FDA Office of Generic Drugs Office of Research & Standards (ORS) Posters Presented by External Collaborators and ORS Staff in Fiscal Year 2016

- 1. Abdelaziz S, Yu T, Constance J, Stockmann C, Sherwin CMT, Constance JE, Balch AH. Changes in Physician Prescribing Patterns in Response to Therapeutic Drug Monitoring of Tacrolimus in Pediatric Patients, 2016 ASCPT, San Diego, CA, March 8-12, 2016.
- 2. Absar M, Petrochenko P, Choi S. Scientific Considerations for Generic Cyclosporine Ophthalmic Emulsion In Vitro Bioequivalence Studies, AAPS 2016, Denver, CO, November 13-17, 2016.
- 3. Alloush J, Jones J, Polli J, Michel S, Kane M. Evaluation Of Biomarkers In Healthy Subjects Treated With Generic And Reference Sodium Ferric Gluconate, 2016 Research Day University of Maryland School of Pharmacy, Baltimore, MD, April 22, 2016.
- 4. Andhariya JV, Shen J, Choi S, Wang Y, Qu W, Zou Y, Burgess DJ. Effect Of Manufacturing Processes On In Vitro And In Vivo Performance Of Naltrexone Microspheres, AAPS 2016, Denver, CO, November 13-17, 2016.
- 5. Andhariya JV, Swarnakar NK, Shen J, Qu W, Choi S, Wang Y, Burgess DJ. Effect of Manufacturing Processes on Critical Quality Attributes of Naltrexone Microspheres, The Controlled Release Society Annual Meeting, Seattle, WA, July 17, 2016.
- 6. Azimi M, Hindle M, Longest PW, Walenga RL. Comparison of the in vitro deposition of Nasonex(R) nasal spray product in two realistic nasal airway models, Respiratory Drug Delivery 2016, Silver Spring, MD, April 17-21, 2016.
- 7. Azimi M, Hindle M, Longest PW. In vitro deposition of a nasal spray product using two realistic airway models, AAPS 2016, Denver, CO, November 13-17, 2016.
- 8. Babiskin A, Fang L, Zhao L. Pharmacokinetic modeling and simulation of naltrexone for extended-release intramuscular injectable suspension to derive alternative bioequivalence metrics, American Society for Clinical Pharmacology and Therapeutics Annual Meeting, San Diego, CA, March 10, 2016.
- 9. Bao Q, Shen J, Newman B, Wang Y, Choi S, Burgess D. Impact Of Excipient Sources On In Vitro Drug Release Characteristics Of Semisolid Ophthalmic Ointments, AAPS 2016, Denver, CO, November 12, 2016.
- Bao Q, Shen J, Newman B, Wang Y, Choi S, Burgess D. Manufacturing Differences On Physicochemical And In Vitro Release Characteristics Of Semisolid Ophthalmic Ointments, AAPS 2016, Denver, CO, November 12, 2016.
- 11. Beekman C, Matta M, Mohammad A, Gandhi A, Sun D, Jiang W, Lionberger R, Rouse R. Determining the Bio-distribution of Colloidal Iron Drug Products in Rats by Inductively Coupled Plasma Mass Spectrometry (ICP-MS), The New York Academy of Sciences Workshop: Equivalence of Complex Drug Products: Scientific and Regulatory Challenges, New York. NY, November 09, 2016.
- 12. Behafarid F, Vijayakumar G, Brasseur JG. The interplay between pharmaceutical dissolution and absorption in the human gut studied with computer simulation, AAPS 2016, Denver, CO, November 13-17, 2016.
- 13. Bodenlenz M, Tiffner K, Raml R, Tschapeller B, Augustin T, Dragatin C, Birngruber T, Kainz S, Schimek D, Schwagerle G, Pieber TR, Raney SG, Kanfer I, Sinner F. Clinical Open Flow

- Microperfusion as a Dermal Pharmacokinetic Approach to Evaluate Topical Bioequivalence in the Dermis In Vivo, Fifteenth International Conference on Perspectives in Percutaneous Penetration, La Grande Motte, France, March, 2016.
