

Posters Presented Relating to GDUFA Research in Fiscal Year 2018

1. Abd, E., Mohammed, Y., Medley, G., Naegel, A., Grice, J., Maibach, H., and Roberts, M. *Relating Regional Variations in Skin Permeability to the Underlying Skin Morphology In Vivo*. Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 12, 2017.
2. Abdulla, T., Patel, N., Polak, S., Martins, F., Rostami-Hodjegan, A., and Jamei, M. *Quantitative Prediction of Dermal Drug Absorption Using MPML-Mechderma Model: Relative Effects of Application Site on Rivastigmine Pharmacokinetics from a Transdermal Delivery System*. Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 12, 2017.
3. Abdulla, T., Patel, N., Martins, F., Salem, F., Clarke, J., Jamei, M., and Polak, S. *Predicting the Pharmacokinetics of Topically Applied Ketoprofen Using Mechanistic Physiologically-Based Pharmacokinetics Modelling*. Poster Presentation at Perspective in Percutaneous Penetration. La Grande Motte, France, Apr. 4, 2018.
4. Ajjarapu, S., Rangappa, S., DeBoyace, K., Wildfong, P., and Murthy, S. *Metronidazole Crystal Patterns Formed During the Metamorphosis of Topical Carbopol Gels*. Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 12, 2017.
5. Ajjarapu, S., Rangappa, S., Ghosh, P., Raney, S., and Murthy, S. *A Novel Strategy for the Efficient Modulation of Topical Drug Delivery to Validate the Sensitivity of an In Vitro Permeation Test (IVPT)*. Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 12, 2017.
6. Al-Ghabeish, M., Feng, X., Mohammad, A., Lionberger, R., Faustino, P., and Ashraf, M. *In Vitro Evaluation of the Performance of a Locally- Acting Gastrointestinal Drug, Sucralfate*. Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 12, 2017.
7. Alinaghi, A., Cheruvu, H., Liu, X., Anissimov, Y., Kuswahyuning, R., Ghosh, P., Grice, J., Raney, S., and Roberts, M. *In Vitro-In Vivo Relationships (IVIVR) for Transdermal Delivery of Nicotine from Patches*. Poster Presentation at Perspective in Percutaneous Penetration. La Grande Motte, France, Apr. 4, 2018.
8. Andhariya, J., Shen, J., Zou, Y., Wang, Y., Choi, S., and Burgess, D. *Development of In Vitro-In Vivo Correlation of Parenteral Naltrexone Loaded Polymeric Microspheres*. Poster Presentation at FDA Workshop: Demonstrating Equivalence of Generic Complex Drug Substances and Formulations. Silver Spring, MD, Oct. 6, 2017.
9. Andhariya, J., Shen, J., Zou, Y., Wang, Y., Choi, S., and Burgess, D. *Effect of Manufacturing Processes on Critical Quality Attributes of Peptide Microspheres*. Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 12, 2017.
10. Andhariya, J., Zou, Y., Wang, Y., Choi, S., and Burgess, D. *Effect of Manufacturing Processes on Burst Release of Risperidone Microspheres*. Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 12, 2017.

11. Andhariya, J., Shen, J., Zou, Y., Choi, S., Wang, Y., and Burgess, *Effect of Manufacturing Difference on the Drug Release Characteristics of Peptide Microspheres*. Poster Presentation at Controlled Release Society Annual Meeting. New York City, NY, July 22, 2018.
12. Andhariya, J., Jog, R., Shen, J., Zou, Y., Choi, S., Wang, Y., and Burgess, D. *Evaluation of Effect of Minor Manufacturing Changes and Establishment of IVIVC for Compositionally Equivalent Parenteral Microsphere Drug Products*. Poster Presentation at GPEN 2018. Singapore, Singapore, Sept. 26, 2018.
13. Bao, Q., Gu, B., Price, C., Zou, Y., Wang, Y., Choi, S., and Burgess, *In Vitro Release Testing of Long-Acting Levonorgestrel Intrauterine System*. Poster Presentation at FDA Workshop: Demonstrating Equivalence of Generic Complex Drug Substances and Formulations. Silver Spring, MD, Oct. 6, 2017.
14. Bao, Q., Shen, J., Newman, B., Wang, Y., Choi, S., and Burgess, D. *Impact of Excipient Sources on In Vitro Drug Release Characteristics of Semisolid Ophthalmic Ointments*. Poster Presentation at FDA Workshop: Demonstrating Equivalence of Generic Complex Drug Substances and Formulations. Silver Spring, MD, Oct. 6, 2017.
15. Bao, Q., Gu, B., Price, C., Zou, Y., Wang, Y., Choi, S., and Burgess, *In Vitro Release Testing of Long-Acting Levonorgestrel Intrauterine System*. Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 12, 2017.
16. Bao, Q., Zou, Y., Wang, Y., Kozak, D., Choi, S., and Burgess, D. *Accelerated Drug Release Method for Long-Acting Levonorgestrel Intrauterine Systems*. Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 12, 2017.
17. Bao, Q., Newman, B., Wang, Y., Choi, S., and Burgess, D. *In Vitro- Ex Vivo Correlation of Drug Release from Semisolid Ophthalmic Ointments*. Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 12, 2017.
18. Beig, A., Hong, J., Feng, L., Chang, R., Zhou, J., Ackermann, R., and Schwendeman, S. *PLGA-Peptide Interactions Relevant for Octreotide- Loaded PLGA Microspheres*. Poster Presentation at FDA Workshop: Demonstrating Equivalence of Generic Complex Drug Substances and Formulations. Silver Spring, MD, Oct. 6, 2017.
19. Bodenlenz, M., Augustin, T., Bimgruber, T., Tiffner, K., Raml, R., Raney, S. G., Sinner, F. Variability of topical penetration data: what do we learn from a BE-study using dermal open flow microfusion. Poster Presentation at Perspective in Percutaneous Penetration. La Grande Motte, France Apr. 3, 2018.
20. Chen, L., Manna, S., Petrochenko, P., Wu, Y., Qin, B., Kozak, D., and Zheng, J. *Importance of Comparative Unit Dose Concentration in the Evaluation of Complex Ophthalmic Suspension Product Quality*. Poster Presentation at Controlled Release Society Annual Meeting. New York City, NY, July 22, 2018.
21. Choi, J., LeBlanc, L., Choi, S., Haghighi, B., Hoffman, E., O'Shaughnessy, P., Wenzel, S., Castro, M., Fain, S., Jarjour, N., Schiebler, M., Denlinger, L., and Lin, C.L. *Characteristics of Inhaled Particle Deposition in the Lungs of Imaging-Based Asthma Clusters: A Numerical Study*. Poster Presentation at American Thoracic Society International Conference. San Diego, CA, May 21, 2018.
22. Desai, R., Gopalakrishnan, C., Dejene, S., Sarpatwari, A., Levin, R., Dutcher, S., Wang, Z., Wittayanukorn, S., Franklin, J., and Gagne, *Comparative Outcomes of*

