V, Uno T. Physiologically-based absorption modeling and simulation for assessing bioequivalence in elderly, children and Gastrointestinal diseases, ASCPT, New Orleans, LA, March 15, 2015.
7. Bai Y, Bourne D, Wang Y, Choi S, Kompella UB. Sustained Release Dexamethasone Implants For In-Vitro Vivo Correlations, The Association for Research in Vision and Ophthalmology (ARVO), Denver CO, May 3-7, 2015.
8. Bhagwat S, Kranich H, Mueller M, Rohrschneider M, Goes A, Broenner S, Jetzer M, Krome A, Hochhaus G. An Optimized Dissolution System For Orally Inhaled Drug Products: Development And Validation, AAPS 2015, Orlando, FL, October 25-29, 2015.
9. Biliouris K, Trame MN, Schmidt S, Fang L, Lesko LJ. Integrated Data Mining And Systems Pharmacology To Explore The Comparative Safety Of Brand-Name And Generic Drugs, Annual meeting of the population approach group in Europe, Abstract 3430, Hersonissos, Crete, June, 2015.
10. Biliouris K, Trame MN, Schmidt S, Fang L, Lesko LJ. Integrated Data Mining And Systems Pharmacology To Explore The Comparative Safety Of Brand-Name And Generic Drugs, Annual Meeting of the American College of Clinical Pharmacology (ACCP), San Francisco, CA, September, 2015.
11. Bodenlenz M, Tiffner K, Raml R, Tschapeller B, Augustin T, Dragatin C, Birngruber T, Kainz S, Schwagerle G, Korsatko S, Raney S, Sinner F. Open Flow Microperfusion As A Dermal Pharmacokinetic Approach To Evaluate Topical Bioequivalence, AAPS 2015, Orlando, FL, October 28, 2015.
12. Bolger MB, Spires J, Mullin JM, Macwan J, Ghosh J, Lukacova V. Fluorometholone Ocular Suspension PBPK Simulations Using The OCAT™, GTCBio conference, San Diego, CA, January 29-30, 2015.
13. Bourne D, Vooturi S, Panda J, Choi S, Kim H, Yandrapu S, Kompella U. Effect of Particle Size and Viscosity of Ophthalmic Suspensions on Ocular Bioavailability, The Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting, Denver, CO, May 1, 2015.

14. Boyce H, Smith D, Byrn S, Saluja B, Qu W, Gurvich VJ, Hoag SW. In Vitro Method to Assess Performance of Abuse Deterrent Formulations (ADFs) For Nasal Route of Abuse, AAPS 2015, Orlando, FL, October 25-29, 2015.
15. Boyce H, Smith D, Byrn S, Saluja B, Qu W, Gurvich VJ, Hoag SW. Investigation Of Abuse Deterrent Properties Of Sintered Polyethylene Oxide And Hypromellose Placebo Tablets, NIPTE 2015 Conference, Rockville, MD, April 30, 2015.
16. Chow ECY, Sun D, Fang L, Wen H, Zhao L, Lapteva L, Jiang W, Lionberger R. Pbpk Modeling For Predicting The In Vivo Performance And Product Quality Of Tacrolimus And Itraconazole Amorphous Solid Dispersions In Humans, AAPS 2015, Orlando, FL, October 25-29, 2015.
17. Connarn J, Li Y, Zhou S, Zhang X, Babiskin A, Fan J, Amini T, Sun D. Formulation Design Considerations And Pharmacokinetics Assessments Of Bupropion Drug Products, AAPS 2015, Orlando, FL, October 25-29, 2015.
18. Cristea S, Patel N, Rose R, Salem F, Abduljalil K, Johnson T, Jamei M, Raney SG, Zhang X, Lin H-P, Newman B, Chow E, Ghosh P, Fan J, Fang L, Polak S. Prediction of Cutaneous PK Profiles after Topical Application - A Comparison Between the Novel MPML-Mechderma Model and the Current Mechderma Model in Simcyp Simulator Case Study: Erythromycin, DMDG Symposium: 100 Years of Drug Delivery, GSK, Ware, October 06, 2015.