- 14. Boyce H, Dave V, Scoggins M, Smith D, Byrn S, Saluja B, Qu W, Gurvich VJ, Hoag SW. Influence of Key Polymer Attributes, Manufacturing Conditions and Sintering on Abuse Deterrence of Physical Barrier Type Abuse Deterrent Formulations (ADF), AAPS 2016, Denver, CO, November 13-17, 2016.
- 15. Boyce H, Smith D, Byrn S, Saluja B, Qu W, Gurvich VJ, Hoag SW. Use Of A Vertical Diffusion Cell For The In Vitro Assessment Of Abuse Deterrence Of Comminuted Abuse Deterrent Formulations, AAPS 2016, Denver, CO, November 13-17, 2016.
- 16. Byron PR, Wei X, Bormann K. Estimating aerosol size distributions and doses entering the trachea, Respiratory Drug Delivery 2016, Scottsdale, AZ, April 17-21, 2016.
- 17. Chow ECY, Zheng N, Qu W, Sun D, Wen H, Zhang X, Jiang W, Zhao L. Bioequivalence Analysis of Lamotrigine Extended-Release (ER) Tablets based on an In Vitro-In Vivo Relationship (IVIVR) Using the Physiologically Based Pharmacokinetic (PBPK) Absorption Model, American Epilepsy Society Annual Meeting, Houston, TX, December 2-6, 2016.
- 18. Conti DS, Holt J, Sheth P, Sandell D, Hickey A, Saluja B. Effects Of Formulation Factors On The Aerosolization Performance Of Metered Dose Inhalers, American Institute of Chemical Engineers (AIChe) Annual Meeting, San Francisco, CA, December 08, 2016.
- 19. Cordery SF, Chiu WS, Shehab MZ, Bunge AL, Delgado-Charro MB, and Guy RH. In Vitro In Vivo Correlation (IVIVC) Of Diclofenac Bioavailability From Three Topical Drug Products, 15th Annual Meeting of Skin Forum, London, UK, June 21, 2016.
- 20. Dahmane E, Gopalakrishnan M, Fang L, Gobburu J, Ivaturi V. Impact of Variabilityon Therapeutic Success for Drugs with Narrow Therapeutic Index, ACCP, Bethesda, MD, September 25-27, 2016.
- 21. Das S, Tung R, Ting TY, Polli JE. Frequency Of Generic Brittleness In Epilepsy Patients, AAPS 2016, Denver, CO, November 13-17, 2016.
- 22. Garner J, Skidmore S, Park H, Park K, Choi S, Wang Y. Assay of PLGA properties in Parenteral Depot Formulation, The Controlled Release Society Annual Meeting, Seattle, WA, July 17, 2016.
- 23. Garner J, Skidmore S, Park H, Park K, Choi S, Wang Y. Assay of polymeric sustained systems for carrier properties, AAPS 2016, Denver, CO, November 13-17, 2016.
- 24. Gomeni R, Bressolle F, Spencer TJ, Faraone SV. Meta-Analytic Approach to Evaluate Alternative Models for Characterizing the PK Profiles of Extended Release Formulations of MPH, ASCPT 2016, San Diego, CA, March 8-12, 2016.
- 25. Gomeni R, Bressolle F, Spencer TJ, Faraone SV. Optimal Study Design to Evaluate the Clinical Response of Extended Release Formulations of Methylphenidate (MPH) in a Pediatric Population, ASCPT 2016, San Diego, CA, March 8-12, 2016.
- 26. Gomeni R, Bressolle F, Spencer TJ, Faraone SV. Use of a Clinical Response Index Derived from a PK/PD Model to Estimate the Optimal In Vivo Release Rate of Extended Release Formulations of MPH, ASCPT 2016, San Diego, CA, March 8-12, 2016.
- 27. Guptill J, Greenberg RG, Melloni C, Wu H, Gonzalez D, Ku L, Hill K, Hornik C, Zheng N, Jiang W, Cohen-Wolkowiez M. Narrow therapeutic index classification of antiepileptic drugs using a

- comprehensive literature search, American Academy of Neurology Annual Meeting, Vancouver, Canada, April, 2016.
