

Journal Articles Published Relating to GDUFA Science and Research in Fiscal Year 2020

1. Andhariya, J., Jog, R., Shen, J., Choi, S., Wang, Y., Zou, Y., and Burgess, D. *In Vitro-In Vivo Correlation of Parenteral PLGA Microspheres: Effect of Variable Burst Release*. Journal of Controlled Release. (2019) **314**:25–37. doi: [10.1016/j.jconrel.2019.10.014](https://doi.org/10.1016/j.jconrel.2019.10.014). PMID: [31654687](https://pubmed.ncbi.nlm.nih.gov/31654687/).
2. Arora, S., Pansari, A., Kilford, P., Jamei, M., Gardner, I., and Turner, D. *Biopharmaceutic In Vitro In Vivo Extrapolation (IVIV_E) Informed Physiologically-Based Pharmacokinetic Model of Ritonavir Norvir Tablet Absorption in Humans Under Fasted and Fed State Conditions*. Mol Pharm. (2020) **17**(7):2329. doi: [10.1021/acs.molpharmaceut.0c00043](https://doi.org/10.1021/acs.molpharmaceut.0c00043). PMID: [32427480](https://pubmed.ncbi.nlm.nih.gov/32427480/).
3. Baek, J., Shin, H., Koo, S., Gao, Y., Qu, H., Feng, X., Xu, X., Pinto, J., Katneni, U., Kimchi-Sarfaty, C., Buehler, P. *Polyethylene Oxide (PEO) Molecular Size Determines the Severity of Atypical Thrombotic Microangiopathy in a Guinea Pig Model of Acute Intravenous Exposure*. Toxicol Sci. (2020) **177**(1): 235-247. doi:[10.1093/toxsci/kfaa099](https://doi.org/10.1093/toxsci/kfaa099). PMID: [32579216](https://pubmed.ncbi.nlm.nih.gov/32579216/).
4. Bao, Q., Zou, Y., Wang, Y., Kozak, D., Choi, S., and Burgess, D. J. *Drug Release Testing of Long-Acting Intrauterine Systems*. Journal of Controlled Release. (2019) **316**:349–358. doi: [10.1016/j.jconrel.2019.11.015](https://doi.org/10.1016/j.jconrel.2019.11.015). PMID: [31733294](https://pubmed.ncbi.nlm.nih.gov/31733294/).
5. Bao, Q., Zou, Y., Wang, Y., Choi, S., and Burgess, D. J. *Impact of Product Design Parameters on In Vitro Release from Intrauterine Systems*. International Journal of Pharmaceutics. (2020): doi: [10.1016/j.ijpharm.2020.119135](https://doi.org/10.1016/j.ijpharm.2020.119135). PMID: [32057890](https://pubmed.ncbi.nlm.nih.gov/32057890/).
6. Barenie, R., Kesselheim, A., Gagne, J., Lu, Z., Campbell, E., Dutcher, S., Jiang, W., and Sarpatwari, A. *Preferences for and Experiences with Pill Appearance Changes: National Surveys of Patients and Pharmacists*. The American Journal of Managed Care. (2020) **26**(8):340-347. doi: [10.37765/ajmc.2020.44070](https://doi.org/10.37765/ajmc.2020.44070). PMID: [32835461](https://pubmed.ncbi.nlm.nih.gov/32835461/).
7. Bermejo, M., Hens, B., Dickens, J., Mudie, D., Paixao, P., Tsume, Y., Shedden, K., and Amidon, G. A *Mechanistic Physiologically-Based Biopharmaceutics Modeling (PBBM) Approach to Assess the In Vivo Performance of an Orally Administered Drug Product: From IVIVC to IVIVP*. Pharmaceutics. (2020) **12**(1): doi: [10.3390/pharmaceutics12010074](https://doi.org/10.3390/pharmaceutics12010074). PMID: [31963448](https://pubmed.ncbi.nlm.nih.gov/31963448/).
8. Bielski, E., Conti, D., Oguntimein, O., Sheth, P., Hallinger, M., Svensson, M., Sandell, D., Bulitta, J., and Hochhaus, G. *The Effects of Formulation Factors and Actuator Design on Mometasone Furoate Metered Dose Inhaler In Vitro Aerosolization Performance*. Respiratory Drug Delivery. (2020) **3**: 497-502.
9. Bodenlenz, M., Augustin, T., Birngruber, T., Tiffner, K., Boulgaropoulos, B., Schwingenschuh, S., Raney, S., Rantou, E., and Sinner, F. *Variability of Skin Pharmacokinetic Data: Insights from a Topical Bioequivalence Study Using Dermal Open Flow Microperfusion*. Pharmaceutical Research. (2020) **37**(10):204. DOI: [10.1007/s11095-020-02920-x](https://doi.org/10.1007/s11095-020-02920-x). PMID: [32989514](https://pubmed.ncbi.nlm.nih.gov/32989514/).