19. Dahmane E, Gobburu J, Gopalakrishnan M, Ivaturi V. Do Anti-Epileptic Drugs Follow the FDA Definitions for Narrow Therapeutic Index Drugs? American Epilepsy Society (AES), Philadelphia, PA, December 07, 2015.
20. Doty AC, Hirota K, Olsen K, Ackermann R, Feng R, Qu W, Wang Y, Choi S, Schwendeman A, Schwendeman SP. A Cage Implant System for Assessing In Vivo Controlled Release Performance Long-Acting Release PLGA Depots, NIPTE 2015 Conference, Rockville, MD, April 30, 2015.
21. Doty AC, Hirota K, Olsen K, Ackermann R, Feng R, Qu W, Wang Y, Choi S, Schwendeman A, Schwendeman SP. A Cage Implant System for assessing in vivo controlled release performance of long-acting release PLGA microspheres, AAPS 2015, Orlando, FL, October 25-29, 2015.
22. Externbrink A, Jiang W, Wen H Gao Z. Dissolution testing of extended release matrix tablets in compendial and biorelevant media, American Association of Pharmaceutical Scientists Annual Meeting, Orlando, FL, October 28, 2015.
23. Fan J, Zhang X, Lionberger R. Impact of Altered in vitro Dissolution Profile on Warfarin in vivo Pharmacokinetics Performance- Population Physiologically Based Pharmacokinetic (PBPK) Simulation, ASCPT, New Orleans, LA, March 15, 2015.
24. Fioritto AF, Baker JR, Collins K, Wen B, Wang Y, Luo R, Bleske B, Johnson M, Koenigsknecht M, Hasler W, Sun D. Contrasting Regional Availability of Different Mesalamine Products in the Gastrointestinal Tract in Healthy Humans using a Novel Multi-Port Luminal Aspiration System and Correlation with Systemic Absorption, 2015 Digestive Disease Week, Washington, DC, May 16-19, 2015.
25. Fraser S, Corvacho E, Viitala T, Peltonen L, Urtti A, Strachan C. Toward Amorphous Indomethacin Ocular Suspensions And The Importance Of Preparation Methods On The Physical Stability, AAPS 2015, Orlando, FL, October 25-29, 2015.
26. Guptill JT, Wu H, Greenberg R, Gostelow M, Gonzalez D, Hornik C, Zheng N, Jiang W, Cohen-Wolkowicz M, Hill K. Clinical Practice Data To Aid Narrow Therapeutic Index Drug Classification:

- Lamotrigine, 2015 American Epilepsy Society Annual Meeting, Philadelphia, PA, December 4-8, 2015.
27. Hirota K, Doty A, Ackerman R, Olsen K, Feng M, Wang Y, Choi S, Qu W, Schwendeman A, Schwendeman S. Characterizing Release Mechanisms of Leuprolide-Loaded PLGA Microparticles for IVIVC Development, AAPS 2015, Orlando, FL, October 25-29, 2015.
 28. Holt J, Sandell D, Hickey A, Vallorz E, Straughn K. The Influence Of Formulation Variables On The Performance Of A Beclomethasone Dipropionate Metered Dose Inhaler, Respiratory Drug Delivery (RDD) Europe Conference, Palais des Congres d'Antibes, Nice, France, May 5-8, 2015.
 29. Hoover A, Sun D, Wen H, Jiang W, Cui M, Keire D, Guo C. Developing Analytical Methods for In Vitro Comparative Nasogastric (NG) Tube Studies of Esomeprazole Magnesium Delayed Release Capsules, American Association of Pharmaceutical Scientists Annual Meeting, Orlando, FL, October 28, 2015.