Treatment Initiation with Brand Versus Generic Warfarin: A Medicare Cohort Study. Poster Presentation at 34th International Conference on Pharmacoepidemiology & Therapeutic Risk Management. Prague, Czech, Aug. 22, 2018.

23. Dong, Y., Qu, H., Pavurala, N., Wang, J., Martinez, M., Fahmy, R., Ashraf, M., Cruz, C., and Xu, X. *Effect of Formulation and Process Variables on the Properties of Cyclosporine Ophthalmic Ointments.* Poster Presentation at FDA Workshop: Demonstrating Equivalence of Generic Complex Drug Substances and Formulations. Silver Spring, MD, Oct. 6, 2017.
24. Dong, Y., Qu, H., Hengst, L., Choi, S., Absar, M., Li, V., Zheng, J., Ashraf, M., Cruz, C., and Xu, X. *Bi-Phasic Mass Transfer and Trans-Membrane Diffusion in Emulsions.* Poster Presentation at FDA Workshop: Demonstrating Equivalence of Generic Complex Drug Substances and Formulations. Silver Spring, MD, Oct. 6, 2017.
25. Dong, Y., Qu, H., Hengst, L., Choi, S., Absar, M., Li, V., Zheng, J., Ashraf, M., Cruz, C., and Xu, X. *Understanding Bi-Phasic Mass Transfer and Trans-Membrane Diffusion Kinetics in Emulsions.* Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 12, 2017.
26. Emoto, C., Fukuda, T., Hahn, D., Christians, U., Alloway, R., and Vinks, A. *TACROLIMUS PBPK MODELING USING REALISTIC PHYSIOLOGICAL FACTORS IN RENAL TRANSPLANT PATIENTS.* Poster Presentation at ASCPT. Orlando, FL, Mar. 22, 2018.
27. Externbrink, A., Sun, D., Sharan, S., Saluja, B., Gao, Z., Keire, D., and Jiang, W. *Development of an In-Vitro Chewing Method for Determining Opioid Availability Following Chewing of Solid Oral Extended Release Opioids.* Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 14, 2017.
28. Externbrink, A. *Application of an In Vitro Chewing Method to Assess the Effect of Shelf-Life and Storage Conditions on the Chewing Resistance and Drug Release Properties of Abuse-Deterrent Hysingla.* Poster Presentation at Controlled Release Society Annual Meeting. New York City, NY, July 23, 2018.
29. Feng, X., Al-Ghabeish, M., Lionberger, R., Cruz, C., and Ashraf, M. *Development of an In-Vitro Protein Binding Method for the Evaluation of Bioequivalence of Sucralfate Suspension.* Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 12, 2017.
30. Gao, Z., Ngo, C., Ye, W., Rodriguez, J., Keire, D., Sun, D., Wen, H., and Jiang, W. *Mechanical Response of Nifedipine Extended-Release Tablet During In Vitro Dissolution Testing.* Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 12, 2017.
31. Garner, J., Skidmore, S., Hadar, J., Park, K., Park, H., Choi, S., and Wang, Y. *Assay of PLGA Types in Microparticle Depo Formulations.* Poster Presentation at FDA Workshop: Demonstrating Equivalence of Generic Complex Drug Substances and Formulations. Silver Spring, MD, Oct. 6, 2017.
32. Gong, X., Hu, M., and Zhao, L. *Big Data Toolsets to Pharmacometrics: Application of Machine Learning for Time-to-Event Analysis.* Poster Presentation at ASCPT Annual Meeting. Orlando, FL, Mar. 22, 2018.
33. Gong, X., Hu, M., Liu, J., and Zhao, L. *Revealing Association Between Kinases and*

Adverse Events for Small-Molecule Tyrosine Kinase Inhibitors Using Machine Learning Method. Poster Presentation at ASCPT Annual Meeting. Orlando, FL, Mar. 22, 2018.

