

Posters Relating to GDUFA Science and Research in Fiscal Year 2023

1. Abdallah I, Gabal Y, Boyce H, Zhu J, and Kim M. *A Retrospective Analysis of Pharmacokinetic Variability Between Fasting and Fasting-Sprinkle Bioequivalence Studies of Generic Modified-Release Drug Products: A Case Study on Esomeprazole Magnesium*. Poster Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 16, 2022.
2. Ako Adounvo A, Niu M, Ghosh P, Ashraf M, and Zidan A. *Development of an In Vitro Release Method for Mechlorethamine Hydrochloride Topical Gel*. Poster Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 16, 2022.
3. Al Shoyaib A, Fang L, Zhao L, and Wu F. *Assessing the Impact of Excipient and Food Intake on Bioequivalence Using PBPK and Virtual Bioequivalence Trial: A Case Example with Acyclovir Immediate Release Tablets*. Poster Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 16, 2022.
4. Anno K, Mina M, Zhang Z, Zhang L, and Jiang W. *Survey of Bioequivalence Data of Abbreviated New Drug Applications of Narrow Therapeutic Index Drug Products*. Poster Presentation at the American College of Clinical Pharmacology (ACCP) 2023 Annual Meeting. Bellevue, WA, Sep. 10, 2023.
5. Anno K, Zhang L, and Jiang W. *Generic Long-acting Injectable Product Availability and Approval Standards*. Poster Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 16, 2022.
6. Bae J, Tran T, Shon J, Kim M, and Li K. *Exploration of Food Conditions and Study Population in Bioequivalence Studies with Pharmacokinetic Endpoints for Oral Antineoplastic Drugs in Generic Drug Development*. Poster Presentation at the FDA Annual Student Scientific Research Day 2023. Virtual Meeting, Aug. 10, 2023.
7. Beringhs AO, Naageshwaran V, Gum G, Seremak D, Malla S, Vo A, Tan M-L, Babiskin A, Wang Y, and Kozak D. *Impact of Variations in Critical Quality Attributes of Brinzolamide Ophthalmic Suspensions on Preclinical Pharmacokinetics and Pharmacodynamics Following Once Daily Topical Instillations*. Poster Presentation at the 2023 Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting. New Orleans, LA, Apr. 23, 2023.
8. Beringhs AO, Naageshwaran V, Gum G, Seremak D, Malla S, Vo A, Tan M-L, Babiskin A, Wang Y, and Kozak D. *Impact of Variations in Critical Quality Attributes of Brinzolamide Ophthalmic Suspensions on Preclinical Pharmacokinetics and Pharmacodynamics Following Once Daily Topical Instillations*. Presentation at the FDA Science Forum 2023. Virtual Meeting, Jun. 14, 2023.
9. Bode C, Bhoopathy S, Mizejewski B, Wu F, Ren P, Wang Z, and Zhao L. *In Vitro Comparative Dissolution and Permeation Testing Using the In-vitro Dissolution Absorption System (IDAS) for Expanding Biowaivers to Non Q1/Q2 BCS Class III Products*. Poster Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 16, 2022.
10. Bode C, Bhoopathy S, Mizejewski B, Wu F, Ren P, Wang Z, and Zhao L. *Using the In-Vitro Dissolution Absorption System (IDAS) to Evaluate the Effects of Excipients on the Permeation of*

Putative Biopharmaceutics Classification System Class III Drugs. Poster Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 16, 2022.