 30. Kitabi EN, Ivaturi V, Gobburu J, Gopalakrishnan M. Implication Of The Current Level Of Evidence For Therapeutic In-Equivalence Between Brand And Generic Anticonvulsant, American Epilepsy Society (AES), Philadelphia, PA, December 07, 2015.
 31. Krieg BJ, Amidon GL, Amidon GE. Using In Vivo Flow Rates in USP Apparatus 4 to Develop a More In Vivo Relevant Hydrodynamic Dissolution Test, AAPS 2015, Orlando, FL, October 25-29, 2015.
 32. La Count TD, Li SK, Kasting GB. Computational Model For Estimating The Effect Of Heat On Dermal Clearance In Skin Transport, AAPS 2015, Orlando, FL, October 28, 2015.
 33. Liu X, Yu T, Balch AH, Sherbotie J, Korgenski EK, Spigarelli MG, Sherwin CMT. Population Pharmacokinetics of Tacrolimus in Pediatric Patients with Kidney Transplant, AAPS 2015, Orlando, FL, October 25-29, 2015.
 34. Merdy ML, Hendriks BS, Cao Y. Cellular Pharmacokinetic/Pharmacodynamic of Doxorubicin in a Wide Array of Cell Lines, AAPS 2015, Orlando, FL, October 25-29, 2015.
 35. Mohammed YH, Namjoshi S, Grice JE, Jung N, Windbergs M, Raney SG, Roberts MS. Simulated "In Use" Conditions To Assess Semisolid Topical Products, AAPS 2015, Orlando, FL, October 25-29, 2015.
 36. Moon J, Nkurunziza J, Jambi A, Seoane-Vazquez E, Qian J, Hansen R. Generic Competition and Authorized Generics in the US, ISPOR 20th Annual International Meeting Philadelphia, PA, May 16-20, 2015.
 37. Mudie D, Brasseur J, Mansfield J, Wang Y, Jayaraman B, Amidon GE. Influence of Fluid Shear Rate on the Dissolution Rate of Poorly Soluble Drug Particles; Implications for In Vivo Predictive In Vitro Dissolution Methodologies and Mechanistic Computational Modeling, AAPS 2015, Orlando, FL, October 25-29, 2015.
 38. Palakurthi S, Cai D, Qiu J, Absar M, Choi S. Preparation And Evaluation Of Difluprednate Topical Ocular Emulsions, AAPS 2015, Orlando, FL, October 25-29, 2015.
 39. Patel N, Cristea S, Rose R, Salem F, Abduljalil K, Johnson T, Jamei M, Raney SG, Zhang X, Lin H-P, Newman B, Chow E, Ghosh P, Fan J, Fang L, Polak S. Mechanistic Modelling Of Dermal Drug Absorption Using The Simcyp Multi-Phase Multi-Layer Mechderma Model: Case Study Of A Transdermal Patch Formulation Of Weak Base Drug Timolol, Barrier Function of Mammalian Skin Gordon Research Conference, Waterville Valley, NH, August 18, 2015.

40. Patere S, Sutthanut K, Newman B, Choi S, Jay M, Lu X. Influence of Excipients on Physicochemical Characteristics of Ocular Semisolid Formulations and Their In Vitro Drug Release, AAPS 2015, Orlando, FL, October 25-29, 2015.
41. Peipert J, Waterman AD, Tsai E, Morisky D, Zonana M, Bunnapradist S. Assessing The Association Of Four Measurements Of Adherence To Tacrolimus For Organ Transplant Recipients, 2015 Pittsburgh Conference on The Science of Medication Adherence, Pittsburgh, PA, June 02, 2015.
42. Polak S, Patel N, Cristea S, Rose R, Salem F, Abduljalil K, Johnson T, Raney SG, Zhang X, Lin H-P, Newman B, Chow E, Ghosh P, Fan J, Fang L, Jamei M. Towards Mechanistic Simulation And Prediction Of Bioequivalence Studies Of Topical Formulations Case Study With Two Diclofenac Formulations, Barrier Function of Mammalian Skin Gordon Research Conference, Waterville Valley, NH, August 18, 2015.