- 28. Hansen RA, Qian J, Berg RL, Linneman JG, Seoane-Vazquez E, Dutcher A, Raofi A, Peissig PL. Comparison Of Outcomes Following A Switch From A Brand To An Authorized Vs Independent Generic Drug,32nd International Conference on Pharmacoepidemiology Abstract #1036, Dublin, Ireland, August 25-28, 2016.
- 29. Hansen RA, Qian J, Berg RL, Linneman JG, Seoane-Vazquez E, Dutcher A, Raofi A, Peissig PL. Comparison Of Generic-To-Brand Switchback Patterns For Authorized Generic Vs Independent Generic Drugs, 32nd International Conference on Pharmacoepidemiology Abstract #610, Dublin, Ireland, August 25-28, 2016.
- 30. He H, Wu Y, Liu C, Cao Y. Integrating Cellular Disposition Of Doxorubicin Into A Multiscale Physiologically Based Pharmacokinetic Model In Mice And Scale-Up To Humans, 2016 ACoP Conference, Arlington, VA, October, 2016.
- 31. Hidau MK, Mehra N, Absar M, Choi S, Potter DE, Palakurthi S. Towards Development of In Vitro Drug Release Methods for Difluprednate Ophthalmic Emulsion, AAPS 2016, Denver, CO, November 13-17, 2016.
- 32. Hirota K, Zhou J, Ackermann R, Wang Y, Choi S, Schwendeman A, Schwendeman SP. Reverse engineering of the one-month Lupron Depot, AAPS 2016, Denver, CO, November 13-17, 2016.
- 33. Huynh B, Wei X, Byron PR. Evaluating electrostatic drug deposition in plastic mouth-throat models with Budelin® Novolizer®, Respiratory Drug Delivery 2016, Scottsdale, AZ, April 17-21, 2016.
- 34. Iyer G, Marimuthi S, Segal JB, Singh S. Identification of Generic Drugs in The FDA Adverse Event Reporting System,32nd International Conference on Pharmacoepidemiology Abstract #696, Dublin, Ireland, August 25-28, 2016.
- 35. Jiang W, Ye H. Characterization of Paclitaxel and Albumin Oligomeric Status in Abraxane during Storage, 2016 NYAS workshop Equivalence of complex drug products Challenges and Opportunities, New York City, NY, November 09, 2016.
- 36. Kannan R, Singh N, Przekwas A, Delvadia R, Tian G, Waleng R. A Multiscale Modeling Approach To Optimize Pulmonary Drug Delivery, Conference on Respiratory and Pulmonary Medicine, Chicago, IL, October 17-19, 2016.
- 37. Kimbell JS, Schroeter JD, Sheth P, Tian G, Delvadia RR, Saluja B, and Walenga R. Effect Of Actuation Force On Simulated Regional Nasal Spray Deposition In A Healthy Nasal Cavity, Respiratory Drug Delivery 2016, Silver Spring, MD, April 17-21, 2016.
- 38. Kimbell JS, Stricklin D, and Schroeter JD. Simulating Nasal Spray Deposition: Effects Of Spray Nozzle Presence In The Nasal Vestibule, International Society for Aerosols in Medicine Conference 2016, Munich, Germany, May 30-June 3, 2016.
- 39. Kitabi EN, Ivaturi V, Zhao L, Fang L, Gobburu J, Gopalakrishnan M. A Signal to Noise Ratio Classification System of Drugs to Investigate Generic Drug Ineffectiveness Claims, American College of Clinical Pharmacology (ACCP), Bethesda, MD, September 25-27, 2016.
- 40. Kozak D, Wang Y, Choi S, Park M, Lannoy I, Brooks M, Araujo J. Bioequivalence Testing Considerations for Complex Periodontal Products: Drug Release, Matrix Degradation, and

- Pharmacodynamics in a Canine Periodontal Disease Model, NYAS Equivalence of Complex Drug Products: Scientific and Regulatory Challenges, New York City, NY, November 09, 2016.
