

Journal Articles Published Relating to GDUFA Research in Fiscal Year 2019

1. Alayoubi, A., Aqueel, M.S., Cruz, C.N., Ashraf, M., Zidan, A.S. *Application of in vitro lipolysis for the development of oral self-emulsified delivery system of Nimodipine*. Int. J. Pharm. (2019) **553**(1-2):441-453. DOI: [10.1016/j.ijpharm.2018.10.066](https://doi.org/10.1016/j.ijpharm.2018.10.066). PMID: [30385374](https://pubmed.ncbi.nlm.nih.gov/30385374/).
2. Andhariya, J., Jog, R., Shen, J., Choi, S., Wang, Y., Zou, Y., and Burgess, D. *Development of Level A In Vitro-In Vivo Correlations for Peptide Loaded PLGA Microspheres*. Journal of Controlled Release. (2019) **308**:1–13. DOI: [10.1016/j.jconrel.2019.07.013](https://doi.org/10.1016/j.jconrel.2019.07.013). PMID: [31301338](https://pubmed.ncbi.nlm.nih.gov/31301338/).
3. Andhariya, J., Shen, J., Wang, Y., Choi, S., and Burgess, D. *Effect of Minor Manufacturing Changes on Stability of Compositionally Equivalent PLGA Microspheres*. International Journal of Pharmaceutics. (2019) **566**:532–540. DOI: [10.1016/j.ijpharm.2019.06.014](https://doi.org/10.1016/j.ijpharm.2019.06.014). PMID: [31181309](https://pubmed.ncbi.nlm.nih.gov/31181309/).
4. Ansar, S.M., Jiang, W., Mudalige, T. *Direct Quantification of Unencapsulated Doxorubicin in Liposomal Doxorubicin Formulations Using Capillary Electrophoresis*. International Journal of Pharmaceutics (2018) **549** (1-2), 109-114. DOI: [10.1016/j.ijpharm.2018.07.019](https://doi.org/10.1016/j.ijpharm.2018.07.019). PMID:[29981410](https://pubmed.ncbi.nlm.nih.gov/29981410/).
5. Bai JPF, Musante CJ, Petanceska S, Zhang L, Zhao L, Zhao P. *American Society for Clinical Pharmacology and Therapeutics 2019 Annual Meeting Pre-Conferences*. CPT: Pharmacometrics & Systems Pharmacology. **8**(6):333-335, 2019. DOI [10.1002/psp4.12424](https://doi.org/10.1002/psp4.12424) PMID: [31087531](https://pubmed.ncbi.nlm.nih.gov/31087531/).
6. Bao, Q., Gu, B., Price, C., Zou, Y., Wang, Y., Kozak, D., Choi, S., and Burgess, D. *Manufacturing and Characterization of Long-Acting Levonorgestrel Intrauterine Systems*. International Journal of Pharmaceutics. (2018) **550**(43102):447–454. DOI: [10.1016/j.jconrel.2018.03.003](https://doi.org/10.1016/j.jconrel.2018.03.003). PMID: [30195080](https://pubmed.ncbi.nlm.nih.gov/30195080/).
7. Basu, S., Yang, H., Fang, L., Gonzalez-Sales, M., Zhao, L., Trame, M., Lesko, L., and Schmidt, S. *Physiologically Based Pharmacokinetic Modeling to Evaluate Formulation Factors Influencing Bioequivalence of Metoprolol Extended-Release Products*. Journal of Clinical Pharmacology. (2019) **59**(9):1252–1263. DOI: [10.1002/jcph.1017](https://doi.org/10.1002/jcph.1017). PMID: [31087553](https://pubmed.ncbi.nlm.nih.gov/31087553/).
8. Brown, J., Henriksen, C., Vozmediano, V., and Schmidt, S. *Real-World Data Approaches for Early Detection of Potential Safety and Effectiveness Signals for Generic Substitution: A Metoprolol Extended-Release Case Study*. Journal of Clinical Pharmacology. (2019) **59**(9):1275–1284. DOI: [10.1002/jcph.1436](https://doi.org/10.1002/jcph.1436). PMID: [31087552](https://pubmed.ncbi.nlm.nih.gov/31087552/).