43. Samant TS, Schmidt S, Fang L, Trame MN, Lesko LJ. Use Of Physiologically Based Pharmacokinetic Modeling As A Computational And Mathematical Tool To Evaluate Switchability Of Generic And Brand Name Products, Annual Meeting of the American College of Clinical Pharmacology (ACCP), San Francisco, CA, September, 2015.
44. Segal JB, Daubresse M, Lee CY, Moechtar M, Dutcher S, Jiang W, Romanelli R. Therapeutic Class Differences In Generic Usage, 31st International Conference on Pharmacoepidemiology Abstract # 245 Boston, MA, August 22-26, 2015.
45. Shen J, Qu W, Choi S, Wang Y, Burgess DJ. Effect of manufacturing process parameters on physicochemical properties of peptide microspheres, AAPS 2015, Orlando, FL, October 25, 2015.
46. Shen J, Tipnis N, Choi S, Qu W, Wang Y, Burgess DJ. In Vitro-In Vivo Correlation Of Risperidone Microspheres, Controlled Release Society Annual Meeting Edinburgh, Scotland, July 26-29, 2015.
47. Sheth P, Vallorz III EL, Susick R, Menzeleev R. A Dual-Internal Standard LC-UV-MSD Method to Improve Accuracy And Efficiency Of Characterizing Mometasone Furoate MDIs, The American Association of Pharmaceutical Scientists (AAPS) Annual Meeting, Orlando, FL, October 25-29, 2015.
48. Sheth P, Vallorz III EL, Susick R, Menzeleev R. A Dual-Internal Standard LC-UV-MSD Method to Improve Accuracy and Efficiency of Characterizing Mometasone Furoate MDIs, AAPS 2015, Orlando, FL, October 25-29, 2015.
49. Shin S, Raney S, Rantou E, Newman B, Ghosh P, Hammell D, Hassan H, Stinchcomb A. Assessing Bioavailability And Estimating Bioequivalence Of Acyclovir Creams By In Vitro Permeation Tests With Excised Human Skin, AAPS 2015, Orlando, FL, October 29, 2015.
50. Shin S, Thomas Sh, Aballah I, Raney SG, Ghosh P, Hammell DC, Hassan HE, Stinchcomb AL. Evaluation Of Bioavailability And In Vitro/In Vivo Correlation Of Nicotine Transdermal Drug Delivery Systems Under The Influence Of Heat, Barrier Function of Mammalian Skin Gordon Research Conference, Waterville Valley, NH, August 18, 2015.
51. Shin SH, Raney SG, Ghosh P, Newman B, Hassan HE, Stinchcomb AL. In Vitro/In Vivo Correlation (IVIVC) of Bioavailability from Nicotine Transdermal Drug Delivery Systems under the Influence of Heat, AAPS 2015, Orlando, FL, October 28, 2015.
52. Shukla S, Hassan H, Raney S, Newman B, Ghosh P, Bunge A, Stinchcomb A. Evaluation of Flector® and Lidoderm® Topical Formulations by Dermal Pharmacokinetic Methods: In Vitro Tape Stripping and In Vitro Permeation Testing (IVPT), AAPS 2015, Orlando, FL, October 29, 2015.

53. Suh M, Kastellorizios M, Qu W, Wang Y, Choi S, Burgess DJ. Effect of Polymer Source and Manufacturing Differences on In Vitro Release of In Situ Forming Implants, AAPS 2015, Orlando, FL, October 25, 2015.
54. Swarnakar N, Shen J, Qu W, Choi S, Wang Y, Burgess DJ. Development of an accelerated in vitro release testing method for Vivitrol, AAPS 2015, Orlando, FL, October 25, 2015.
55. Swarnakar NK, Shen J, Qu W, Choi S, Wang Y, Burgess DJ. Development Of An Accelerated In Vitro Release Testing Method For Naltrexone Microspheres, AAPS 2015, Orlando, FL, October 25-29, 2015.