10. Bois, F., Hsieh, N-H, Gao, W., Chiu, W., Reisfeld, B. *Well-tempered MCMC simulations for population pharmacokinetic models*. J Pharmacokinet Pharmacodyn. 2020 Jul 31. doi: [10.1007/s10928-020-09705-0](https://doi.org/10.1007/s10928-020-09705-0). Online ahead of print. PMID: [32737765](https://pubmed.ncbi.nlm.nih.gov/32737765/).
11. Boyce, H., Dave, V., Scoggins, M., Gurvich, V., Smith, D., Byrn, S., and Hoag, S. *Physical Barrier Type Abuse-Deterrent Formulations: Mechanistic Understanding of Sintering-Induced Microstructural Changes in Polyethylene Oxide Placebo Tablets*. AAPS Pharm-SciTech. (2020) **21**(3):86. doi: [10.1208/s12249-019-1594-6](https://doi.org/10.1208/s12249-019-1594-6). PMID: [31997096](https://pubmed.ncbi.nlm.nih.gov/31997096/).

12. Brito, J., Ross, J., Sangaralingham, L., Dutcher, S., Graham, D., Wang, Z., Wu, Y., Yao, X., Smallridge, R., Bernet, V., Shah, N., and Lipska, K. *Comparative Effectiveness of Generic vs Brand-Name Levothyroxine in Achieving Normal Thyrotropin Levels*. JAMA Network Open. (2020) **3**(9): doi: [10.1001/jamanetworkopen.2020.17645](https://doi.org/10.1001/jamanetworkopen.2020.17645). PMID: [32997127](https://pubmed.ncbi.nlm.nih.gov/32997127/).
13. *CDER Statistical Studies Innovate Measures of Adhesion to Assess Generic Products*, In: Regulatory Science in Action, Regulatory Science Impact Story. Available at <https://www.fda.gov/drugs/regulatory-science-action/cder-statistical-studies-innovate-measures-adhesion-assess-generic-products>. Content current as of 06/25/2020.
14. Chen, L., Li, C., Huo, N., Mishuk, A. U., Hansen, R., Harris, I., Kiptanui, Z., and Qian, J. *Oral Generic Tacrolimus Initiation and Substitution in the Medicaid Population: A New User Cohort Study*. Curr Med Res Opin. 2020 Jul 22:1-8. doi: [10.1080/03007995.2020.1793750](https://doi.org/10.1080/03007995.2020.1793750). PMID: [32644886](https://pubmed.ncbi.nlm.nih.gov/32644886/).
15. Dhapare, S., Bielski, E., Conti, D., Oguntimein, O., Sheth, P., Hallinger, M., Svensson, M., Sandell, D., Bulitta, J., and Hochhaus, G. *Effects of Formulation and Actuator Design on Spray Pattern and Plume Geometry of Mometasone Furoate Metered Dose Inhalers*. Respiratory Drug Delivery. (2020) **3**: 503-507.
16. Desai, R., Gopalakrishnan, C., Dejene, S., Sarpatwari, A., Levin, R., Dutcher, S., Wang, Z., Wittayanukorn, S., Franklin, J., and Gagne, J. *Comparative Outcomes of Treatment Initiation with Brand vs. Generic Warfarin in Older Patients*. Clin Pharmacol Ther. 2020 Jun; **107**(6): 1334–1342. doi: [10.1002/cpt.1743](https://doi.org/10.1002/cpt.1743). Epub 2020 Jan 19. PMID: [31872419](https://pubmed.ncbi.nlm.nih.gov/31872419/).
17. Dong, Y., Hengst, L., Hunt, R., Feng, X., Kozak, D., Choi, S., Ashraf, M., and Xu, X. *Evaluating Drug Distribution and Release in Ophthalmic Emulsions: Impact of Release Conditions*. Journal of Controlled Release. (2020) **327**:360–370. doi: [10.1016/j.jconrel.2020.08.020](https://doi.org/10.1016/j.jconrel.2020.08.020). PMID:[32822741](https://pubmed.ncbi.nlm.nih.gov/32822741/).
18. Dong, Y., Hengst, L., Hunt, R., Patel, D., Vo, A., Choi, S., Ashraf, M., Cruz, C.N., and Xu, X. *Understanding Drug Distribution and Release in Ophthalmic Emulsions through Quantitative Evaluation of Formulation-Associated Variables*. Journal of Controlled Release. (2019) **313**:96-105. doi: [10.1016/j.jconrel.2019.09.010](https://doi.org/10.1016/j.jconrel.2019.09.010). PMID: [31536731](https://pubmed.ncbi.nlm.nih.gov/31536731/).
19. Dong, Z., Li, J., Wu, F., Zhao, P., Lee, S.-C., Zhang, L., Seo, P., and Zhang, L. *Application of Physiologically-Based Pharmacokinetic Modeling to Predict Gastric pH-Dependent Drug-Drug Interactions for Weak Base Drugs*. CPT: Pharmacometrics & Systems Pharmacology, (2020) **9**(8): 456-465. doi: [10.1002/psp4.12541](https://doi.org/10.1002/psp4.12541). PMID: [32633893](https://pubmed.ncbi.nlm.nih.gov/32633893/).