9. Cao LN, O'Connor T, Siddiqui A, Tian G, Coowanitwong I, Abd El-Shafy M, Delvadia RR, Coburn J, Di Prima M, Lee SL, Liu X. *Supporting Inhalation Drug-Device Combination Product Quality Using 3D Printing Technology*. Respiratory Drug Delivery Europe. (2019) **1**:149-154.
10. Chockalingam, A., Xu, L., Stewart, S., LeMerdy, M., Tsakalozou, E., Fan, J., Patel, V., and Rouse, R. *Protocol for Evaluation of Topical Ophthalmic Drug Products in Different Compartments of Fresh Eye Tissues in a Rabbit Model*. Journal of Pharmacological and Toxicological Methods. (2019) **96**:9–14. DOI: [10.1016/j.vascn.2018.12.002](https://doi.org/10.1016/j.vascn.2018.12.002). PMID: [30552958](https://pubmed.ncbi.nlm.nih.gov/30552958/).
11. Choi, J. LeBlanc, L.J., Choi, S., Haghghi, B., Hoffman, EA., O'Shaughnessy, P., Wenzel, SE., Castro, M., Fain, S., Jarjour, N., Schiebler, ML., Denlinger, L., Delvadia, R., Walenga, R., Babiskin, A., Lin, CL. *Differences in Particle Deposition Between Members of Imaging-Based Asthma Clusters*. J Aerosol Med Pulm Drug Deliv. (2019) **32**(4):213-223 DOI: [10.1089/jamp.2018.1487](https://doi.org/10.1089/jamp.2018.1487). PMID: [30888242](https://pubmed.ncbi.nlm.nih.gov/30888242/).
12. Choi, S., Yoon, S., Jeon, J., Zou, C., Choi, J., Tawhai, M., Hoffman, E., Delvadia, R., Babiskin, A., Walenga, R., and Lin, C. *1d Network Simulations for Evaluating Regional Flow and Pressure Distributions in Healthy and Asthmatic Human Lungs*. Journal of Applied Physiology. (2019) **127**(1):122–133. DOI: [10.1152/jappphysiol.00016.2019](https://doi.org/10.1152/jappphysiol.00016.2019). PMID: [31095459](https://pubmed.ncbi.nlm.nih.gov/31095459/).
13. Desai, R., Sarpatwari, A., Dejene, S., Khan, N., Lii, J., Rogers, J., Dutcher, S., Raofi, S., Bohn, J., Connolly, J., Fischer, M., A, K., and Gagne, J. *Comparative Effectiveness of Generic and Brand-*

- Name Medication Use: A Database Study of US Health Insurance Claims*. PLOS Medicine. (2019) **16**(3). DOI: [10.1371/journal.pmed.1002763](https://doi.org/10.1371/journal.pmed.1002763). PMID: [30865626](https://pubmed.ncbi.nlm.nih.gov/30865626/).
14. Dong, Y., Hengst, L., Patel, D., Hunt, R., Qu, H., Choi, S., Ashraf, M., Cruz, C.N., Xu, X. *A Kinetic Approach to Determining Drug Distribution in Complex Biphasic Systems*. Journal of Pharmaceutical Sciences (2019). **108**(6), pp 2002–2011. 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/).
 15. Emoto, C., Johnson, T. N., Hahn, D., Christians, U., Alloway, R. R., Vinks, A. A., and Fukuda, T. *A Theoretical Physiologically-Based Pharmacokinetic Approach to Ascertain Covariates Explaining the Large Interpatient Variability in Tacrolimus Disposition*. CPT: Pharmacometrics & Systems Pharmacology. (2019) **8**(5):273–284. DOI: [10.1002/psp4.12392](https://doi.org/10.1002/psp4.12392). PMID: [30843669](https://pubmed.ncbi.nlm.nih.gov/30843669/).