- 41. Li Z, Zheng N, Wen H, Fang L, Zhang X, Sun S, Kinjo M, Zhao L, Jiang W, Lionberger R. Bioequivalence Assessment of Brand and Generic Lamotrigine Extended-Release Tablets, American Epilepsy Society Annual Meeting, Houston, TX, December 2-6, 2016.
- 42. Longest PW, Rygg A, Hindle M. Bioequivalence testing: Can systemic pharmacokinetic profiles from corticosteroid nasal sprays be used to elucidate local drug deposition within the nose? Respiratory Drug Delivery 2016, Scottsdale, AZ, April 17-21, 2016.
- 43. Marimuthu S, Iyer G, Segal JB, Singh S. Patient Relevant Outcomes Associated with Generic Drugs in FDA's Adverse Event Reporting System,32nd International Conference on Pharmacoepidemiology Abstract #723, Dublin, Ireland, August 25-28, 2016.
- 44. Martins FS, Patel N, Cristea S, Polak S. Development And Validation Of Dermal PbPK Model Towards Virtual Bioequivalence Assessment: Prediction Of Dermal Drug Absorption Of Various Ibuprofen Formulations Using Simcyp Mechdermamodel, Drug Metabolism Discussion Group Annual Meeting, Paris, France, October 19-21, 2016.
- 45. Matta M, Beekman C, Gandhi A, Rouse R. Quantification of Drug Bound Iron, Non-Transferrin Bound Iron, Transferrin Bound Iron, and Total Iron in Serum in a Rat Pharmacokinetic Study, The New York Academy of Sciences Workshop: Equivalence of Complex Drug Products: Scientific and Regulatory Challenges, Newyork, NY, November 9, 2016.
- 46. Matter BM, Ghaffari A, Bourne D, Wang Y, Choi S, Kompella UB. Dexamethasone Degradation During In Vitro Release From An Intravitreal Implant, ARVO 2016, Seattle, WA, May, 2016.
- 47. Maurya A, Srinatha A, Raney SG, Ghosh P, S Repka MA, Murthy SN. The pH of Topical Creams can Change Rapidly Following Application on the Skin In Vivo, AAPS 2016, Denver, CO, November 13-17, 2016.
- 48. Mohammed YH, Namjoshi SN, Jung N, Shewan H, Stokes J, Benson, HA, Grice JE, Windbergs M, Raney SG, Roberts MS. Are Topical Products Dispensed from Different Packaging Q3 Equivalent and Bioequivalent? The American Association of Pharmaceutical Scientists (AAPS) Annual Meeting, Denver, CO, November 13-17, 2016.
- 49. Mullin J, Lukacova V, Woltosz W, Bolger MB. Development Of An In Vitro Mechanistic Model That Describes Drug Release From Risperidone Long-Acting Injectable Microspheres, AAPS 2016, Denver, CO, November 13-17, 2016.
- 50. Namjoshi SN, Mohammed YH, Benson, HA, Grice JE, Clegg J, Raney SG, Roberts MS. Water Content and Product Drying Rate as Well as the Amount of Propylene Glycol May Impact the Topical Bioavailability of Acyclovir from Cream Products, The American Association of Pharmaceutical Scientists (AAPS) Annual Meeting, Denver, CO, November 13-17, 2016.
- 51. Neu HM, Smith AD, Wilks A, Polli JE, Kane MA, Ting TY, Michel SL. Bioanalytical Approaches To Measure Iron Speciation In The Plasma Of Patients Treated With Iron-Nanoparticle Drug Products, 2016 ACS National Meeting, Philadelphia, PA, August 21-25, 2016.
- 52. Nimbal V, Segal JB, Romanelli RJ. Estimating Generic Drug Utilization With Electronic Health Records From A Mixed-Payer Ambulatory Healthcare Delivery System, 22nd Annual Health Care Systems Research Network Conference, Atlanta, GA, April 13-16, 2016.

- 53. Patel N, Cristea S, Polak S. Towards Development and Validation of the Dermal PBPK Model for Virtual Bioequivalence Model Description and Validation Case Studies, Controlled Release Society Annual Meeting, Seattle, WA, July 17-20, 2016.