20. Elserfy, K., Kourmatzis, A., Chan, H. K., Walenga, R., and Cheng, S. *Effect of an Upstream Grid on the Fluidization of Pharmaceutical Carrier Powders*. International Journal of Pharmaceutics. (2020): doi: [10.1016/j.ijpharm.2020.119079](https://doi.org/10.1016/j.ijpharm.2020.119079). PMID: [31988029](https://pubmed.ncbi.nlm.nih.gov/31988029/).
21. Feng, X., Zidan, A., Kamal, N. S., Xu, X., Sun, D., Walenga, R., Boyce, H., Cruz, C., and Ashraf, M. *Assessing Drug Release from Manipulated Abuse Deterrent Formulations*. AAPS Pharm-SciTech. (2020) **21**(2):40. doi: [10.1208/s12249-019-1595-5](https://doi.org/10.1208/s12249-019-1595-5). PMID: [31897805](https://pubmed.ncbi.nlm.nih.gov/31897805/).
22. Gao, Z., Tian, L., and Rodriguez, J. *Nifedipine Release from Extended-Release Solid Oral Formulations Using In Vitro Dissolution Testing Under Simulated Gastrointestinal Compression*. Journal of Pharmaceutical Sciences. (2020) **109**(7):2173-2179. doi: [10.1016/j.xphs.2020.03.023](https://doi.org/10.1016/j.xphs.2020.03.023). PMID: [32240693](https://pubmed.ncbi.nlm.nih.gov/32240693/).

23. Golshahi, L., Manniello, M., Hosseini, S., Alfaifi, A., Schuman, T., Hindle, M., Longest, W., and Sandell, D. *In Vitro Bioequivalence Testing of Nasal Sprays Using Multiple Anatomically-Correct Nasal Airway Models*. *Respiratory Drug Delivery*. (2020) **1**: 155-164.
24. Hadar, J., Skidmore, S., Garner, J., Park, H., Park, K., Wang, Y., Qin, B., Jiang, X., and Kozak, D. *Method Matters: Development of Characterization Techniques for Branched and Glucose-Poly(Lactide-Co-Glycolide) Polymers*. *Journal of Controlled Release*. (2020) **320**:484–494. doi: [10.1016/j.jconrel.2020.02.005](https://doi.org/10.1016/j.jconrel.2020.02.005). PMID: [32027937](https://pubmed.ncbi.nlm.nih.gov/32027937/).
25. Herpin, M., Hefnawy, A., Smyth, H. *In Vitro Investigations into Batch-to-Batch Variability in a Fluticasone Propionate and Salmeterol Dry Powder Inhaler*. *Respiratory Drug Delivery*. (2020) **3**: 595-600.
26. Hochhaus, G., Chen, M., Shur, J., Kurumaddali, A., Schilling, U., Jiao, Y., Drescher, S., Amini, E., Seay, B., Baumstein, S., Abu Hasan, M., Hindle, M., Wei, X., Oguntimein, O., Carrasco, C., Winner, L., Delvadia, R., Saluja, B., Kandala, B., Sandell, D., Lee, S., Price, R., Conti, D., Bullitta, J. *Unraveling the Pulmonary Fate of Fluticasone and Friends: Meeting the Physiologic and Pharmacokinetic Challenges*. *Respiratory Drug Delivery*. (2020): **1**: 139-146.
27. Holtgrewe, N., Reed, N., Kaviratna, A., Rodriguez, J., Guo, C. Evaluation of the Fast Screening Impactor with Dry Powder Inhalers. *Respiratory Drug Delivery*. (2020): **3**:509-514.
28. Hosseini, S., Schuman, T., Walenga, R., Wilkins Jr., J., Babiskin, A., Golshahi, L. *Use of Anatomically-Accurate 3-dimensional Nasal Airway Models of Adult Human Subjects in a Novel Methodology to Identify and Evaluate the Internal Nasal Valve*. *Computers in Biology and Medicine*. (2020) **123**: doi: [10.1016/j.compbiomed.2020.103896](https://doi.org/10.1016/j.compbiomed.2020.103896). PMID: [32768043](https://pubmed.ncbi.nlm.nih.gov/32768043/).
29. Huo, N., Chen, L., Ullah Mishuk, A., Li, C., Hansen, R., Harris, I., Kiptanui, Z., Wang, Z., Dutcher, S., and Qian, J. *Generic Levothyroxine Initiation and Substitution among Medicare and Medicaid Populations: a New User Cohort Study*. *Endocrine*. (2020) **68**(2): 336–348. doi: [10.1007/s12020-020-02211-w](https://doi.org/10.1007/s12020-020-02211-w). PMID: [31993992](https://pubmed.ncbi.nlm.nih.gov/31993992/).
30. Jarrells, T., Zhang, D., Li, S., and Munson, E. *Quantification of Monomer Units in Insoluble Polymeric Active Pharmaceutical Ingredients Using Solid-State NMR Spectroscopy I: Patiromer*. *AAPS PharmSciTech*. (2020) **21**(3):116. doi: [10.1208/s12249-020-01654-8](https://doi.org/10.1208/s12249-020-01654-8). PMID: [32296974](https://pubmed.ncbi.nlm.nih.gov/32296974/).