34. Gonzalez Sales, M., Fan, J., Fang, L., Hu, M., Lionberger, R., and Zhao, L. *Age Is a Statistically Significant Predictor of the Within Subject Variability in Dabigatran Pharmacokinetics.* Poster Presentation at America Conference of Pharmacometrics. Ft. Lauderdale, FL, Oct. 15, 2017.
35. Hadar, J., Garner, J., Skidmore, S., Park, K., Choi, S., and Wang, Y. *The Effect of Lactide: Glycolide Ratio on PLGA Solubility in Selective Solvents.* Poster Presentation at FDA Workshop: Demonstrating Equivalence of Generic Complex Drug Substances and Formulations. Silver Spring, MD, Oct. 6, 2017.
36. Hadar, J., Garner, J., Skidmore, S., Park, H., Park, K., Kozak, D., and Wang, Y. *Solvent-Dependent PLGA Solubility for Separation of PLGAs with Different L: G Ratios.* Poster Presentation at Controlled Release Society Annual Meeting. New York City, NY, July 22, 2018.
37. Hadar, J., Garner, J., Skidmore, S., Park, K., Park, H., Kozak, D., and Wang, Y. *Correlation Analysis of Refractive Index (D_n/D_c) for PLGAs with Different Ratios of Lactide to Glycolide,* Poster Presentation at Controlled Release Society Annual Meeting. New York City, NY, July 22, 2018.
38. Hahn, D., Emoto, C., Christians, U., Alloway, R., Vinks, A., and Fukuda, T. *GENETIC POLYMORPHISMS AT THE PREGNANE X RECEPTOR AND Cyp3a5 LOCI INFLUENCE THE PHARMACOKINETICS OF TACROLIMUS IN RENAL TRANSPLANT PATIENTS.* Poster Presentation at ASCPT. Orlando, FL, Mar. 22, 2018.
39. Hens, B. et al. *Dynamic Change in pH by Low Buffer Capacity of Gastrointestinal Fluids Along the Human Gastrointestinal Tract: Implications for In Vivo Dissolution and Absorption of Ionizable Compounds.* Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 14, 2017.
40. Hens, B., Bermejo, M., Tsume, Y., Gonzalez-Alvarez, I., Ruan, H., Matsui, K., Amidon, G., Cavanagh, K., Kuminek, G., Rodriguez Hornedo, N., and Amidon, G. L. *Exploring Dissolution, Supersaturation and Precipitation of Posaconazole in the Gastrointestinal Simulator (GIS) in Parallel with Visualization of Precipitated Drug by Microscopy Studies.* Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 14, 2017.
41. Nan-Hung, H., Brad, R., Frederic, B., and Weihsueh, C. *Applying A Global Sensitivity Analysis Workflow to Improve Computational Efficiencies in Physiologically-Based Pharmacokinetic Model.* Poster Presentation at SOT Annual Meeting. San Antonio, TX, Mar. 11, 2018.
42. Hu, M., Jiang, X., Absar, M., Choi, S., Shen, M., Weng, Y., Zhao, L., and Lionberger, R. *A Statistical Bioequivalence Approach Based on Earth Mover's Distance for Equivalence Testing of Particle Size Distribution.* Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 12, 2017.
43. Hu, P., Zhang, D., Kozak, D., and Jiang, X. *Scientific Considerations for Synthetic Peptides Referencing Peptide Drugs of rDNA Origin.* Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 12, 2017.

44. Lamar, H., Murimi, I., Scharfstein, D., Mojtabei, R., Segal, J., and Varadhan, R. *Assessing Therapeutic Equivalence of Brand and Generic Drugs Using Observational Data*. Poster Presentation at Atlanta Causal Inference Conference. Pittsburgh, PA, Aug. 22, 2018.
45. Lamar, H., Murimi, I. B., Scharfstein, D., Mojtabei, R., Varadhan, R., and Segal, J. *Overcoming Temporal Confounding in the Assessment of Therapeutic Equivalence of Brand and Generic Drugs*. Poster Presentation at International Society for Pharmacoepidemiology. Lyon, France, May 22, 2018.
46. Jung, N., Namjoshi, S., Mohammed, Y., Grice, J., Raney, S., Roberts, M., and Windbergs, M. *Evaluation of Penetration Kinetics of Commercial Topical Formulations in Human Skin Using Non-Invasive Confocal Raman Microscopy*. Poster Presentation at International Conference and Workshop on Biological Barriers. Sept. 27, 2018.
47. Kedia, K., Bilbao, A., Zhou, M., Payne, S. H., and Cort, J. R. *Universal Open-Source Software for Detecting Metabolites in Complex Mixtures by Scanning Precursors with Predetermined Neutral Losses from MS/MS*. Poster Presentation at 14th Annual Conference of the Metabolomics Society. Seattle, WA, June 24, 2018.
48. Khalaf, A., Hoad, C., Menys, A., Mudie, D., Wright, J., Heissam, K., Abrehart, N., Gowland, G., Amidon, P., Spiller, R., Amidon, G., and Marciani, L. *Fasted and Fed Motility of the Undisturbed Small Bowel: Development of Novel MRI Methods to Advance In Vivo Predictive Dissolution Studies*. Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 14, 2017.
49. Kim, H., Fang, L., and Zhao, L. *Quantitative Assessment of Additional Metrics in the Bioequivalence Evaluation of Oxcarbazepine Extended Release Tablet*. Poster Presentation at ASCPT Annual Meeting. Orlando, FL, Mar. 22, 2018.
50. Kiptanui et al. *Consistency of Publicly- Accessible Generic Drug Labels with Reference Listed Drug Labels in DailyMed: A Case Analysis for the Special Populations*. Poster Presentation at International Society for Pharmacoepidemiology and Outcomes Research. Baltimore, MD, May 19, 2018.
51. Kiptanui et al. *Consistency of Publicly- Accessible Generic Drug Labels with Reference Listed Drug Labels in DailyMed: A Case Analysis for the Special Populations*. Poster Presentation at 33th International Conference on Pharmacoepidemiology & Therapeutic Risk Management. Prague, Czech, Aug. 22, 2018.
52. Koo, B., Qin, B., Jiu, Y., Wu, Y., Choi, S., Kozak, D., and Zheng, *Characterizing How Size Distribution and Concentration Affect Echogenicity of Ultrasound Contrast Agent Products: Scientific Considerations for an In Vitro Bioequivalence Approach*. Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 12, 2017.
53. Koo, B., Qin, B., Liu, Y., Wu, Y., Choi, S., Kozak, D., and Zheng, *Scientific Considerations for an In Vitro Bioequivalence Approach for Ultrasound Contrast Agent Products: How Size Distribution and Total Volume of Microbubbles Affect Its Echogenicity*. Silver Spring, MD, Aug. 6, 2018.