11. Bodenlenz M, Augustin T, Teles Barbosa F, Birngruber T, Tiffner K, Raml R, Ramezanli T, Raney S, and Sinner F. *Dermal OFM Indicates Differences in Acyclovir Skin Permeation between Males and Females*. Poster Presentation at the Gordon Research Conference (GRC) - Barrier Function of Mammalian Skin 2023. Waterville Valley, NH, Aug. 09, 2023.
12. Burroughs L, Yenduri G, Smith W, Patri A, and Xu X. *Continuous Processing of Liposomal Nanoparticles as Potential Reference Materials for Drug Product Development*. Poster Presentation at the Controlled Release Society (CRS) 2023 Annual Meeting and Exposition. Las Vegas, NV, Jul. 24, 2023.
13. Chakma M, Usmani O, Meah S, Biddiscombe M, Bielski E, Feibus K, Natarajan K, Li K, Kinjo M, Illoh O, Han L, Newman B, and Murnane D. *The Importance of Inter-patient Peak Inspiratory Flow Variance in Simplifying DPI Prescribing in COPD: A Meta-Analysis*. Poster Presentation at the European Respiratory Society (ERS) International Congress 2023. Milan, Italy, Sep. 09, 2023.
14. Clark A, Wang R, Wang Y, Qin B, Burgess D, and Zhang S. *Assessing the Impact of Formulation on Microstructure Critical Quality Attributes in PLGA Microspheres*. Poster Presentation at the Controlled Release Society (CRS) 2023 Annual Meeting and Exposition. Las Vegas, NV, Jul. 24, 2023.
15. Clarke J, Murthy N, Zhang Y, Paterson D, Dancik Y, Djehizian A, Tsakalozou E, Ghosh P, Alam K, and Polak S. *Designing an In Vitro Study to Understand Release of API from the Dispersed Phase of Clobetasol Creams – Verification of the Mechanistic Emulsion Model in the MPML MechDerMA*. Poster Presentation at the Controlled Release Society (CRS) 2023 Annual Meeting and Exposition. Las Vegas, NV, Jul. 24, 2023.
16. Costello M, Zhang F, Liu J, Chen B, Wang Y, and Qin B. *Dexamethasone Intravitreal Implants: Manufacture, Characterization, and Elucidation of Drug Release Mechanism*. Poster Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 16, 2022.
17. Das J, Hasan M, Smith W, Graner J, Qin B, Wang Y, Park K, Tian G, and Xu X. *AI-Assisted Tool to Improve the Quality and Assessment of PLGA Formulations*. Poster Presentation at the Controlled Release Society (CRS) 2023 Annual Meeting and Exposition. Las Vegas, NV, Jul. 24, 2023.
18. Dick A, Panchal B, Prakash S, Ramezanli T, Ghosh P, Raney S, Roberts M, and Mohammed Y. *Tribological Response of Hydroxyethylcellulose Gels as a Function of Isopropyl Alcohol Concentration and Angular Velocity Profile*. Poster Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 16, 2022.
19. Dieke N, Shipman J, Sommers C, Rodriguez J, Zhang D, Kozak D, and Yang K. *High-Resolution Ion Mobility Mass Spectrometry (IMMS) for Oligonucleotide Impurity Analysis*. Poster Presentation at the FDA Science Forum 2023. Virtual Meeting, Jun. 14, 2023.
20. Don R, Lex T, Zhang L, Jiang W, and Gao Z. *In Vitro Drug Disintegration and Dissolution Testing of BCS Class I Drug Midodrine Hydrochloride Under Simulated Food-Induced Viscous Conditions*. Poster Presentation at the FDA Science Forum 2023. Virtual Meeting, Jun. 14, 2023.