 16. Externbrink, A., Sharan, S., Sun, D., Jiang, W., Keire, D., and Xu, X. *An In Vitro Approach for Evaluating the Oral Abuse Deterrence of Solid Oral Extended-Release Opioids with Properties Intended to Deter Abuse Via Chewing*. International Journal of Pharmaceutics. (2019) **561**:305–313. DOI: [10.1016/j.ijpharm.2019.03.017](https://doi.org/10.1016/j.ijpharm.2019.03.017). PMID: [30862508](https://pubmed.ncbi.nlm.nih.gov/30862508/).
 17. Gagne, J., Sarpatwari, A., and Desai, R. *Role of Authorized Generics in Postapproval Surveillance of Generic Drug Products*. Clinical Pharmacology & Therapeutics. (2019) **105**(2):313–315. DOI: [10.1002/cpt.1283](https://doi.org/10.1002/cpt.1283). PMID: [30593655](https://pubmed.ncbi.nlm.nih.gov/30593655/).
 18. Gomeni, R., Fang, L., Bressolle-Gomeni, F., Spencer, T. J., Faraone, S. V., and Babiskin, A. *A General Framework for Assessing IVIVC As a Tool for Maximizing the Benefit-Risk Ratio of a Treatment Using a Convolution-Based Modeling Approach*. CPT: Pharmacometrics & Systems Pharmacology. (2019) **8**(2):97–106. DOI: [10.1002/psp4.12378](https://doi.org/10.1002/psp4.12378). PMID: [30659771](https://pubmed.ncbi.nlm.nih.gov/30659771/).
 19. Gopalakrishnan, C., Gagne, J., Sarpatwari, A., Dejene, S., Dutcher, S., Levin, R., Franklin, J., Scheeweiss, S., and Desai, R. *Evaluation of Socioeconomic Status Indicators for Confounding Adjustment in Observational Studies of Medication Use*. Clinical Pharmacology & Therapeutics. (2019) **105**(6):1513–1521. DOI: [10.1002/cpt.1348](https://doi.org/10.1002/cpt.1348). PMID: [30659590](https://pubmed.ncbi.nlm.nih.gov/30659590/).
 20. Hadar, J., Skidmore, S., Garner, J., Park, H., Park, K., Wang, Y., Qin, B., and Jiang, X. *Characterization of Branched Poly(Lactide-Co-Glycolide) Polymers Used in Injectable, Long-Acting Formulations*. Journal of Controlled Release. (2019) **304**:75–89. DOI: [10.1016/j.jconrel.2019.04.039](https://doi.org/10.1016/j.jconrel.2019.04.039). PMID: [31054992](https://pubmed.ncbi.nlm.nih.gov/31054992/).
 21. Haute, D., Jiang, W., 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/).
 22. He, H., Liu, C., Liu, Y., Liu, X., Wu, Y., Fan, J., Zhao, L., Cao, Y. *Mathematical Modeling of the Heterogeneous Distributions of Nanomedicines in Solid Tumors*. European Journal of Pharmaceutics and Biopharmaceutics. (2019) **142**:153–164. DOI:[10.1016/j.ejpb.2019.06.005](https://doi.org/10.1016/j.ejpb.2019.06.005). PMID: [31226367](https://pubmed.ncbi.nlm.nih.gov/31226367/).
 23. Helmuth, M., Liu, Q., Turenne, M., Park, J., Qguntimein, M., Dutcher, S., Balkrishnan, R., Sharma, P., Zee, J., Leichtman, A., and Smith, A. *Secular Trends in the Cost of Immunosuppressants After Solid Organ Transplantation in the United States*. CJASN ePress. (2019) **14**(3):421–430. DOI: [10.2215/CJN.10590918](https://doi.org/10.2215/CJN.10590918). PMID: [30819667](https://pubmed.ncbi.nlm.nih.gov/30819667/).