31. Kamal, N., Krishnaiah, Y., Xu, X., Zidan, A., Raney, S., Cruz, C., and Ashraf, M. *Identification of Critical Formulation Parameters Affecting the In Vitro Release, Permeation, and Rheological Properties of the Acyclovir Topical Cream*. *International Journal of Pharmaceutics*. (2020) **590**: doi: [10.1016/j.ijpharm.2020.119914](https://doi.org/10.1016/j.ijpharm.2020.119914). PMID: [32979451](https://pubmed.ncbi.nlm.nih.gov/32979451/).
32. Kohno, M., Andhariya, J., Wan, B., Bao, Q., Rothstein, S., Hezel, M., Wang, Y., and Burgess, D. *The Effect of PLGA Molecular Weight Differences on Risperidone Release from Microspheres*. *International Journal of Pharmaceutics*. (2020) **582**: doi: [10.1016/j.ijpharm.2020.119339](https://doi.org/10.1016/j.ijpharm.2020.119339). PMID: [32305366](https://pubmed.ncbi.nlm.nih.gov/32305366/).
33. Kolanjiyil, A., Manniello, M., Alfaifi, A., Farkas, D., Hosseini, S., Hindle, M., Golshahi, L., and Longest, W. *Effect of Spray Momentum on Nasal Spray Droplet Transport and Deposition*. *Respiratory Drug Delivery*. (2020) **3**: 691-696.
34. Kwa, M. C., Tegtmeyer, K., Welty, L. J., Raney, S. G., Luke, M. C., Xu, S., and Kong, B. *The Relationship Between the Number of Available Therapeutic Options and Government Payer (Medicare Part D) Spending on Topical Drug Products*. *Archives of Dermatological Research*. (2020): DOI: [10.1007/s00403-020-02042-9](https://doi.org/10.1007/s00403-020-02042-9). PMID: [32055932](https://pubmed.ncbi.nlm.nih.gov/32055932/).

35. La Count, T., Zhang, Q., Hao, J., Ghosh, P., Raney, S., Talattof, A., Kasting, G., and Li, K. *Modeling Temperature-Dependent Dermal Absorption and Clearance for Transdermal and Topical Drug Applications*. The AAPS Journal. (2020) **22**(3): 70. doi: [10.1208/s12248-020-00451-2](https://doi.org/10.1208/s12248-020-00451-2). PMID: [32390069](https://pubmed.ncbi.nlm.nih.gov/32390069/).
36. La Count, T., Zhang, Q., Murawsky, M., Hao, J., Ghosh, P., Dave, K., Raney, S., Talattof, A., Kasting, G., and Li, K. *Evaluation of Heat Effects on Transdermal Nicotine Delivery In Vitro and In Silico Using Heat-Enhanced Transport Model Analysis*. The AAPS Journal. (2020) **22**(4): 82. doi: [10.1208/s12248-020-00457-w](https://doi.org/10.1208/s12248-020-00457-w). PMID: [32488395](https://pubmed.ncbi.nlm.nih.gov/32488395/).
37. Lee, J., Feng, K., Xu, M., Gong, X., Sun, W., Kim, J., Zhang, Z., Wang, M., Fang, L., and Zhao, L. *Applications of Adaptive Designs in Generic Drug Development*. Clinical Pharmacology & Therapeutics. (2020): doi: [10.1002/cpt.2050](https://doi.org/10.1002/cpt.2050). PMID: [32940349](https://pubmed.ncbi.nlm.nih.gov/32940349/).
38. LeMerdy, M., Tan, M. L., Babiskin, A., and Zhao, L. *Physiologically Based Pharmacokinetic Model to Support Ophthalmic Suspension Product Development*. AAPS Journal. (2020) **22**(2):26. doi: [10.1208/s12248-019-0408-9](https://doi.org/10.1208/s12248-019-0408-9). PMID: [31907674](https://pubmed.ncbi.nlm.nih.gov/31907674/).
39. Li, C., Chen, L., Huo, N., Mishuk, A., Hansen, R., Harris, I., Kiptanui, Z., Wang, Z., and Qian, J. *Generic Escitalopram Initiation and Substitution Among Medicare Beneficiaries: A New User Cohort Study*. PLoS One. 2020 Apr 30; **15**(4): e0232226. doi: [10.1371/journal.pone.0232226](https://doi.org/10.1371/journal.pone.0232226). PMID: [32353006](https://pubmed.ncbi.nlm.nih.gov/32353006/).
40. Liu, H., Rivnay B., Avery K., Myung J.H., Kozak, D., Landrau, N., Nivorozhkin, A., Ashraf, M., and Yoon, S. *Optimization of the Manufacturing Process of a Complex Amphotericin B Liposomal Formulation Using Quality by Design Approach*. International Journal of Pharmaceutics. (2020) Jul 30;**585**: doi: [10.1016/j.ijpharm.2020.119473](https://doi.org/10.1016/j.ijpharm.2020.119473). PMID: [32473373](https://pubmed.ncbi.nlm.nih.gov/32473373/).