21. Fpanse S, Bao Q, Zou Y, Wang Y, and Burgess D. *Role of Excipients on Drug Release from Long-Acting Intrauterine Systems*. Poster Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 16, 2022.
22. Gamage P, Jiang W, and Mudalige T. *Qualitative and Quantitative Analysis of Lipids in Exparel® Injectable Liposomal Drug Formulation*. Poster Presentation at the FDA Science Forum 2023. Virtual Meeting, Jun. 14, 2023.
23. Gan J, Juang V, Wang K, Hong K, Xia Z, Ackermman R, Olsen K, Wang Y, Liang J, Zheng J, Xu X, Park J, and Schwendeman A. *Characterization and Quantification Analysis of Onivyde Irinotecan Liposome Injection*. Poster Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 16, 2022.
24. Gao H, Thomas S, and Wu F. *Developing an R Shiny App for Dissolution Profile Similarity Analysis*. Poster Presentation at the FDA Annual Student Scientific Research Day 2023. Virtual Meeting, Aug. 10, 2023.
25. Garner J, Hadar J, Skidmore S, Jessmon F, Park H, Park K, Otte A, Xu X, Jhon Y, Qin B, and Wang Y. *Scanning Analysis of Semi-solvent Vapor Impact (SAVI): Microstructural and Compositional Analysis of Leuprolide-loaded Poly(lactide-co-glycolide) Microparticles*. Poster Presentation at the Controlled Release Society (CRS) 2023 Annual Meeting and Exposition. Las Vegas, Nevada, Jul. 24, 2023.
26. Ghosh P, Ramezanli T, and Luke M. *Facilitating Drug Development Through GDUFA Regulatory Science and Research Opportunities for Collaboration with FDA*. Poster Presentation at the Gordon Research Conference (GRC) - Barrier Function of Mammalian Skin 2023. Waterville Valley, NH, Aug. 09, 2023.
27. Hamad G, Kelchen M, Ghosh P, Ramezanli T, Raney S, Ashraf M, and Zidan A. *Evaluation of In Vitro Performance Attributes of Imvexxy® (Estradiol) Vaginal Insert*. Poster Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 16, 2022.
28. Ibrahim A, Wang F, Hollenbeck G, Mostofa A, Sun W, Boyce H, Al Ghabeish M, and Hoag S. *Strategies for Correcting Peak Fronting of Oxycodone Hydrochloride, Naloxone Hydrochloride and Related Substances Observed in Reversed - Phase Liquid Chromatography*. Poster Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 16, 2022.
29. Iliopoulos F, Pence I, Ghosh P, Raney S, Luke M, and Evans C. *Stimulated Raman Scattering (SRS) Microscopy and Deep Learning: Novel Pharmacokinetic Approach for Evaluation of Topical Bioequivalence*. Poster Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 16, 2022.
30. Islam A, Abdullah A, Sommers C, Rodriguez J, Zhang D, Kozak D, and Yang K. *Validation of HILIC-HRMS Method for Quantitative Oligonucleotide Analysis*. Poster Presentation at the American Society for Mass Spectrometry (ASMS) - 71st Conference on Mass Spectrometry and Allied Topics. Houston, TX, Jun. 04, 2023.
31. Islam M, Abdullah A, Sommers C, Rodriguez J, Zhang D, Kozak D, and Yang K. *Validation of HILIC-HRMS Method for Oligonucleotide Analysis*. Poster Presentation at the FDA Science Forum 2023. Virtual Meeting, Jun. 14, 2023.

32. Jayaraj S, Jiang W, and Mudalige T. *Doxorubicin HCl Release from Liposomal Doxorubicin Formulations Autonomous Capillary Electrophoretic (CE) In Vitro Release Test (IVRT) Method*. Poster Presentation at the FDA Science Forum 2023. Virtual Meeting, Jun. 14, 2023.
33. Kamal N, Acheampong S, Us Zaman R, Strasinger C, Norman J, Tang Y, Zidan A, and Ashraf M. *Identification of Formulation Variables Affecting the Performance of Dissolvable Microneedles*. Poster Presentation at the Microneedle Conference 2023. Seattle, WA, May 16, 2023.
34. Kamal N, Acheampong S, Us Zaman R, Strasinger C, Norman J, Tang Y, Zidan A, and Ashraf M. *Investigation of Formulation Variables Affecting the Performance of Dissolvable Microneedles*. Poster Presentation at the FDA Science Forum 2023. Virtual Meeting, Jun. 14, 2023.
35. Kelchen M, Ghosh P, Ramezanli T, and Raney S. *Developing Efficient Bioequivalence Approaches for Generic Vaginal Drug Products*. Poster Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 16, 2022.
36. Kelchen M, Xie L, Luke M, and Ghosh P. *Current Methods for Assessing Bioequivalence of Drug Products Applied to the Skin – a US FDA Perspective*. Poster Presentation at the Gordon Research Conference (GRC) - Barrier Function of Mammalian Skin 2023. Waterville Valley, NH, Aug. 09, 2023.
37. Kelchen M, Xie L, Luke M, and Ghosh P. *How Comparative Clinical Endpoint Bioequivalence Studies Facilitate the Development of Generic Topical Drug Products*. Poster Presentation at the International Dermatology Outcome Measures (IDEOM) 2023 Annual Meeting. Washington, DC, Jun. 23, 2023.
38. Koleske M, Kulkarni C, Alam K, Raw A, Rege B, Zhao L, Lu D, Zhang L, Giacomini K, Kroetz D, and Yee S. *Effects of Antioxidants in Drug Products on Intestinal Drug Transporters*. Poster Presentation at the American Society for Clinical Pharmacology and Therapeutics (ASCPT) 2023 Annual Meeting. Atlanta, GA, Mar. 23, 2023.
39. Kotsybar J, Zhang L, and Jiang W. *The Impact of Cyclodextrin on Fasting and Fed Bioequivalence Studies in Solid Oral Immediate-Release Drug Products*. Poster Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 16, 2022.
40. Kozak D, Zhu D, Zhang Y, Dong Y, Patel D, and Xu X. *Measuring Drug Partitioning and Release to Support In Vitro Bioequivalence of Generic Ophthalmic Emulsion Drugs*. Poster Presentation at the 2023 Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting. New Orleans, LA, Apr. 23, 2023.
41. Kumar S, Cook N, Gum G, Manza L, Naageshwaran V, Lyulkin M, Xu X, Patel D, Qu H, Walenga R, Tan M-L, Babiskin A, and Kaiser M. *Impact of Changes in Ophthalmic Emulsion Globule Size Distribution and Viscosity on Tear Film Thickness and Menisci Characteristics*. Poster Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 16, 2022.
42. Le Merdy M, Alqaraghuli F, and Lukacova V. *Clinical Ocular Exposure Extrapolation Using PBPK Modeling and Simulation: Besifloxacin Suspension Case Study*. Poster Presentation at the 2023 Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting. New Orleans, LA, Apr. 23, 2023.