 24. Hohmann, N.S., Garza, K.B., Surry, D., Hansen, R.A., Harris, I., Kiptanui, Z., Oguntimein, O., Frost, M.M. and Qian, J. *Communicating Benefits and Risks of Generic Drugs to Consumers: Patient and Caregiver Opinions of Two FDA-Developed Educational Materials*. Research in Social and Administrative Pharmacy. (2019) **15**(12):1489–1493. DOI: [10.1016/j.sapharm.2019.01.013](https://doi.org/10.1016/j.sapharm.2019.01.013). PMID: [30744957](https://pubmed.ncbi.nlm.nih.gov/30744957/).

25. Hohmann, N.S., Garza, K.B., Surry, D., Hansen, R.A., Harris, I., Kiptanui, Z., Oguntimein, O., Frost, M.M., and Qian, J. *Communicating Benefits and Risks of Generic Drugs to Consumers: Patient and Caregiver Opinions of Two FDA-Developed Educational Materials*. Res Social Adm Pharm. (2019): DOI: [10.1016/j.sapharm.2019.01.013](https://doi.org/10.1016/j.sapharm.2019.01.013). PMID: [30744957](https://pubmed.ncbi.nlm.nih.gov/30744957/).
26. Hsu, H., Yang Y., Pavuluri, V., Abraham, C., Narahariseti, S., Ashraf, M., Al-Ghabeish, M. *Effect of Formulation Variables on the Nasal Permeability and Stability of Naloxone Intranasal Formulations*. AAPS PharmSciTech (2019) **20**:232. DOI: [10.1208/s12249-019-1452-6](https://doi.org/10.1208/s12249-019-1452-6). PMID: [31236738](https://pubmed.ncbi.nlm.nih.gov/31236738/).
27. Hu, M., Babiskin, A., Wittayanukorn, S., Schick, A., Rosenberg, M., Gong, X., Kim, M.-J., Zhang, L., Lionberger, R., and Zhao, L. *Predictive Analysis of First Abbreviated New Drug Application Submission for New Chemical Entities Based on Machine Learning Methodology*. Clinical Pharmacology & Therapeutics. (2019) **106**(1):174–181. DOI: [10.1002/cpt.1479](https://doi.org/10.1002/cpt.1479). PMID: [31009066](https://pubmed.ncbi.nlm.nih.gov/31009066/).
28. Jayachandran, P., Okochi, H., Frassetto, LA., Park, W., Fang, L., Zhao, L., Benet, LZ. *Evaluating Within-Subject Variability for Narrow Therapeutic Index Drugs*. Clin Pharmacol Ther. (2019) **105**(2):411–416. DOI:[10.1002/cpt.1293](https://doi.org/10.1002/cpt.1293). PMID: [30652304](https://pubmed.ncbi.nlm.nih.gov/30652304/).
29. Kaviratna, A., Tian, G., Liu, X., Delvadia, R., Lee, S., and Guo, C. *Evaluation of Bio-Relevant Mouth-Throat Models for Characterization of Metered Dose Inhalers*. AAPS Pharm Sci Tech (2019) **20**:130: DOI: [10.1208/s12249-019-1339-6](https://doi.org/10.1208/s12249-019-1339-6). PMID: [30815748](https://pubmed.ncbi.nlm.nih.gov/30815748/).
30. Keire, D. *Manufacturing Heparin with Equivalent Chemical Composition from Different Animal Sources*. Thromb Haemost. (2019) **119**(5):688. DOI: [10.1055/s-0039-1685164](https://doi.org/10.1055/s-0039-1685164). PMID: [30965368](https://pubmed.ncbi.nlm.nih.gov/30965368/)
31. Kharasch, E. D., Neiner, A., Kraus, K., Blood, J., Stevens, A., Schweiger, J., Miller, J. P., and Lenze, E. J. *Bioequivalence and Therapeutic Equivalence of Generic and Brand Bupropion in Adults with Major Depression: A Randomized Clinical Trial*. Clin Pharmacol Ther. (2019) **105**(5):1164–1174. DOI: [10.1002/cpt.1309](https://doi.org/10.1002/cpt.1309). PMID: [30460996](https://pubmed.ncbi.nlm.nih.gov/30460996/).