41. Liu, X., Yousef, S., Anissimov, Y., Van der Hoek, J., Tsakalozou, E., Ni, Z., Grice, J., and Roberts, M. *Diffusion Modelling of Percutaneous Absorption Kinetics. Predicting Urinary Excretion from In Vitro Skin Permeation Tests (IVPT) for an Infinite Dose*. European Journal of Pharmaceutics and Biopharmaceutics. (2020) **149**:30–44. doi:[10.1016/j.ejpb.2020.01.018](https://doi.org/10.1016/j.ejpb.2020.01.018). PMID: [32018051](https://pubmed.ncbi.nlm.nih.gov/32018051/).
42. Matter, B., Ghaffari, A., Bourne, D., Wang, Y., Choi, S., and Kompella, U. *Dexamethasone Degradation in Aqueous Medium and Implications for Correction of In Vitro Release from Sustained Release Delivery Systems*. AAPS PharmSciTech. (2019) **20**(8):320. doi: [10.1208/s12249-019-1508-7](https://doi.org/10.1208/s12249-019-1508-7). PMID: [31646399](https://pubmed.ncbi.nlm.nih.gov/31646399/).
43. Miao, L., Mousa, Y. M., Zhao, L., Raines, K., Seo, P., and Wu, F. *Using a Physiologically Based Pharmacokinetic Absorption Model to Establish Dissolution Bioequivalence Safe Space for Oseltamivir in Adult and Pediatric Populations*. AAPS J. (2020) **22**(5):107. doi: [10.1208/s12248-020-00493-6](https://doi.org/10.1208/s12248-020-00493-6). PMID: [32779046](https://pubmed.ncbi.nlm.nih.gov/32779046/).
44. *Modeling Tools Could Modernize Generic Drug Development*, In: Regulatory Science in Action, Regulatory Science Impact Story. Available at [Impact Story: Modeling Tools Could Modernize Generic Drug Development | FDA](https://www.fda.gov/oc/impact-story-modeling-tools-could-modernize-generic-drug-development). Content current as of 06/02/2020.
45. Mohamed, L., Kamal, N., Elfakhri, K., Willett, D., Wokovich, A., Strasinger, C., Cruz, C., Raney, S., Ashraf, M., and Zidan, A. *Drug Recrystallization in Drug-in-Adhesive Transdermal Delivery System: A Case Study of Deteriorating the Mechanical and Rheological Characteristics of Testosterone TDS*. International Journal of Pharmaceutics. (2020) **578**: 119-132. doi: [10.1016/j.ijpharm.2020.119132](https://doi.org/10.1016/j.ijpharm.2020.119132). PMID: [32057892](https://pubmed.ncbi.nlm.nih.gov/32057892/).

46. Mohamed, L., Kamal, N., Elfakhri, K., Ibrahim, S., Ashraf, M., Zidan, A. *Application of Synthetic Membranes in Establishing Bio-predictive IVPT for Testosterone Transdermal Gel*. International Journal of Pharmaceutics. (2020) **586**:119572. DOI: [10.1016/j.ijpharm.2020.119572](https://doi.org/10.1016/j.ijpharm.2020.119572). PMID: [32599131](https://pubmed.ncbi.nlm.nih.gov/32599131/).
47. Mollenhoff, K., Loingeville, F., Bertrand, J., Nguyen, T., Sharan, S., Zhao, L., Fang, L., Sun, G., Grosser, S., Mentre, F., and Dette, H. *Efficient Model-Based Bioequivalence Testing*. Biostatistics. (2020): 1–14. doi: [10.1093/biostatistics/kxaa026](https://doi.org/10.1093/biostatistics/kxaa026). PMID: [32696053](https://pubmed.ncbi.nlm.nih.gov/32696053/).
48. Newman, B., and Witzmann, K. *Addressing the Regulatory and Scientific Challenges with Generic Orally Inhaled Drug Products*. Pharmaceutical Medicine. (2020) **34**(2): 93-102. doi: [10.1007/s40290-020-00327-y](https://doi.org/10.1007/s40290-020-00327-y). PMID: [32112304](https://pubmed.ncbi.nlm.nih.gov/32112304/).
49. O’Shaughnessy, P., LeBlanc, L., Pratt, A., Altmaier, R., Rajaraman, P., Walenga, R., and Lin, C. *Assessment and Validation of a Hygroscopic Growth Model with Different Water Activity Estimation Methods*. Aerosol Science and Technology. (2020): doi: [10.1080/02786826.2020.1763247](https://doi.org/10.1080/02786826.2020.1763247). PMID: [33100458](https://pubmed.ncbi.nlm.nih.gov/33100458/).