43. Le Merdy M, and Lukacova V. *Ocular Exposure Extrapolation Across Multiple Species Using PBPK Modeling and Simulation: Latanoprost Solution Case Study*. Poster Presentation at the Population Approach Group Europe (PAGE) Annual Meeting. La Coruna, Spain, Jun. 28, 2023.
44. Li X, He X, Le Y, Guo X, Bryant M, Atrakchi A, MCGovern T, Davis Bruno K, Keire D, Heflich R, and Mei N. *Nitrosamine Drug Impurities Induce Genotoxicity in Human Lymphoblastoid TK6 Cells*. Poster Presentation at the 62nd Annual Meeting of Society of Toxicology (SOT). Nashville, TN, Mar. 19, 2023.
45. Li X, Le Y, Seo J, Guo X, Atrakchi A, MCGovern T, Davisburno K, Keire D, Heflich R, and Mei N. *Assessing the In Vitro Mutagenicity and Genotoxicity of Nitrosamine Drug Substance-Related Impurities (NDSRIs): A Case Study on N-nitroso Propranolol*. Poster Presentation at the 54th Annual Meeting of Environmental Mutagenesis and Genomics Society (EMGS). Chicago, IL, Sep. 10, 2023.
46. Lim H, Boyce H, Kim M, and Sun W. *Improving Administration Method Consistency of Product-Specific Guidances for Chewable Tablets and Tablet Products with Chewing in Labeling*. Poster Presentation at the American College of Clinical Pharmacology (ACCP) 2023 Annual Meeting. Bellevue, WA, Sep. 10, 2023.
47. Lin X, Berings A, Hargrove D, Jay M, Wang Y, Bin Q, and Lu X. *Assessing In Situ Forming Implant Formulations Using In Vivo Imaging*. Poster Presentation at the 2022 The National Institute for Pharmaceutical Technology and Education (NIPTE) Research Conference. Virtual Meeting, Nov. 29, 2022.
48. Lin X, O'Reilly Berings A, Hargrove D, Jay M, Wang Y, Bin Q, and Lu X. *Assessing In Situ Forming Implant Formulations Using In Vivo Imaging*. Poster Presentation at the 2022 NIPTE Research Conference. Virtual Meeting, Nov. 29, 2022.
49. Lin X, O'Reilly Berings A, Hargrove D, Jay M, Wang Y, Bin Q, and Lu X. *Assessing In Situ Forming Implants Using Real-Time Imaging*. Poster Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 16, 2022.
50. Lin X, Zouabi N, Ward L, Zhen Z, Masese F, Hargrove D, Yuan H, Berings A, Kasi R, Bin Q, Wang Y, and Lu X. *Assessing In Situ Forming Implant Formulations Using In Vivo Imaging*. Poster Presentation at the Controlled Release Society (CRS) 2023 Annual Meeting and Exposition. Las Vegas, NV, Jul. 24, 2023.
51. McGuire M, Mostofa A, Shon J, Frost M, Kim M, and Li K. *Swallowability of Solid Oral Drug Products in Regulatory Submissions: Patient-Specific Features, Product Physical Attributes, and Clinical Swallowability Study Designs*. Poster Presentation at the American College of Clinical Pharmacology (ACCP) 2023 Annual Meeting. Seattle, WA, Sep. 10, 2023.
52. Mekjaruskul C, Berings A, Meng T, Bin Q, Wang Y, Xu Q, Halquist M, and Lu X. *Novel In Vitro, Ex Vivo and In Vivo Assessment of Ophthalmic Semi-Solid Drug Products*. Poster Presentation at the Controlled Release Society (CRS) 2023 Annual Meeting and Exposition. Las Vegas, NV, Jul. 24, 2023.
53. Mohan A, Dhapare S, Newman B, Svensson M, Elfman P, Stuckel J, Sandell D, Winner L, Bulitta J, and Hochhaus G. *Effect of Coating of Andersen Cascade Impactor and Next Generation Impactor on the Aerodynamic Particle Size Distribution of Nine Commercial Metered Dose Inhalers*. Poster

Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 17, 2022.

54. Naageshwaran V, Gum G, Kumar S, Manza L, Lyulkin M, Cook N, Xu X, Patel D, Qu H, Walenga R, Tan M-L, Babiskin A, Kaisar M, and Kozak D. *Tear Film Thickness (TFT) is the Most Sensitive Measure to Capture Differences in the Critical Quality Attributes of a Formulation Using Anterior Optical Coherence Tomography (AS-OCT)*. Poster Presentation at the 2023 Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting. New Orleans, LA, Apr. 23, 2023.
55. Nair V, Hefnawy A, Herpin M, Feng K, Reed N, Ma T, Bielski E, Dhapare S, Newman B, Boc S, and Smyth H. *Development of a Low-Volume In-Vitro Dissolution Method for Assessing Variability in Fine Particle Doses of Dry Powder Inhalers*. Poster Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 16, 2022.
56. Nejad H, Zaman R, Smith W, Wu K, Feng X, Beringsh A, Wang Y, Kozak D, and Xu X. *Impact of Material and Manufacturing Process on Performance of a Dexamethasone Ophthalmic Implant*. Poster Presentation at the 2023 Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting. New Orleans, LA, Apr. 23, 2023.
57. Nejad H, Zaman R, Smith W, Wu K, Feng X, O'Reilly Beringsh AO, Wang Y, Kozak D, and Xu X. *Impact of Material and Manufacturing Process on Performance of an Ophthalmic Implant*. Poster Presentation at the 2023 Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting. New Orleans, LA, Apr. 23, 2023.
58. Niu M, Ghosh P, Ramezanli T, Luke M, and Raney S. *Recommendations Related to In Vitro Permeation Test Studies in Product-Specific Guidances for Topical Drug Products*. Poster Presentation at the Controlled Release Society (CRS) 2023 Annual Meeting and Exposition. Las Vegas, NV, Jul. 24, 2023.
59. Oh C, Mostofa A, Natarajan K, Sun W, Boyce H, and Kim M. *A Science-based Approach for Recommendation of Antagonist Blockade in the Bioequivalence Studies of Opioid Drug Products*. Poster Presentation at the American College of Clinical Pharmacology (ACCP) 2023 Annual Meeting. Bellevue, WA, Sep. 10, 2023.
60. Paleracio C, Nguyen D, Li K, Tsui C, Frost M, Kim M, and Shon J. *Exploration for Exclusion of Females of Reproductive Potential as a Bioequivalence Study Population in Product-Specific Guidances for Generic Drug Development*. Poster Presentation at the American Society for Clinical Pharmacology and Therapeutics (ASCPT) 2023 Annual Meeting. Atlanta, GA, Mar. 22, 2023.
61. Panchal B, Namjoshi S, Ramezanli T, Ghosh P, Raney S, Roberts M, and Mohammed Y. *In Vitro Assessment of Cooling Potential of the Topical Gel System and Influence of Inactive Ingredients*. Poster Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 16, 2022.
62. Pang E, Liao K, Holley C, Dobrovolskaia M, and Verthelyi D. *In-Vitro Assessment of Comparative Immunogenicity for Generic Synthetic Peptide Drug Products*. Poster Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 16, 2022.
63. Park S, Nguyen D, Tran T, Li K, Kim M, and Shon J. *Exploration for Exclusion of Males of Reproductive Potential as a Bioequivalence Study Population in Product-Specific Guidances for Generic Drug*

Development. Poster Presentation at the FDA Annual Student Scientific Research Day 2023. Virtual Meeting, Aug. 10, 2023.