32. Kim, H., Fang, L., Yu, J., Meng, Z., Trame, MN., Schmidt, S., Lesko, LJ., Zhao, L. *Is Bioequivalence Established Based on the Reference Scaled Average Bioequivalence Approach? Relevant to Chronic Administration of Phenytoin? Perspectives Based on Population Pharmacokinetic Modeling and Simulations*. J Clin Pharmacol. (2019) **59**(8):1061–1069. DOI:[10.1002/jcph.1380](https://doi.org/10.1002/jcph.1380). PMID: [30716169](https://pubmed.ncbi.nlm.nih.gov/30716169/).
33. Kim, S., Sharma, V., Lingineni, K., Farhan, N., Fang, L., Zhao, L., Brown, J., Cristofolletti, R., Vozmediano, V., Ait-Oudhia, S., Lesko, L., Trame, M., and Schmidt, S. *Evaluating the Clinical Impact of Formulation Variability: A Metoprolol Extended-Release Case Study*. The Journal of Clinical Pharmacology. (2019) **59**(9):1266–1274. DOI: [10.1002/jcph.1433](https://doi.org/10.1002/jcph.1433). PMID: [31087554](https://pubmed.ncbi.nlm.nih.gov/31087554/).
34. Kurumaddali, A., Christopher, D., Sandell, D., Strickland, H., Morgan, B., Bulitta, J., Wiggerhorn, C., Stein, S., Lyapustina, S, Hochhaus, G. *Cascade Impactor Equivalence Testing: Comparison of the Performance of the Modified Chi-Square Ratio Statistic (Mcsrs) with the Original CSRS and Ema’s Average Bioequivalence Approach*. AAPS PharmSciTech. (2019) **20**(6):249. DOI: [10.1208/s12249-019-1443-7](https://doi.org/10.1208/s12249-019-1443-7). PMID: [31286316](https://pubmed.ncbi.nlm.nih.gov/31286316/).
35. Le Merdy, M., Fan, J., Bolger, MB., Lukacova, V., Spires, J., Tsakalozou, E., Patel, V., Xu, L., Stewart, S., Chockalingam, A., Narayanasamy, S., Rouse, R., Matta, M., Babiskin, A., Kozak, D., Choi, S., Zhang, L., Lionberger, R., Zhao, L. *Application of Mechanistic Ocular Absorption Modeling and Stimulation to Understand the Impact of Formulation Properties on Ophthalmic Bioavailability in Rabbits: A Case Study Using Dexamethasone Suspension*. AAPS J. (2019) **21**(4):65. DOI: [10.1208/s12248-019-0334-x](https://doi.org/10.1208/s12248-019-0334-x). PMID: [31111305](https://pubmed.ncbi.nlm.nih.gov/31111305/).
36. Leino, A., King, E., Jiang, W., Vinks, A., Klawitter, J., Christians, U., Woodle, E., Alloway, R., and Rohan, J. *Assessment of Tacrolimus Inpatient Variability in Stable Adherent Transplant*

- Recipients: Establishing Baseline Values*. Am J Transplant. (2018) **19**(5):1410–1420. DOI: [10.1111/ajt.15199](https://doi.org/10.1111/ajt.15199). PMID: [30506623](https://pubmed.ncbi.nlm.nih.gov/30506623/).
37. Lenti, G., Norenberg, A., Farnan, J.M., Weissman, A., Cook, M., Shah, N., Moriates, C., Wallingford, S., Lynch, S., Stebbins, M., Millard, S., Samarth A., Zhang J., Thaver A., Meltzer D., Oguntimein M., Frost M., Arora V. (2019). *Development and Testing of a Web Module to IMPROVE Generic Prescribing of Oral Contraceptives Among Primary Care Physicians*. Journal of clinical pharmacy and therapeutics (2019) **44**(4):579–587. DOI: [10.1111/jcpt.12853](https://doi.org/10.1111/jcpt.12853). PMID: [31152684](https://pubmed.ncbi.nlm.nih.gov/31152684/).