54. Koo, B., Qin, B., Liu, Y., Wu, Y., Choi, S., Kozak, D., and Zheng, J. *Scientific Considerations for an In Vitro Bioequivalence Approach for Ultrasound Contrast Agent Products: How Size Distribution and Total Volume of Microbubbles Affect Its Echogenicity*. Poster Presentation at Microscopy and Microanalysis Annual Meeting. Baltimore, MD, Aug. 6, 2018.
55. Kurumaddali, A., Schilling, U., Chen, M., Jiao, Y., Seay, Y., Baumstein, S., Abu-Hasan, M., Conti, D., Oguntimein, M., Delvadia, R., Winner, L., Tabulov, C., Saluja, B., Bulitta, J., and Hochhaus, G. *Inhalation Profile Modeling for Fluticasone Propionate Dry Powder Inhalers in Healthy Volunteers During A Four Way Crossover Bioequivalence Study*. Poster Presentation at ASCPT Annual Meeting. Orlando, FL, Mar. 21, 2018.
56. LeMerdy, M., Eleftheria, T., Stephanie, C., Myong-Jin, K., Lin, X., Sharron, S., Ashok, C., Rodney, R., Murali, M., Liang, Z., Robert, L., and Jianghong, F. *Application of Ocular Physiologically Based Pharmacokinetic Modeling to Understand the Impact of Particle Size and Viscosity on Ophthalmic Bioavailability of Tobradex ST Suspension in Rabbits*. Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 12, 2017.
57. LeMerdy, M., Sun, D., Ni, Z., Babiskin, A., Lee, S.-C., Zhao, L., and Fan, J. *Physiologically-Based Pharmacokinetic Modeling Approach to Identify the Drug-Drug Interaction Mechanism of Nifedipine and a Proton Pump Inhibitor, Omeprazole*. Poster Presentation at American College of Clinical Pharmacy. Bethesda, MD, Sept. 24, 2018.
58. Lichvar, A., Tremblay, S., Naik, D., King, E., Vinks, A., Christians, U., and Alloway, R. *Evaluation of Clinical and Safety Outcomes Following Uncontrolled Tacrolimus Conversion in Adult Renal Transplant Recipients*. Poster Presentation at ACCP Annual Meeting. Phoenix, AZ, Oct. 7, 2017.
59. Lichvar, A., Tremblay, S., Naik, D., King, E., Vinks, A., Christians, U., and Alloway, R. *Evaluation of Clinical and Safety Outcomes Following Uncontrolled Tacrolimus Conversion in Adult Renal Transplant Recipients*. Poster Presentation at American Transplant Congress. Seattle, WA, June 2, 2018.
60. Liu, D., Jamei, M., and Turner, D. *A New Particle Population Balance Model (PPB) for PBPK Modelling of Orally Dosed Drugs Accounting for Two Solid States*. Sept. 11, 2018.
61. Manna, S., Petrochenko, P., Wu, Y., Dong, Y., Koo, B., Chen, L., Ren, K., Oktem, B., Choi, S., Xu, X., Kozak, D., Wang, Y., and Zheng, J. *Assessing In Vitro Drug Release from Multivesicular Liposome: Comparison of Reverse Dialysis and Rotary Shaking Methods*. Poster Presentation at FDA Workshop: Demonstrating Equivalence of Generic Complex Drug Substances and Formulations. Silver Spring, MD, Oct. 6, 2017.
62. Manna, S., Petrochenko, P., Wu, Y., Koo, B., Ren, K., Chen, L., Dong, Y., Xu, X., Choi, S., Kozak, D., Wang, Y., and Zheng, J. *Assessing In Vitro Drug Release from Multivesicular Liposome: Comparison of Reverse Dialysis and Rotary Shaking Methods*. Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 12, 2017.