56. Tang J, Acevedo FM, Yuan W, Dai Z, Li D, Zheng N, Jiang W, Noble C, Hayes M, Szoka FC, Schwendeman A. Development Of The Liposomal Amphotericin B Release, AAPS 2015, Orlando, FL, October 25-29, 2015.
57. Tang J, Yuan W, Dai Z, Li D, Zheng N, Jiang W, Noble C, Hayes M, Szoka FC, Schwendeman A. Development Of The Liposomal Amphotericin B Release Assay, NIPTE 2015 Conference, Rockville, MD, April 30, 2015.
58. Thomas S, Ghosh P, Newman, B, Raney SG, Hammell DC, Hassan HE, Stinchcomb AL. A Pharmacokinetic Study of the Effect of a Standardized Exposure to Heat on Nicotine Transdermal Delivery in Adult Smokers, The American Association of Pharmaceutical Scientists Annual Meeting, Orlando, FL, October 25-29, 2015.
59. Tiffner K, Bodenlenz M, Schwingenschuh S, Hajnsek M, Reisenegger P, Kainz S, Augustin T, Baumann P, Tschapeller B, Schwagerle G, Raml R, Kanfer I, Sinner F. Can we predict skin penetration by using TEWL or skin impedance? European Epidermal Barrier Research Network Meeting, Rotterdam, The Netherlands, September 9, 2015.
60. Tiffner K, Bodenlenz M, Schwingenschuh S, Hajnsek M, Reisenegger P, Kainz S, Augustin T, Baumann P, Tschapeller B, Schwagerle G, Raml R, Kanfer I, Sinner F. Characterization of TEWL and Skin Impedance in a Clinical Study Measuring Acyclovir Permeation by Dermal Open Flow Microperfusion , 13th Meeting of the European Epidermal Barrier Research Network, Rotterdam, The Netherlands, September 09, 2015.
61. Tiffner K, Kanfer I, Schimek D, Reisenegger P, Raml R, Raney S, Sinner F. Comparative In Vitro Release of Six Different Topical Acyclovir Products using a Vertical Diffusion Cell (VDC) Apparatus, AAPS 2015, Orlando, FL, October 26, 2015.
62. Trasi NS, Taylor LS. Dissolution Behavior And Solubility Of Marketed Amorphous Solid Dispersions Of Tacrolimus, AAPS 2015, Orlando, FL, October 25-29, 2015.
63. Trasi NS, Taylor LS. Solubility And Dissolution Of Binary Co-Amorphous Ritonavir-Lopinavirsolid Dispersions, AAPS 2015, Orlando, FL, October 25-29, 2015.
64. Trasi NS, Taylor LS. Stability Of Marketed Tacrolimus Amorphous Dispersions Against Crystallization, AAPS 2015, Orlando, FL, October 25-29, 2015.
65. Wei X, Bormann K, Byron PR. Predicting variations in aerodynamic particle size distribution of the lung dose from Budelin Novolizer, RDD Europe 2015, Nice, France, May, 2015.
66. Yu T, Liu X, Balch AH, Molina KM, Constance JE, Prevedel JA, Korgenski EK, Spigarelli MG, Sherwin CMT. Population Pharmacokinetics of Tacrolimus in Pediatric Heart Transplant Patients, AAPS 2015, Orlando, FL, October 25-29, 2015.

67. Yuan W, Kuai R, Dai Z, Tang J, Zheng N, Jiang W, Noble C, Hayes M, Szoka F, Schwendeman A. Comparison Of Drug Release Profiles Of Doxorubicin Liposomes Prepared By Different Processes, AAPS 2015, Orlando, FL, October 25-29, 2015.
68. Zheng N. Assessment of Partial AUC Requirement for Bioequivalence Evaluation of Methylphenidate Hydrochloride Extended-Release Oral Suspension, ACoP, Orland, FL, October 1, 2015.