- 54. Patel SK, Greene AC, Rothstein S, Zou Y, Choi S, Glowacki A, Gottardi R, Sfeir CS, Little SR, Rohan LC. Application of USP 4 Dissolution Apparatus to Assess Dissolution of Microparticles for Periodontal Disease, AAPS 2016, Denver, CO, November 13-17, 2016.
- 55. Pensado A, Chiu WS, Cordery SF, Bunge AL, Delgado-Charro MB, and Guy RH.

 Dermatopharmacokinetics As A Tool For Bioequivalence Testing: A Case Study Comparing

 Acyclovir Creams From The US And UK, 15th Annual Meeting of Skin Forum, London, UK, June 21, 2016.
- 56. Petrochenko P, Wong S, Wu Y, Zheng J, Xu X, Choi S, Kozak D. Continuous Monitoring of Nanoparticle Albumin-Bound Paclitaxel Dissolution Profiles Using Dynamic light scattering and In Situ UV/Vis Fiber-Optic Probes, Generic Drug Science Day, Silver Spring, MD, December 08, 2016.
- 57. Price CF, Shen J, Zou Y, Wang Y, Kozak D, Choi S, Burgess DJ. The Effect Of Crosslinking Reagent Ratio Of A 5-Year Contraceptive Implant On Drug Release, AAPS 2016, Denver, CO, November 13-17, 2016.
- 58. Purohit H, Osterling D, Jenkins G, Stolarik D, Gao W, Gao Y, Zhang G, Taylor L. Effect Of Crystallinity On The Bioavailability Of Marketed Tacrolimus Amorphous Solid Dispersions, AAPS 2016, Denver, CO, November 13-17, 2016.
- 59. Purohit H, Gao Y, Zhang G, Sun D, Wen H, Taylor L. Limitation In The Pharmacopeial Dissolution Testing Of Marketed Tacrolimus Amorphous Solid Dispersions, AAPS 2016, Denver, CO, November 13-17, 2016.
- 60. Qian J, Hansen R, Surry D, Howard J, Kiptanui Z, and Harris I. Identifying And Understanding Who And What Influences Generic Drug Utilization In The US, The American Public Health Association (APHA) 2016 annual meeting, Denver, CO, October 29-November 2, 2016.
- 61. Qian J, Hansen R, Surry D, Howard J, Kiptanui Z, and Harris I. Identifying And Understanding Who And What Influences Generic Drug Utilization Among Medicare Beneficiaries, The Gerontological Society of America (GSA) 2016 annual scientific meeting, New Orleans, LA, November 16-20, 2016.
- 62. Ren W, Kelm G, Choi S, Kozak D, Absar M, Wang Y, Chow E, Walenga R, Li SK. Low Volume Dissolution Devices for Long Acting Periodontal Drug Products, The American Association of Pharmaceutical Scientists (AAPS) Annual Meeting, Denver, CO, November 13-17, 2016.
- 63. Sailor MJ, Wang J, Kumeria T, Cheng L, Hou HY, Freeman WR. Silicon-Based Nanomaterials for Ocular Drug Delivery, Controlled Release Society Annual Meeting, Seattle, WA, July 17-20, 2016.
- 64. Schroeter JD, Kimbell JS, Saluja B, Delvadia RR, Vallorz III EL, Sheth P. The Impact Of Actuation Force On Droplet Size Distribution And Spray Duration Of Three Commercially Available Nasal Sprays, Respiratory Drug Delivery 2016, Silver Spring, MD, April 17-21, 2016.
- 65. Schroeter JD, Stricklin D, Kimbell JS, Delvadia RR, and Zhang X. A Physiologically-Based Pharmacokinetic Model Framework To Estimate Systemic Bioavailability Of Fluticasone Propionate Nasal Spray, Respiratory Drug Delivery 2016, Silver Spring, MD, April 17-21, 2016.

- 66. Segal JB, Daubresse M, Onasanya O. Determinants Of Generic Drug Substitution In The United States,32nd International Conference on Pharmacoepidemiology Abstract #612, Dublin, Ireland, August 25-28, 2016.