63. Manna, S., Petrochenko, P., Wu, Y., Koo, B., Ren, K., Chen, L., Dong, Y., Xu, X., Choi, S., Kozak, D., Wang, Y., and Zheng, J. *Probing Mechanism of Drug Release from Multivesicular Liposomes*. Poster Presentation at Controlled Release Society Annual Meeting. New York City, NY, July 23, 2018.
64. Manna, S., Petrochenko, P., Wu, Y., Dong, Y., Koo, B., Chen, L., Ren, K., Oktem, B., Choi, S., Xu, X., Kozak, D., Wang, Y., and Zheng, J. *Developing Physicochemical Characterization and In Vitro Release Test Methods to Probe Drug Release Mechanism from Multivesicular Liposomes*. Poster Presentation at Microscopy and Microanalysis Annual Meeting. Baltimore, MD, Aug. 6, 2018.
65. Manna, S., Petrochenko, P., Wu, Y., Dong, Y., Koo, B., Chen, L., Ren, K., Oktem, B., Choi, S., Xu, X., Kozak, D., Wang, Y., and Zheng, J. *Mechanistic Understanding of In Vitro Drug Release of Bupivacaine from Multivesicular Liposomes*. Poster Presentation at AAPS Pharmsci 360. Washington, DC, Nov. 6, 2018.
66. Khalaf, A., Hoad, C.L., Menys, A., Mudie, D., Wright, J., Heissam, K., Abreheart, N., Gowland, P.A., Amidon, G.E., Spiller, R.C., Amidon, G.L., and Marciani, L. *Fasted and Fed Motility of the Undisturbed Small Bowel: Development of Novel MRI Methods to Advance In Vivo Predictive Dissolution Studies*. Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 14, 2017.
67. Martins, F., Patel, N., Salem, F., Jamei, M., and Polak, S. *Multi-Phase Multi-Layer Mechderma Model: Development, Verification and Application of a PBPK-PD Model of Dermal Absorption for Transdermal Product Assessment*. Poster Presentation at Perspective in Percutaneous Penetration. La Grande Motte, France, Apr. 4, 2018.
68. Martins, F., Patel, N., Jamei, M., and Polak, S. *Mechanistic Physiologically- Based Pharmacokinetic Modelling for Prediction of Dermal Absorption in Psoriatic Patients*. Poster Presentation at Perspective in Percutaneous Penetration. La Grande Motte, France, Apr. 4, 2018.
69. Myung, J., Kozak, D., and Zheng, J. *Assessing High-Resolution Nanoparticle Counting Techniques for the Regulatory Science of Complex Drug Products*. Poster Presentation at FDA Workshop: Demonstrating Equivalence of Generic Complex Drug Substances and Formulations. Silver Spring, MD, Oct. 6, 2017.
70. Myung, J., Zheng, J., and Kozak, D. *Assessing High-Resolution Single Nanoparticle Counting Techniques to Improve the Regulatory Science of Complex Drug Products*. Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 12, 2017.
71. Pan, L., Lionberger, R., and Zhao, L. *The Development of a Novel Measure for Subject by Formulation Interaction*. Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 12, 2017.
72. Patel, N., Martins, F., Jamei, M., Ghosh, P., Raney, S., Zhang, X., Tsakalozou, E., Ni, Z., and Polak, S. *Integration of Physicochemical Product Characteristics Within a Mechanistic Dermal PBPK Model to Support Virtual Bioequivalence Evaluation of Topical Drug Products: A Case Study with Acyclovir Topical Creams*. Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 12, 2017.
73. Patel, S., Greene, A., MacPherson, J., Basha, I., Desai, S., Zou, Y., Sfeir, C., Rothstein, S., Little, S., and Rohan, L. *Design, Fabrication, and Evaluation of a Small Volume*

Biorelevant Dissolution Apparatus for Extended-Release Periodontal Microparticles. Poster Presentation at Controlled Release Society Annual Meeting. New York City, NY, July 18, 2018.

74. Petrochenko, P., Hu, P., Wu, Y., Choi, S., Kozak, D., and Zheng, J. *Physicochemical Characterization of Tobradex and Tobradex ST Under Physiological Conditions.* Poster Presentation at FDA Workshop: Demonstrating Equivalence of Generic Complex Drug Substances and Formulations. Silver Spring, MD, Oct. 6, 2017.
75. Petrochenko, P., Wong, S., Wu, Y., Zheng, J., Xu, X., Choi, S., and Kozak, D. *Continuous Monitoring of Albumin-Bound Paclitaxel Dis- solution Profiles Using Dynamic Light Scattering and in Situ UV/VIS Fiber-Optic Probes.* Poster Presentation at FDA Workshop: Demonstrating Equivalence of Generic Complex Drug Substances and Formulations. Silver Spring, MD, Oct. 6, 2017.
76. Patel, N. and Polar, S. *Development of the Dermal Absorption Model for the Ketoprofen Local and Systemic Exposure Prediction.* Poster Presentation at Skin Forum 2018 Annual Meeting. June 20, 2018.
77. Shahraz, A., Mullin, J., Lukacova, M., Bolger, B., Woltosz, W. *Development of In Vitro-In Vivo Correlation for Long Acting Injectable Microsphere Formulations.* Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 12, 2017.
78. Qian, J., Li, C., Huo, N., Mishuk, A., Chen, L., Hansen, R., Harris, I., and Kiptanui, Z. *Generic Substitution Patterns of Levothyroxine and Escitalopram in Subgroups of U.S. Medicare Beneficiaries.* Poster Presentation at 33th International Conference on Pharmacoepidemiology & Therapeutic Risk Management. Prague, Cech, Aug. 22, 2018.
79. Qu, H., Wang, J., Wu, Y., Zheng, J., Yellela, K., Absar, M., Choi, S., Ashraf, M., Cruz, C., and Xu, X. *Asymmetric Flow Field Flow Fractionation as an Analytical Tool for the Size Based Separation and Characterization of Complex Ophthalmic Emulsions.* Poster Presentation at FDA Workshop: Demonstrating Equivalence of Generic Complex Drug Substances and Formulations. Silver Spring, MD, Oct. 6, 2017.
80. Ramezanli, T., Ghosh, P., Zhang, Y., Luke, M., Shin, S., Hassan, H., Stinchcomb, A., Zhang, Q., and Raney, S. *Developing In Vitro-In Vivo Correlations (IVIVCs) for In Vitro Permeation Test and In Vivo Pharmacokinetic Studies to Evaluate the Effects of Heat on Nicotine Transdermal Delivery Systems.* Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 28, 2017.
81. Rangappa, S., Ajjarapu, S., Ghosh, P., Raney, S., and Murthy, S. *Evaluation of Different Dose Application Techniques on the In Vitro Cutaneous Pharmacokinetics of Metronidazole from Topical Gel and Cream Products.* Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 12, 2017.
82. Rangappa, S., Ajjarapu, S., Hashemnejad, S., Prado, R., Ghosh, P., Raney, S., Kundu, S., Murthy, and SN. *Correlation Between the Quality Attributes and Performance Characteristics of Metronidazole Gels and Creams: Implications for the Evaluation of Bioequivalence.* Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 12, 2017.
83. Sales, M., Fang, L., and Zhao, L. *Population Pharmacokinetic Analysis of*