50. Pensado, A., Chiu, W. S., Cordery, S., Rantou, E., Bunge, A., Delgado-Charro, M., and Guy, R. *Stratum Corneum Sampling to Assess Bioequivalence Between Topical Acyclovir Products*. Pharmaceutical Research. (2019) **36**(12):180–196. DOI: [10.1007/s11095-019-2707-3](https://doi.org/10.1007/s11095-019-2707-3). PMID: [31728737](https://pubmed.ncbi.nlm.nih.gov/31728737/).
51. Pepin, X., Parrott, N., Dressman, J., Delvadia, P., Mitra, A., Zhang, X., Babiskin, A., Kolhatkar, V. and Suarez-Sharp, S. *Current State and Future Expectations of Translational Modeling Strategies to Support Drug Product Development, Manufacturing Changes and Controls: A Workshop Summary Report*. Journal of Pharmaceutical Sciences. (2020): doi: [10.1016/j.xphs.2020.04.021](https://doi.org/10.1016/j.xphs.2020.04.021).
52. Pepin, X., Dressman, J., Parrott, N., Delvadia, P., Mitra, A., Zhang, X., Babiskin, A., Kolhatkar, V., Seo, P., Taylor, L.S., Sjögren, E., Butler, J., Kostewicz, E., Tannergren, C., Koziolok, M., Kesisoglou, F., Dallman, A., Zhao, Y. and Saurez-Sharp, S. *In Vitro Biopredictive Methods: A Workshop Summary Report*. Journal of Pharmaceutical Sciences. (2020): doi: [10.1016/j.xphs.2020.09.021](https://doi.org/10.1016/j.xphs.2020.09.021).
53. Pottel J., Armstrong, D., Zou, L., Fekete, A., Huang, X-P., Torosyan, H., Bednarczyk, D., Whitebread, S., Bhatarai, B., Liang, G., Jin, H., Ghaemi, N., Slocum, S., Lukacs, K., Irwin, J., Berg, E., Giacomini, K., Roth, B., Shoichet, B., and Urban, L. *The Activities of Drug Inactive Ingredients on Biological Target*. Science. (2020) **369**(6502): 403-413. doi: [10.1126/science.aaz9906](https://doi.org/10.1126/science.aaz9906). PMID: [32703874](https://pubmed.ncbi.nlm.nih.gov/32703874/).
54. Price, R., Shur, J., Ganley, W., Farias, G., Fotaki, N., Conti, D. S., Delvadia, R., Absar, M., Saluja, B., and Lee, S. *Development of an Aerosol Dose Collection Apparatus for In Vitro Dissolution Measurements of Orally Inhaled Drug Products*. AAPS Journal. (2020) **22**(2):47. doi:[10.1208/s12248-020-0422-y](https://doi.org/10.1208/s12248-020-0422-y). PMID: [32060670](https://pubmed.ncbi.nlm.nih.gov/32060670/).
55. Rajaraman, P., Choi, J., Hoffman, E., O’Shaughnessy, P., Choi, S., Delvadia, R., Babiskin, A., Walenga, R., and Lin, C-L. *Transport and Deposition of Hygroscopic Particles in Asthmatic Subjects with and Without Airway Narrowing*. Journal of Aerosol Science. (2020): doi: [10.1016/j.jaerosci.2020.105581](https://doi.org/10.1016/j.jaerosci.2020.105581). PMID:[32346183](https://pubmed.ncbi.nlm.nih.gov/32346183/).
56. Raney, S. and Luke, M. C. *A New Paradigm for Topical Generic Drug Products: Impact on Therapeutic Access*. Journal of the American Academy of Dermatology. (2020) **82**(6):1570–1571. DOI: [10.1016/j.jaad.2020.01.062](https://doi.org/10.1016/j.jaad.2020.01.062). PMID: [32032691](https://pubmed.ncbi.nlm.nih.gov/32032691/).
57. Sandell, D. *Use of Realistic Testing for Lifecycle Changes: A Proposal for Discussion and Possible Future Regulatory Guidance*. Respiratory Drug Delivery. (2020) **1**: 131-138.

58. Sandell, D., Svensson, M., Conti, D.S., Sheth, P., Oguntimein, O., Bielski, E., Bulitta, J.B., and Hochhaus, G. *Coating Stages of Next Generation Impactor (NGI) When Testing Metered Dose Inhalers (MDIs) - A Comparative Study on US Commercial MDI Products*. *Respiratory Drug Delivery*. (2020) **2**: 463-468.
59. Shi, N., Zhou, J., Walker, J., Li, L., Hong, J., Olsen, K., Tang, J., Ackermann, R., Wang, Y., Qin, B., Schwendeman, A., and Schwendeman, S. *Microencapsulation of Luteinizing Hormone-Releasing Hormone Agonist in Poly (Lactic-Co-Glycolic Acid) Microspheres by Spray Drying*. *Journal of Controlled Release*. (2020) **321**:756–772. doi: [10.1016/j.jconrel.2020.01.023](https://doi.org/10.1016/j.jconrel.2020.01.023). PMID: [31935481](https://pubmed.ncbi.nlm.nih.gov/31935481/).