- 67. Sharan S, Zhang X. Application of Pharmacokinetic Modeling and Simulation Approach to Assess Bioequivalence at Steady State for Two Paliperidone Formulations, American Association of Pharmaceutical Scientists (AAPS) Annual Meeting, Denver, CO, November 13, 2016.
- 68. Sharan S, Zhang X. Evaluation of Proton Pump Inhibitor (PPI) Effect for Two Formulation of Paliperidone by Utilizing a Multi-pH Dissolution Model and Physiologically Based Pharmacokinetic (PBPK) Absorption Modeling and Simulation Approach, American Association of Pharmaceutical Scientists (AAPS) Annual Meeting, Denver, CO, November 13, 2016.
- 69. Sharma PK, Srinatha A, Muralikrishnan A, Raney SG, Ghosh P, S Murthy SN. Determination Of Ph For An Oil-In-Water Based Semisolid Cream: Method Development And Standardization, AAPS 2016, Denver, CO, November 13-17, 2016.
- 70. Shen J, Qu W, Wang Y, Choi S, Burgess DJ. Effect of Manufacturing Process Parameters on In Vitro Performance of Peptide Microspheres, The Controlled Release Society Annual Meeting, Seattle, WA, July 17, 2016.
- 71. Sheth P, Sandell D, Svensson M, Vallorz III EL, Sullivan JB, Saluja B, Conti DS. The Influence of Formulation Variables on Mometasone Furoate pMDIs, Respiratory Drug Delivery (RDD) Conference, Phoenix, AZ, April 17-21, 2016.
- 72. Shin S, Ghosh P, Raney SG, Hammell DC, Hassan HE, Stinchcomb AL. Effect Of Heat On Nicotine And Fentanyl Transdermal Delivery Evaluated In Vitro Using Different Skin/Membranes, Fifteenth International Conference on Perspectives in Percutaneous Penetration, La Grande Motte, France, March 30, 2016.
- 73. Shivva V, Fang L, Yang X, Zheng N, Zhu H, Raney S, Zhao L. Use of a Model Based Approach for Evaluation of partial Area Under the Curve for Bioequivalence Assessment of Methylphenidate Transdermal products, Conference on Pharmacometrics (ACoP7), Bellevue, WA, October 25, 2016.
- 74. Shivva V, Qin M, Wen H, Zhao L, Fang L. Assessment of Pharmacokinetic Profile Similarity in Bioequivalence Evaluation for Quetiapine fumerate extended release tablets, American Association of Pharmaceutical Scientists (AAPS) Annual Meeting, Denver, CO, November 13, 2016.
- 75. Shukla S, Ghosh P, Raney SG, Hassan HE, Bunge A, Stinchcomb AL. Evaluation Of Two Lidocaine Topical Patch 5% Products By Cutaneous Pharmacokinetic Methods: In Vitro Tape Stripping And In Vitro Permeation Testing, AAPS 2016, Denver, CO, November 13-17, 2016.
- 76. Sontak E, Holmes A, Pastore M, Studier H, Abd E, Grice J, Roberts M, Brandner J, Heisig M, Nägel A, Wittum G. Steps Towards Microscopic Simulations Of Skin Penetration,5th Galenus Workshop, Berlin, Germany, November 16-20, 2016.
- 77. Srinatha A, Ghosh P, S Raney SG, Maibach HI, Murthy SN. Is Water Activity The Primary Determinant Of Metamorphosis For Topical Creams? AAPS 2016, Denver, CO, November 13-17, 2016.

- 78. Srinatha A, Hashemnejad SM, Kundu S, Ghosh P, S Raney SG, Murthy SN. Clinical Relevance Of Rheological Characteristics Of Topical Creams: Relationship Between Yield Stress And Dose Spreading Area, AAPS 2016, Denver, CO, November 13-17, 2016.
- 79. Srinatha A, Maurya A, Ghosh P, S Raney SG, Murthy SN. Influence Of The Method Of Dose Application On The In Vitro Permeation Profile Of Acyclovir From Topical Creams, AAPS 2016, Denver, CO, November 13-17, 2016.