Dabigatran in Bioequivalence Studies. Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 12, 2017.

84. Shahraz, A., Mullin, J., Lukacova, M., Bolger, B., and Woltosz, W. *Development of In Vitro-In Vivo Correlation for Long Acting Injectable Microsphere Formulations*. Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 12, 2017.
85. Sharan, S., Externbrink, A., Sun, D., Zhang, X., Fan, J., Jiang, W., Gao, Z., Keire, D., Lionberger, R., and Zhao, L. *Development of Mechanistic In Vitro In Vivo Correlation (IVIVC) of Abuse-Deterrent Hydrocodone Bitartrate Extended Release Tablets*. Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 14, 2017.
86. Sharan, S., Choi, S., Zhang, X., Zou, Y., Wang, Y., Kim, M.-J., Choi, S., Makhoul, F., Grosser, S., Fang, L., and Zhao, L. *Evaluation of Residual Levonorgestrel As Potential Bioequivalence Metric for A Long Acting Intrauterine System Using Quantitative Modeling and Simulation Approach*. Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 14, 2017.
87. Sharma, P., Srinatha, A., Raney, S., Ghosh, P., Hashemnejad, S., Kundu, S., Repka, M., and Murthy, S. *The Systematic Influence of Changes in Manufacturing Process Variables on the Microstructure and Performance of Topical Emulsions*. Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 12, 2017.
88. Shin, S., Yu, M., Thomas, S., Hammell, D., Ghosh, P., Raney, S., Hassan, H., and Stinchcomb, A. *Evaluation of Level A In Vitro-In Vivo Correlations (IVIVC) for Nicotine and Fentanyl Transdermal Delivery Systems with Transient Heat Exposure by Using Multiple Approaches*. Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 12, 2017.
89. Shukla, S., Thomas, S., Hammell, D., Bunge, A., Hassan, H., and Stinchcomb, A. *In Vivo Evaluation of Lidocaine Bioavailability from Two Topical Patch Products by Pharmacokinetic and Skin (Tape) Stripping Analyses*. Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 12, 2017.
90. Skidmore, S., Garner, J., Park, K., Park, H., Choi, S., and Wang, Y. *The Impact of In Vitro Test Methods on Drug Release from PLGA Microparticles*. Poster Presentation at FDA Workshop: Demonstrating Equivalence of Generic Complex Drug Substances and Formulations. Silver Spring, MD, Oct. 6, 2017.
91. Stern, S., Skoczen, S., Snapp, K., Crist, R., and McNeil, S. *Novel Method to Determine Bioequivalence of Complex Drugs*. Poster Presentation at FDA Workshop: Demonstrating Equivalence of Generic Complex Drug Substances and Formulations. Silver Spring, MD, Oct. 6, 2017.
92. Suh, M., Kastellorizios, M., Zou, Y., Wang, Y., Choi, S., and Burgess, D. *Formulation and Microstructural in Situ Forming Implants: In Vitro and In Vivo*. Poster Presentation at FDA Workshop: Demonstrating Equivalence of Generic Complex Drug Substances and Formulations. Silver Spring, MD, Oct. 6, 2017.
93. Suh, M., Kastellorizios, M., Zou, Y., Wang, Y., Choi, S., and Burgess, D. *Effect of Polymer Characteristics on Formation of in Situ Forming Implants in*

Subcutaneous Tissue. Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 12, 2017.