38. Lesko, L., Fang, L., Schmidt, S., and Trame, M. *An Integrated Bioinformatics and Quantitative Modeling Approach to Investigate Potential Claims of Oral Generic Drug Product Bioequivalence: Introduction*. The Journal of Clinical Pharmacology. (2019) **59**(9):1245–1248. DOI: [10.1002/jcph.901](https://doi.org/10.1002/jcph.901). PMID: [31087551](https://pubmed.ncbi.nlm.nih.gov/31087551/).
39. Liu, Q., Absar, M., Saluja, B., Guo, C., Chowdhury, B., Lionberger, R., Conner, D. P., and Li, B. V. *Scientific Considerations for the Review and Approval of First Generic Mometasone Furoate Nasal Suspension Spray in the United States from the Bioequivalence Perspective*. AAPS J. (2019) **21**(2):14. DOI: [10.1208/s12248-018-0283-9](https://doi.org/10.1208/s12248-018-0283-9). PMID: [30617594](https://pubmed.ncbi.nlm.nih.gov/30617594/).
40. Mauri, L., Marinozzi, M., Phatak, N., Karfunkle, M., St. Ange, K., Guerrini, M., Keire, D.A., Linhardt, R.J. *1D and 2D-HSQC NMR: two methods to distinguish and characterize heparin from different animal and tissue sources*. Front Med. (2019) **6**(142). DOI: [10.3389/fmed.2019.00142](https://doi.org/10.3389/fmed.2019.00142). PMID: [31316989](https://pubmed.ncbi.nlm.nih.gov/31316989/).
41. Merdy, M. Fan, J., Bolger, M.B., Lukacova, V., Spires, J., Tsakalozou, E., Patel, V., Xu, L., Stewart, S., Chockalingam, A., Narayanasamy, S., Rouse, R., Matta, M., Babiskin, A., Kozak, D., Choi, S., Zhang, L., Lionberger, R., Zhao, L. *Application of Mechanistic Ocular Absorption Modeling and Stimulation to Understand the Impact of Formulation Properties on Ophthalmic Bioavailability in Rabbits: A Case Study Using Dexamethasone Suspension*. AAPS J. (2019): [10.1208/s12248-019-0334-x](https://doi.org/10.1208/s12248-019-0334-x). PMID: [31111305](https://pubmed.ncbi.nlm.nih.gov/31111305/).
42. Murawsky, M., Kelm, G. R., Kozak, D., Qin, B., Zou, Y., and Li, S. K. *Influencing Factors on Gelatin Matrix for Chlorhexidine Delivery*. Drug Development and Industrial Pharmacy. (2018) **45**(2):314–322. DOI: [10.1016/j.ijpharm.2018.10.055](https://doi.org/10.1016/j.ijpharm.2018.10.055). PMID: [30372644](https://pubmed.ncbi.nlm.nih.gov/30372644/).
43. Neu, H., Alexishin, S., Brandis, J., Williams, A., Li, W., Sun, D., Zheng, N., Jiang, W., Zimrin, A., Fink, J., Polli, J., Kane, M., and Michel, S. *Snapshots of Iron Speciation: Tracking the Fate of Iron Nanoparticle Drugs Via a Liquid Chromatography-Inductively Coupled Plasma-Mass Spectrometric Approach*. Molecular Pharmaceutics. (2019) **16**(3):1272–1281. DOI: [10.1021/acs.molpharmaceut.8b01215](https://doi.org/10.1021/acs.molpharmaceut.8b01215). PMID: [30676753](https://pubmed.ncbi.nlm.nih.gov/30676753/).
44. Park, K. *Probing the Mechanism of Drug Release from Liposomes*. Journal of Controlled Release. (2019) 294:390. DOI: [10.1016/j.jconrel.2019.01.003](https://doi.org/10.1016/j.jconrel.2019.01.003). PMID: [30660324](https://pubmed.ncbi.nlm.nih.gov/30660324/).