- 80. Suh M, Kastellorizios M, Qu W, Wang Y, Choi S, Burgess DJ. Effect of Polymer Source on the In Vitro Release Characteristics of In Situ-forming Implants, Controlled Release Society Annual Meeting, Seattle, WA, July 12, 2016.
- 81. Suh MS, Kastellorizios M, Qu W, Zou Y, Wang Y, Choi S, and Burgess DJ. Effect Of Solvent Diffusion From In Situ-Forming Implants On Drug Release, AAPS 2016, Denver, CO, November 13-17, 2016.
- 82. Suh MS, Kastellorizios M, Qu W, Zou Y, Wang Y, Choi S, Burgess DJ. Effect Of Polymer Source And Manufacturing Differences On In Vitro Release Of In Situ Forming Implants, AAPS 2016, Denver, CO, November 13-17, 2016.
- 83. Talattof A, Amidon GL. A Stochastic Fluid Packet Emptying And Transit Model: A Physiological Approach To Gastrointestinal Transit Of Fluid, AAPS 2016, Denver, CO, November 13-17, 2016.
- 84. Thomas S, Ghosh P, Raney SG, Hammell DC, Hassan HE, Stinchcomb AL. Effect of Controlled Heat Application on Topical Diclofenac Formulations Evaluated by In Vitro Permeation Tests (IVPT) Using Porcine And Human Skin, AAPS 2016, Denver, CO, November 14, 2016.
- 85. Tiffner K, Kanfer I, Schimek D, Reisenegger P, Raml R, Augustin T, Raney SG, Sinner F. Comparative In Vitro Release Tests (IVRT) of Seven Topical Acyclovir Products using a Validated IVRT Method with a Vertical Diffusion Cell (VDC) Apparatus, Fifteenth International Conference on Perspectives in Percutaneous Penetration, La Grande Motte, France, March 30, 2016.
- 86. Tiffner K, Kanfer I, Schimek D, Reisenegger P, Raml R, Raney SG, Sinner F. Comparative In Vitro Release of Six Different Topical Acyclovir Products using a Vertical Diffusion Cell (VDC) Apparatus, The American Association of Pharmaceutical Scientists (AAPS) National Biotechnology Conference, Boston, MA, May 16, 2016.
- 87. Toropainen E, Novakovic D, Fraser S, Tuomainen M, Hagstrm M, Del Amo E, Vellonen K-S, Peltoniemi J, Tengvall U, Pelkonen L, Reinisalo M, Ruponen M, Auriola S, Viitala T, Absar M, Choi S, Strachan C, Urtti A. Physical Formulation Features and Ocular Absorption from Topical Suspensions: Toward Mechanistic Understanding, AAPS 2016, Denver, CO, November 13, 2016.
- 88. Tsakalozou E, Hu M, Zhang X, Andrew Babiskin, Zhao L, Jiang W, Lionberger R. Searchable Database of FDA Product-specific Recommendations Used to Establish Therapeutic Equivalence of Generic Drug Products, American Association of Pharmaceutical Scientists (AAPS) Annual Meeting, Denver, CO, November 13, 2016.
- 89. Tsakalozou E, Sun D, Wen H, Zhang X. In vitro-in vivo relationship development for oxybutynin chloride extended-release tablets to assess bioequivalence, American Association of Pharmaceutical Scientists (AAPS) Annual Meeting, Denver, CO, November 13, 2016.
- 90. Tsume Y, Igawa N, Drelich AJ, Amidon GL. The Incorporation of Absorptive Phase into the In Vivo Predictive Dissolution (IPD) System to Predict Better In Vivo Dissolution for Ketoconazole and Raloxifene, AAPS 2016, Denver, CO, November 13-17, 2016.

- 91. Wang J, Kumeria T, Sailor M, Warther D. Design and Validation of an Intraocular In Vitro Simulator, Controlled Release Society Annual Meeting, Seattle, WA, July 17-20, 2016.
- 92. Wang J, Kumeria T, Warther D, Bezem MT, Sailor MJ. Self-Reporting Porous Silicon Microparticles for Drug Delivery, Porous Semiconductors Science and Technology (PSST), Tarragona, Spain, March 6-11, 2016.