64. Phan K, Liu D, Panchal B, Namjoshi S, Ramezanli T, Ghosh P, Raney S, Luke M, Roberts M, and Mohammed Y. *In vitro-In vivo Comparison of Cooling Sensation in Topical Gel Products*. Poster Presentation at the Controlled Release Society (CRS) 2023 Annual Meeting and Exposition. Las Vegas, NV, Jul. 24, 2023.
65. Qaraghuli F, Tan M-L, Walenga R, Babiskin A, Zhao L, Lukacova V, and Le Merdy M. *Clinical Ocular Exposure Extrapolation Using PBPK Modeling and Simulation: Gatifloxacin Solution Case Study*. Poster Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 16, 2022.
66. Qin B, Wang Y, Zhang Q, Li Q, and Kozak D. *What do We Know About PLGA Polymers in FDA-approved Drug Products: A Journey of Characterizing PLGA Polymers and Formulations*. Poster Presentation at the Controlled Release Society (CRS) 2023 Annual Meeting and Exposition. Las Vegas, NV, Jul. 24, 2023.
67. Rana M, Jordan L, Wu K, Feng X, Sun W, Xia L, Hwang S, Nwakama P, Kim M, Tampal N, Boyce H, and Tian L. *Dissolution Rate Increases for Morphine Sulfate Extended-Release Drug Product when Mixed with High pH Soft Food for Long Contact Times*. Poster Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 16, 2022.
68. Rana M, Wu K, Feng X, Sun W, Xia L, Nwakama P, Kim M, Tampal N, Abdallah I, Boyce H, and Tian L. *In Vitro Evaluation of Morphine Sulfate Extended - Release Formulation Sprinkled on Soft Foods - A Comparison of Two Dosage Strengths of T=0 M and T=6 M Drug Products*. Poster Presentation at the FDA Science Forum 2023. Virtual Meeting, Jun. 14, 2023.
69. Rangappa S, Ghosh P, Jiang Y, Raney S, and Murthy S. *Influence of Varying Amount of an Inactive Ingredient on the Microstructure and Performance of Metronidazole Topical Gels*. Poster Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 16, 2022.
70. Ren P, Yang W, Choi S, and Zhang Y. *Impact of Solubility and Dissolution Performance on Bioequivalence Recommendations for Immediate-Release Locally Acting Gastrointestinal Drug Products*. Poster Presentation at the American College of Clinical Pharmacology (ACCP) 2023 Annual Meeting. Bellevue, WA, Sep. 10, 2023.
71. Ren P. *Impact of Solubility and Dissolution Performance on Bioequivalence Recommendations for Immediate-Release Locally Acting Gastrointestinal Drug Products*. Poster Presentation at the American College of Clinical Pharmacology (ACCP) 2023 Annual Meeting. Virtual Meeting, Sep. 10, 2023.
72. Senemar S, Ramezanli T, Ghosh P, Raney S, Kuzma B, and Stagni G. *Investigation of the Relationship Between Product-Dose and Dermal Exposure of Lidocaine and Prilocaine from a Topical Cream Product Using Dermal Microdialysis*. Poster Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 16, 2022.