45. Park, K., Skidmore, S., Hadar, J., Garner, J., Park, H., Otte, A., Soh, B. K., Yoon, G., Yu, D., Yun, Y., Lee, B. K., (Jeff), X. J., Wang, Y. *Injectable, Long-Acting PLGA Formulations: Analyzing PLGA and Understanding Microparticle Formation*. (2019) **304**:125–134. DOI: [10.1016/j.jconrel.2019.05.003](https://doi.org/10.1016/j.jconrel.2019.05.003). PMID: [31071374](https://pubmed.ncbi.nlm.nih.gov/31071374/).
46. Patil, S. M., Li, V., Peng, J., Kozak, D., Xu, J., Cai, B., Keire, D. A., and Chen, K. *A Simple and Noninvasive DOSY NMR Method for Droplet Size Measurement of Intact Oil-in-Water Emulsion Drug Products*. Journal of Pharmaceutical Science. (2019) **108**:815–820. DOI: [10.1016/j.xphs.2018.09.027](https://doi.org/10.1016/j.xphs.2018.09.027). PMID: [30291851](https://pubmed.ncbi.nlm.nih.gov/30291851/).
47. Price, R., Farias, G., Ganley, W, Shur, J. *Challenging the Bioequivalence Hurdles for OINDPs:*

- Achieving Q3 Structural Equivalence*. Respiratory Drug Delivery Asia. (2018) 1:1–14.
48. Ren, W., Murawsky, M., La Count, T., Wanasathop, A., Hoa, X., Kelm, G. R., Kozak, D., Qin, B., Li, S. K. *Dissolution Chamber for Small Drug Delivery System in the Periodontal Pocket*. The AAPS Journal. (2019) **21**(3):51. DOI: [10.1208/s12248-019-0317-y](https://doi.org/10.1208/s12248-019-0317-y) PMID: [30972562](https://pubmed.ncbi.nlm.nih.gov/30972562/).
49. Rivnay, B., Wakim, J., Avery, K., Petrochenko, P., Myung, J., Kozak, D., Yoon, S., Landrau, N., Nivorozhkin, A. *Critical Process Parameters in Manufacturing of Liposomal Formulations of Amphotericin B*. International Journal of Pharmaceutics. (2019) **565**:447–457. DOI: [10.1016/j.ijpharm.2019.04.052](https://doi.org/10.1016/j.ijpharm.2019.04.052). PMID: [31071418](https://pubmed.ncbi.nlm.nih.gov/31071418/).
50. Rogstad, S., Boyne, M., Ruth, A. *Mass Spectrometry in the Characterization of Complex Drugs*. Chapter the Science and Regulation of Naturally Derived Complex Products. 139-155.
51. Ross, J. S., Rohde, S., Sangaralingham, L., Brito, J. P., Choi, L., Dutcher, S. K., Graham, D. J., Jenkins, M. R., Lipska, K. J., Mendoza, M., Qiang, Y., Wang, Z., Wu, Y., Yao, X., and Shah, N. D. *Generic and Brand-Name Thyroid Hormone Drug Use Among Commercially-Insured and Medicare Beneficiaries, 2007-2016*. The Journal of Clinical Endocrinology & Metabolism. (2019) **104**(6):2305–2314. DOI: [10.1210/jc.2018-02197](https://doi.org/10.1210/jc.2018-02197). PMID: [30690529](https://pubmed.ncbi.nlm.nih.gov/30690529/).
52. Sakagami, M., Li, H., and Venitz, J. *In Vivo-Relevant Transwell Dish-Based Dissolution Testing for Orally Inhaled Corticosteroid Products*. Pharm Res. (2019) **36**(7):95. DOI: [10.1007/s11095-019-2635-2](https://doi.org/10.1007/s11095-019-2635-2). PMID: [31073686](https://pubmed.ncbi.nlm.nih.gov/31073686/).
53. Sarpatwari, A., Gagne, J., Lu, Z., Campbell, E., Carman, W., Enger, C., Dutcher, S., Jiang, W., and Kesselheim, A. A Survey of Patients' Perceptions of Pill Appearance and Responses to Changes in Appearance for Four Chronic Disease Medications. Journal of General Internal Medicine. (2019) **34**(3):420–428. DOI: [10.1007/s11606-018-4791-1](https://doi.org/10.1007/s11606-018-4791-1). PMID: [30632102](https://pubmed.ncbi.nlm.nih.gov/30632102/).