94. Sun, W., Grosser, S., Kim, C., and Raney, S. G. *A Comparison of the European Medicines Agency (EMA) and United States Food and Drug Administration Approaches to Assessing/Comparing In Vivo Adhesion for Transdermal Delivery Systems (TDS)*. Poster Presentation at GBHI Conference. Amsterdam, NE, Apr. 10, 2018.
95. W, S., Grosser, S, Kim, C., and Raney, S. *Impact of the Statistical Approach in the United States Food and Drug Administration (US FDA)'S 2016 Draft Guidance on Assessing Adhesion with Transdermal Delivery Systems (TDS) for Abbreviated New Drug Applications (ANDAs)*. Poster Presentation at GBHI Conference. Amsterdam, NE, Apr. 10, 2018.
96. Thomas, S., Ghosh, P., Raney, S., Hammell, D., Hassan, H., and Stinchcomb, A. *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*. Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 12, 2017.
97. Tiffner, K., Bodenlenz, M., Raml, R., Raney, S., Sinner, F., Augustin, T., and Birngruber, T. *Variability of Topical Penetration Data: What Do We Learn from a BE-Study Using Dermal Open Flow Microperfusion*. Poster Presentation at Perspective in Percutaneous Penetration. La Grande Motte, France, Apr. 3, 2018.
98. Tiffner, K., Bodenlenz, M., Schimek, D., Reisenegger, P., Rantou, E., Raml, R., Raney, S., and Sinner, F. *Bioequivalence of Topical Products in Excised Human Skin Assessed with Dermal Open Flow Microperfusion (dOFM)*. Poster Presentation at Perspective in Percutaneous Penetration. La Grande Motte, France, Apr. 3, 2018.
99. Walenga, R., Babiskin, A., Absar, M., Zhang, X., Zhao, L., and Lionberger, R. *Modeling Approach for Assessing the Impact of Physicochemical Properties on Bioequivalence of Cyclosporine Ophthalmic Emulsion*. Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 14, 2017.
100. Wang, X., Patil, S., and Chen, K. *Novel Method for Bench-Top ¹⁹F NMR in Measuring API Phase Partition for Oil-in-Water Emulsion Drug Products*. Poster Presentation at FDA Workshop: Demonstrating Equivalence of Generic Complex Drug Substances and Formulations. Silver Spring, MD, Oct. 6, 2017.
101. Wang, X., Pang, E., Jiang, X., and Rogstad, S. *Identification and Quantitation of Host Cell Protein Impurities in Peptide Biotherapeutics Using Liquid Chromatography-Mass Spectrometry*. Poster Presentation at FDA Workshop: Demonstrating Equivalence of Generic Complex Drug Substances and Formulations. Silver Spring, MD, Oct. 6, 2017.
102. Wittayanukorn, S., Rosenberg, M., Schick, A., Hu, M., Wang, Z., Babiskin, A., and Zhao, L. *What Factors May Impact the Likelihood of First Abbreviated New Drug Application (ANDA) Submission for a Reference Product?* Poster Presentation at International Society for Pharmacoeconomics and Outcomes Research. Baltimore, MD, May 22, 2018.

103. Wood, E. and Tyner, K. *A Critical Evaluation of Emerging High-Resolution Imaging Technologies for the Characterization of Complex Formulations*. Poster Presentation at FDA Workshop: Demonstrating Equivalence of Generic Complex Drug Substances and Formulations. Silver Spring, MD, Oct. 6, 2017.
104. Wu, Y., Petrochenko, P., Liu, J., Manna, S., Koo, B., Myung, J., Chen, L., Choi, S., Kozak, D., and Zheng, J. *Evaluating Complex Emulsion and Liposome Morphology in Propofol Drug Products with High Resolution Cryogenic Electron Microscopy*. Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 12, 2017.
105. Yong, W., Peter, P., Bonhwe, K., Soumyarwit, M., Ja, H. M., Stephanie, C., Darby, K., and Jiwen, Z. *Revealing Complex Morphology in Propofol Drug Products Using Cryogenic Transmission Electron Microscopy (Cryo-TEM)*. Poster Presentation at FDA Workshop: Demonstrating Equivalence of Generic Complex Drug Substances and Formulations. Silver Spring, MD, Oct. 6, 2017.
106. Yu, M., Thomas, S., Hammell, D., Hassan, H., and Stinchcomb, A. *A Fully Validated LC MS/MS Method for Simultaneous Determination of Oxybutynin and Its Metabolite N-Desethyloxybutynin in Human Serum*. Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 12, 2017.
107. Zeng, K., Pang, E., and Keire, D. *Develop and Validate a LC-MS Method to Establish Impurity Profile in the RLD for Teriparatide*. Poster Presentation at FDA Workshop: Demonstrating Equivalence of Generic Complex Drug Substances and Formulations. Silver Spring, MD, Oct. 6, 2017.
108. Zeng, K., Pang, E., and Keire, D. *Therapeutic Teriparatide Peptides Quality Control by Liquid Chromatography Mass Spectrometry*. Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 12, 2017.
109. Zeng, K., Pang, E., Keire, D., Wang, X., and Rogstad, S. *Therapeutic Teriparatide Peptides Quality Control by Liquid Chromatography Mass Spectrometry*. Poster Presentation at 66th American Society for Mass Spectrometry. June 3, 2018.
110. Zhang, Q., Ghosh, P., Raney, S., Hammell, D., Hassan, H., and Stinchcomb, A. *Characterization of the Cutaneous Pharmacokinetics of Three Metronidazole Topical Drug Products Evaluated by an In Vitro Permeation Test (IVPT) with Excised Human Skin*. Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 12, 2017.
111. Zhou, J., Walker, J., Ackermann, R., Olsen, K., Hong, J., Wang, Y., Jiang, X., Schwendeman, A., and Schwendeman, S. *Development and Characterization of Composition-Equivalent Formulations to the One Month Lupron Depot*. Poster Presentation at Controlled Release Society Annual Meeting. New York City, NY, July 22, 2018.
112. Zhou, J., Hirota, K., Ackermann, R., Walker, J., Wang, Y., Choi, S., Schwendeman, A., and Schwendeman, S. *Reverse Engineering of the 1-Month Lupron Depot and Development of Q1/Q2 Formulations*. Poster Presentation at FDA Workshop: Demonstrating Equivalence of Generic Complex Drug Substances and Formulations. Silver Spring, MD, Oct. 6, 2017.
113. Zhou, J., Hirota, K., Feng, M., Doty, A., Olsen, K., Ackermann, R., Wang, Y., Choi,