73. Seo J, Yu J, Mei N, Heflich R, and Guo X. *Assessment of DNA Damage–induced by 10 Nitrosamine Impurities using 2D and 3D HepaRG Models*. Poster Presentation at the 62nd Annual Meeting of Society of Toxicology (SOT). Nashville, Tennessee, Mar. 19, 2023.
74. Shukla S, Ramezanli T, Rantou E, Tiffner K, Birngruber T, Sinner F, and Raney S. *Quantitative Analysis to Discriminate Cutaneous Pharmacokinetic Profiles for Topical Drug Products*. Poster Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 16, 2022.
75. Silva D, Bao Q, Wan B, Malavia N, Burgess D, and Lukacova V. *Establishment of Preclinical Mechanistic In Vitro-In Vivo Correlations for Long-Acting Injectable Suspensions*. Poster Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 16, 2022.
76. Smith W, Feng X, Qu H, Zheng K, and Xu X. *Determining Critical Overlap Concentration of Polyethylene Oxide (PEO) to Support Excipient Safety Assessment for Opioid Products*. Poster Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 16, 2022.
77. Smith W, Liu H, Wang Y, Kozak D, and Xu X. *Impact of Formulation Processes on Dosage Form Determination of Phytonadione Injectables*. Poster Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 16, 2022.
78. Smith W, Liu H, Wang Y, Kozak D, and Xu X. *Phytonadione Injectables: Understanding Dosage Form and Formulation Processes*. Poster Presentation at the Controlled Release Society (CRS) 2023 Annual Meeting and Exposition. Las Vegas, NV, Jul. 24, 2023.
79. Smith W, Liu H, Wang Y, Kozak D, and Xu X. *Understanding Formulation Processes and Implications for Dosage Form Determination of Phytonadione Injectables*. Poster Presentation at the FDA Science Forum 2023. Virtual Meeting, Jun. 13, 2023.
80. Smith W, Qu H, Costa A, Burgess D, and Xu X. *Assessing Morphological Variation in Liposomal Drug Products using Asymmetrical Flow Field-Flow Fractionation*. Poster Presentation at the Controlled Release Society (CRS) 2023 Annual Meeting and Exposition. Las Vegas, NV, Jul. 24, 2023.
81. Smith W, Qu H, Costa A, Burgess D, and Xu X. *Investigation of Advanced Separation Techniques in the Assessment of Liposomal Drug Products Produced via Continuous Manufacturing*. Poster Presentation at the Controlled Release Society (CRS) 2023 Annual Meeting and Exposition. Las Vegas, NV, Jul. 24, 2023.
82. Spires J, Osdol W, and Lukacova V. *Development of an In Silico Model of Topical Acyclovir to Explore Formulation Design*. Poster Presentation at the Gordon Research Conference (GRC) - Barrier Function of Mammalian Skin 2023. Waterville Valley, NH, Aug. 09, 2023.
83. Telaprolu K, Arora S, Clarke J, Dancik Y, Tsakalozou E, Ghosh P, Alam K, Roberts M, and Polak S. *Evaluating Influence of Critical Quality Attributes of Metronidazole Topical Gel on Bioequivalence Using the Dermal Virtual Bioequivalence (VBE) Module in Simcyp Simulator*. Poster Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 16, 2022.
84. Wang R, Bao Q, Clark A, Wang Y, Qin B, Zhang S, and Burgess D. *Effect of Coacervation Processing Parameters on In vitro Drug Release from Minocycline Hydrochloride Microspheres*. Poster Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 16, 2022.

85. Wang R, Clark A, Bao A, Wang Y, Qin B, Zhang S, and Burgess D. *Impact of Microstructural Properties on Drug Release from PLGA Microspheres*. Poster Presentation at the Controlled Release Society (CRS) 2023 Annual Meeting and Exposition. Las Vegas, NV, Jul. 24, 2023.
86. Wu K, Rana M, Tian L, Sun W, Xia L, Nwakama P, Kim M, Tampal N, Xu X, Boyce H, and Feng X. *A Brief Review of FDA-Approved New Drug Applications Labeled with Sprinkle Administration*. Poster Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 16, 2022.
87. Wu K, Rana M, Tian L, Sun W, Xia L, Nwakama P, Kim M, Tampal N, Xu X, Boyce H, and Feng X. *In Vitro Evaluation of an Extended-Release Methylphenidate Hydrochloride Product Sprinkled on Food Vehicles*. Poster Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 16, 2022.
88. Xie L, Yue W, Kelchen M, Ghosh P, Niu M, Raney S, and Shen J. *Impact of Material Attributes on In Vitro Performance of Clindamycin Phosphate Vaginal Creams*. Poster Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 16, 2022.
89. Xin E, Babiskin A, and Al Shoyaib A. *Ensuring Therapeutic Equivalence for Drugs to be Used in Pregnant Patients: A Literature Review and Modeling Exercise to Extrapolate BE Results from Non-pregnant Individuals to Pregnant Individuals*. Poster Presentation at the FDA Annual Student Scientific Research Day 2023. Virtual Meeting, Aug. 10, 2023.
90. Xu X, Wang Y, Kozak D, Smith W, and Liu H. *Understanding Formulation Processes and Implications for Dosage Form Determination of Phytonadione Injectables*. Poster Presentation at the Controlled Release Society (CRS) 2023 Annual Meeting and Exposition. Las Vegas, Nevada, Jul. 24, 2023.
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