60. Shin, S., Rantou, E., Raney, S., Ghosh, P., Hassan, H., and Stinchcomb, A. *Cutaneous Pharmacokinetics of Acyclovir Cream 5% Products: Evaluating Bioequivalence with an In Vitro Permeation Test and an Adaptation of Scaled Average Bioequivalence*. *Pharmaceutical Research* (2020) **37**(10), 1-13. doi: [10.1007/s11095-020-02821-z](https://doi.org/10.1007/s11095-020-02821-z). PMID: [33001286](https://pubmed.ncbi.nlm.nih.gov/33001286/).
61. Siriwardane, D.A., Wang, C., Jiang, W. and Mudalige, T. *Quantification of Phospholipid Degradation Products in Liposomal Pharmaceutical Formulations by Ultra Performance Liquid Chromatography-Mass Spectrometry (UPLC-MS)*. (2020) *International Journal of Pharmaceutics*. (2020) **578**: doi: [10.1016/j.ijpharm.2020.119077](https://doi.org/10.1016/j.ijpharm.2020.119077). PMID: [31988036](https://pubmed.ncbi.nlm.nih.gov/31988036/).
62. Skoczen, S., Snapp, K., Crist, R., Kozak, D., Jiang, X., Liu, H., and Stern, S. *Distinguishing Pharmacokinetics of Marketed Nanomedicine Formulations Using a Stable Isotope Tracer Assay*. *ACS Pharmacology & Translational Science*. (2020) doi: [10.1021/acsptsci.0c00011](https://doi.org/10.1021/acsptsci.0c00011). PMID: [32566919](https://pubmed.ncbi.nlm.nih.gov/32566919/).
63. Stamatopoulos, K., Pathak, S., Marciani, L., and Turner, D. *Population-Based PBPK Model for the Prediction of Time Variant Bile Salt Disposition within GI Luminal Fluids*. *Mol Pharm*. (2020) **17**(4):1310: doi: [10.1021/acs.molpharmaceut.0c00019](https://doi.org/10.1021/acs.molpharmaceut.0c00019). PMID: [32176503](https://pubmed.ncbi.nlm.nih.gov/32176503/).
64. Suh, M., Patil, S., Kozak, D., Pang, E., Choi, S., Jiang, X., Rodriguez, J., Keire, D., and Chen, K. *An NMR Protocol for In Vitro Paclitaxel Release from an Albumin-Bound Nanoparticle Formulation*. *AAPS PharmSciTech*. (2020) **21**(5):136. doi: [10.1208/s12249-020-01669-1](https://doi.org/10.1208/s12249-020-01669-1). PMID: [32419122](https://pubmed.ncbi.nlm.nih.gov/32419122/).
65. Thomas, S., Shin, S., Hammell, D., Hassan, H. and Stinchcomb, A. *Effect of Controlled Heat Application on Topical Diclofenac Formulations Evaluated by In Vitro Permeation Tests (IVPT) Using Porcine and Human Skin*. *Pharmaceutical Research*. (2020) **37**(3):49. doi: [10.1007/s11095-019-2741-1](https://doi.org/10.1007/s11095-019-2741-1). PMID: [32034502](https://pubmed.ncbi.nlm.nih.gov/32034502/).
66. Van Haute, D., Jiang, W. and Mudalige, T. *Evaluation of Size-Based Distribution of Drug and Excipient in Amphotericin B Liposomal Formulation*. *International Journal of Pharmaceutics*. (2019) **569**: doi: [10.1016/j.ijpharm.2019.118603](https://doi.org/10.1016/j.ijpharm.2019.118603). PMID: [31401296](https://pubmed.ncbi.nlm.nih.gov/31401296/).
67. Vo, A., Feng, X., Patel, D., Mohammad, A., Kozak, D., Choi, S., Ashraf, M., and Xu, X. *Factors Affecting the Particle Size Distribution and Rheology of Brinzolamide Ophthalmic Suspensions*. *International Journal of Pharmaceutics*. (2020) **586**: doi: [10.1016/j.ijpharm.2020.119495](https://doi.org/10.1016/j.ijpharm.2020.119495). PMID: [32553495](https://pubmed.ncbi.nlm.nih.gov/32553495/).
68. Vo, A., Feng, X., Patel, D., Mohammad, A., Patel, M., Zheng, J., Kozak, D., Choi, S., Ashraf, M., and Xu, X. *In Vitro Physicochemical Characterization and Dissolution of Brinzolamide Ophthalmic Suspensions with Similar Composition*. *International Journal of Pharmaceutics*. (2020) **588**: doi: [10.1016/j.ijpharm.2020.119761](https://doi.org/10.1016/j.ijpharm.2020.119761). PMID: [32795488](https://pubmed.ncbi.nlm.nih.gov/32795488/).

69. Vooturi, S., Bourne, D., Jyoti Panda, J., Choi, S., Kim, H., Yandrapu, S., and Kompella, U. *Effect of Particle Size and Viscosity of Suspensions on Topical Ocular Bioavailability of Budesonide, a Corticosteroid*. *Journal of Ocular Pharmacology and Therapeutics*. (2020) **36**(6):404–409. doi: [10.1089/jop.2019.0150](https://doi.org/10.1089/jop.2019.0150). PMID: [32678687](https://pubmed.ncbi.nlm.nih.gov/32678687/).