- S., Schwendeman, A., and Schwendeman, S. *In Vitro In Vivo Correlation of Leuprolide Acetate-Loaded PLGA Microspheres*. Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 12, 2017.
114. Zou, L., Spanogiannopoulos, P., Ni, Z., Tsakalozou, E., Zhang, L., Turnbaugh, P., and Giacomini, K. *Interactions of Azo Dyes Commonly Used in Oral Drug Products with the Organic Anion Transporting Peptide 2b1 and Human Gut Bacteria*. Poster Presentation at ASCPT Annual Meeting. Orlando, FL, Mar. 21, 2018.
115. Wood, E. L., Tyner, K. A Critical Evaluation of Emerging High-Resolution Imaging Technologies for the Characterization of Complex Formulations. Poster Presentation at NIPTE 2018 Research Conference. Brooklyn, NY, Aug. 22, 2018.
116. Li, J., Taylor, C., Yang, M., Hughes, K., Wu, C., Tyner, K. Development of Botanicals as New Drugs: Revised Guidance and Review Experience from US FDA. Poster Presentation at International Conference on the Science of Botanicals. Oxford, MS, Apr. 11, 2018.
117. Dong, Y., Qu, H., Hengst, L., Choi, S., Absar, M., Li, V., Zheng, J., Ashraf, M., Cruz, C., and Xu, X. Phasic Mass Transfer and Trans- Membrane Diffusion in Emulsions. Poster Presentation at FDA Workshop: Demonstrating Equivalence of Generic Complex Drug Substances and Formulations. Silver Spring, MD, Oct. 6, 2017.
118. Dong, Y., Hengst, L., Patel, D., Hunt, R., Qu, H., Choi, S., Ashraf, M., Cruz, C.N., Xu, X. A Kinetic Approach to Determine Partitioning Coefficient. Poster Presentation at Controlled Release Society Annual Meeting. New York, NY, July 24, 2018.
119. Kaviratna, A., Ngo, D., Liu, X., Delvadia, R., Guo, C., Evaluation of Bio-Relevant Mouth-Throat (MT) Models to Determine the Aerosol Deposition and Particle Size Distribution of a Dry Powder inhaler (DPI). Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 12, 2017.
120. Mohamed L. A., Kamal, N., Alayoubi, A., Cruz, C. N., Ashraf, M., Zidan, A. S. "Snowflakes" in transdermal systems: Effects of drug crystallization on TDS performance. Poster Presentation at Controlled Release Society Annual Meeting. New York, NY, July 23, 2018.
121. Mohamed L. A., Kamal, N., Alayoubi, A., Cruz, C. N., Ashraf, M., Zidan, A. S. Development and validation of IVVC Model for Testosterone Transdermal Gel Products. Poster Presentation at Controlled Release Society Annual Meeting. New York, NY, July 23, 2018.
122. Externbrink, A., Sun, D., Sharan, S., Saluja, B., Gao, Z., Keire, D., and Jiang, W. Development of an In-Vitro Chewing Method for Determining Opioid Availability Following Chewing of Solid Oral Extended-Release Opioids. Poster Presentation at AAPS Annual Meeting. San Diego, CA, Nov. 14, 2017.
123. Feng, X., Balajee, V., Leissa, J., Ashraf, M., Cruz, C.N., Xu, X. Standardization of Syringe ability and Injectability Assessment for Abuse Deterrent Formulations using a Time-dependent Force-distance Profile. Poster Presentation at Controlled Release Society Annual Meeting. New York, NY, July 23, 2018.
124. Xu, X. Dissecting Drug Release from Emulsions: A balance between Kinetics and Equilibrium. Poster Presentation at Controlled Release Society Annual Meeting.

New York, NY, July 24, 2018.

125. Wang, X. Identification and Quantitation of Host Cell Protein Impurities in Peptide Therapeutics Using Liquid Chromatography-Mass Spectrometry. Poster Presentation at 4th USP Workshop on Synthetic Therapeutic Peptides: Regulations, Standards and Quality. Rockville, MD, Nov. 6, 2017.
126. Guo, C. Analytical Method Development for Ingredient-Specific Particle Sizing of Nasal Spray Suspensions. Poster Presentation at FDA Public Workshop: Orally Inhaled and Nasal Drug Products. Silver Spring, MD, Jan. 9, 2018.
127. Rodriguez, J. Development of Enhanced Analytical Tools for Evaluation of Complex Generic Products. Poster Presentation at IFPAC. Bethesda, MD, Feb. 14, 2018.
128. Xu, X., Sun, D. In Vitro and In Vivo Abuse Deterrence (AD) Evaluation of Generic Opioid Products. Poster Presentation at SBIA/FDA Complex Generic Drug Product Development Workshop. Silver Spring, MD, Sept. 12, 2018.