- 93. Wei X and Byron PR. Clinically relevant in vitro performance tests for powder inhalers, RDD Asia 2016, Goa, India, November, 2016.
- 94. Wen H, Sun D, Zhang X, Fang L, Dutcher S, Babiskin A, Zhao L, Jiang W, Lionberger R. Brand-to-generic therapeutic equivalence analysis of modified-release (MR) oral drug products, American Association of Pharmaceutical Scientists (AAPS) Annual Meeting, Denver, CO, November 13, 2016.
- 95. Wittayanukorn S. Patterns of Bioequivalence Recommendations and Trends of Abbreviated New Drug Applications Approval over Time, 2016 International Society For Pharmacoeconomics and Outcomes Research Annual International Meeting, Washington DC, May 25, 2016.
- 96. Wu M, Sun D, Tyner K, Jiang W, Rouse R. Comparative In Vitro Cellular Uptake Study on Reference and Generic Sodium Ferric Gluconate in Mononuclear Phagocyte Systems, The New York Academy of Sciences Workshop: Equivalence of Complex Drug Products: Scientific and Regulatory Challenges, New York. NY, November 09, 2016.
- 97. Wu Y, Petrochenko P, Absar M, Wong S, Choi S, Zheng J. Characterization Of The Globule Size Distribution Of Cyclosporine Ophthalmic Emulsion By Cryogenic Electron Microscopy, Microscopy & Microanalysis Annual Meeting, Columbus, OH, July 24, 2016.
- 98. Yu A, Jackson TL, Amidon GL, Marciani L, Sun D. Modeling Dynamic Gastrointestinal Fluid Transit As A Basis For Dissolution And Absorption, AAPS 2016, Denver, CO, November 13-17, 2016.
- 99. Yu M, Shin SH, Hammell DC, Hassan HE, Stinchcomb AL. Pharmacokinetics Of Fentanyl After Using Reference And Generic Transdermal Fentanyl Patches With And Without Standardized Heat Application In Healthy Human Volunteers, AAPS 2016, Denver, CO, November 13-17, 2016.
- 100. Yu T, Rower JE, Liu X, Balch AH, Halford Z, Korgenski EK. Development of a Physiologically Based Pharmacokinetic Model of Tacrolimus in Adult Organ Transplant Patients, 2016 ASCPT, San Diego, CA, March 8-12, 2016.
- 101. Zhang D, Jhon Y, Ye Y, Berendt R, Cai B, Jiang X. Development of Product-Specific Guidance for Polymeric Drugs: A Case Study on Sevelamer and Colesevelam, American Association of Pharmaceutical Scientists (AAPS) Annual Meeting, Denver, CO, November 13, 2016.
- 102. Zhang D. Scientific Considerations in Submitting Synthetic Peptide Drug Products as ANDAs Referencing Peptide Drug products of rDNA origin, 3rd Synthetic Therapeutic Peptide Workshop, Rockville, MD, November 14-15, 2016.
- 103. Zhang Q, Murawsky MK, La Count T, Hao J, Raney SG, Ghosh P, Kasting G, Li S. Evaluation of Heat Effects on Transdermal Delivery Systems using an In Vitro Permeation Test (IVPT) Strategy, AAPS 2016, Denver, CO, November 14, 2016.
- 104. Zhou T, Chow E, Wen H, Jiang W, Zhao L, Zhang X. Evaluation of the impact of in vitro release alterations on pharmacokinetics of metoprolol succinate extended-release (ER) tablets using the physiologically based pharmacokinetic (PBPK) absorption model, American Association of Pharmaceutical Scientists (AAPS) Annual Meeting, Denver, CO, November 13, 2016.

105. Zuckerman I, Pradel F, Palumbo F, Shen X, Kiptanui Z, Polli J, Gardner J, Franey C, Malik S. Post-marketing Surveillance of Generic Drug Usage and Substitution Patterns, FDA-JHU CERSI workshop: Substitutability of Generic Drugs: Perception and Reality, Silver Spring, MD, November 18, 2016.