70. Wang, C., Siriwardane, D., Jiang, W., and Mudalige, T. *Quantitative Analysis of Cholesterol Oxidation Products and Desmosterol in Parenteral Liposomal Pharmaceutical Formulations*. *International Journal of Pharmaceutics*. (2019) **569**: doi: [10.1016/j.ijpharm.2019.118576](https://doi.org/10.1016/j.ijpharm.2019.118576). PMID: [31362094](https://pubmed.ncbi.nlm.nih.gov/31362094/).
71. Wittayanukorn, S., Rosenberg, M., Schick, A., Hu, M., Wang, Z., Babiskin, A., Lionberger, R., and Zhao, L. *Factors That Have an Impact on Abbreviated New Drug Application (ANDA) Submissions*. *Therapeutic Innovation & Regulatory Science*. (2020). doi: [10.1007/s43441-020-00163-x](https://doi.org/10.1007/s43441-020-00163-x). PMID: [32495310](https://pubmed.ncbi.nlm.nih.gov/32495310/).
72. Wu, Y., Manna, S., Petrochenko, P., Koo, B., Chen, L., Xu, X., Choi, S., Kozak, D., and Zheng, J. *Coexistence of Oil Droplets and Lipid Vesicles in Propofol Drug Products*. *International Journal of Pharmaceutics*. (2020) **577**: doi: [10.1016/j.ijpharm.2019.118998](https://doi.org/10.1016/j.ijpharm.2019.118998). PMID: [31935473](https://pubmed.ncbi.nlm.nih.gov/31935473/).
73. Zhang, L. and Lionberger, R. A. *Generics 2030: Where Are We Heading in 2030 for Generic Drug Science, Research, and Regulation?* *Clinical Pharmacology & Therapeutics*. (2020) **107**(6):1293–1295. doi: [10.1002/cpt.1742](https://doi.org/10.1002/cpt.1742). PMID: [31944274](https://pubmed.ncbi.nlm.nih.gov/31944274/).
74. Zhang, Q., Murawsky, M., LaCount, T., Hao, J., Ghosh, P., Raney, S., Kasting, G., and Li, S. *Evaluation of Heat Effects on Fentanyl Transdermal Delivery Systems Using In Vitro Permeation and In Vitro Release Methods*. *Journal of Pharmaceutical Sciences*. (2020) **109**(10): 3095–3104. doi: [10.1016/j.xphs.2020.07.013](https://doi.org/10.1016/j.xphs.2020.07.013). PMID: [32702372](https://pubmed.ncbi.nlm.nih.gov/32702372/).
75. Zhao, Y., Raco, J., Kourmatzis, A., Diasinos, S., Chan, H-K., Yang, R., and Cheng, S. *The Effects of Upper Airway Tissue Motion on Air-flow Dynamics*. *Journal of Biomechanics*. (2020) **99**: doi: [10.1016/j.jbiomech.2019.109506](https://doi.org/10.1016/j.jbiomech.2019.109506). PMID: [31780123](https://pubmed.ncbi.nlm.nih.gov/31780123/).
76. Zhou, J., Walker, J., Ackermann, R., Olsen, K., Hong, J., Wang, Y., and Schwendeman, S. *Effect of Manufacturing Variables and Raw Materials on the Composition-Equivalent PLGA Microspheres for 1-Month Controlled Release of Leuprolide*. *Molecular Pharmaceutics*. (2020) **17**(5):1502–1515. doi: [10.1021/acs.molpharmaceut.9b01188](https://doi.org/10.1021/acs.molpharmaceut.9b01188). PMID: [32074448](https://pubmed.ncbi.nlm.nih.gov/32074448/).
77. Zou, L., Pottel, J., Khuri, N., Ngo, H., Ni, Z., Tsakalozou, E., Warren, M., Huang, Y., Shoichet, B., and Giacomini, K. *Interactions of Oral Molecular Excipients with Breast Cancer Resistance Protein, BCRP*. *Mol Pharm*. (2020) **17**(3):748: doi: [10.1021/acs.molpharmaceut.9b00658](https://doi.org/10.1021/acs.molpharmaceut.9b00658). PMID: [31990564](https://pubmed.ncbi.nlm.nih.gov/31990564/).
78. Zou, L., Spanogiannopoulos, P., Pieper, L., Chien, H-C., Cai, W., Khuri, N., Pottel, J., Vora, B., Ni, Z., Tsakalozou, E., Zhang, W., Shoichet, B., Giacomini, K., and Turnbaugh, P. *Bacterial Metabolism Rescues the Inhibition of Intestinal Drug Absorption by Food and Drug Additives*. *Proc Natl Acad Sci U S A* . (2020) **117**(27):16009: doi: [10.1073/pnas.1920483117](https://doi.org/10.1073/pnas.1920483117). PMID: [32571913](https://pubmed.ncbi.nlm.nih.gov/32571913/).