54. Schroeter, J. D., Sheth, P., Hickey, A. J., Asgharian, B., Price, O. T., Holt, J. T., Conti, D. S., Saluja, B. *Exploring the Relationship Between Suspension and Solution Metered Dose Inhaler Formulation Variables and Predicted Lung Deposition*. Respiratory Drug Delivery Asia. (2018) **1**:111–118. DOI: [10.1002/cpt.884](https://doi.org/10.1002/cpt.884).
55. Schroeter, J. D., Sheth, P., Hickey, A. J., Asgharian, B., Price, O. T., Holt, J. T., Conti, D. S., Saluja, B. *Effects of Formulation Variables on Lung Dosimetry of Albuterol Sulfate Suspension and Beclomethasone Dipropionate Solution Metered Dose Inhalers*. AAPS PharmSciTech. (2018) **19**(5):2335–2345. DOI:[10.1208/s12249-018-1071-7](https://doi.org/10.1208/s12249-018-1071-7). PMID:[29858973](https://pubmed.ncbi.nlm.nih.gov/29858973/).
56. Segal, J. B., Onasanya, O., Daubresse, M., Lee, C.-Y., Moechtar, M., Pu, X., Dutcher, S. K., and Romanelli, R. J. *Determinants of Generic Drug Substitution in the United States*. Therapeutic Innovation & Regulatory Science. (2019): e0113. DOI: [10.1177/2168479018820050](https://doi.org/10.1177/2168479018820050). PMID: [30636440](https://pubmed.ncbi.nlm.nih.gov/30636440/).
57. Skidmore, S., Hadar, J., Garner, J., Park, H., Park, K., Wang, Y., and Jiang, X. *Complex Sameness: Separation of Mixed Poly(Lactide-Co-Glycolide)S Based on the Lactide:Glycolide Ratio*. Journal of Controlled Release. (2019) **300**:174–184. DOI: [10.1016/j.jconrel.2019.03.002](https://doi.org/10.1016/j.jconrel.2019.03.002) PMID: [30853529](https://pubmed.ncbi.nlm.nih.gov/30853529/).
58. Soumyarwit, M., Wu, Y., Wang, Y., Koo, B., Chen, L., Petrochenko, P., Dong, Y., Choi, S., Kozak, D., Oktem, B., Xu, X., and Zheng, J. *Probing the Mechanism of Bupivacaine Drug Release from Multivesicular Liposomes*. Journal of Controlled Release. (2019) **294**:279–287. DOI: [10.1016/j.jconrel.2018.12.029](https://doi.org/10.1016/j.jconrel.2018.12.029) PMID: [30576748](https://pubmed.ncbi.nlm.nih.gov/30576748/).
59. Vlioger, J., Crommelin, D., Tyner, K., Drummond, D., Jiang, W., McNeil, S., Neervannan, S., Crist, R., Shah, V. *Report of the AAPS Guidance Forum on the FDA Draft Guidance for Industry: Drug*

- Products, Including Biological Products, That Contain Nanomaterials*. The AAPS Journal. (2019) **21**(56): DOI: [10.1208/s12248-019-0329-7](https://doi.org/10.1208/s12248-019-0329-7).
60. Walenga R., Babiskin A., Zhao L. *In Silico Methods for Development of Generic Drug–Device Combination Orally Inhaled Drug Products*. CPT: Pharmacometrics & Systems Pharmacology. (2019) **8**(6):359–370. DOI: [10.1002/psp4.12413](https://doi.org/10.1002/psp4.12413). PMID: [31044532](https://pubmed.ncbi.nlm.nih.gov/31044532/).
61. Walenga, R., Babiskin, A., Zhang, X., Absar, M., Zhao, L., and Lionberger, R. *Impact of Vehicle Physicochemical Properties on Modeling-Based Predictions of Cyclosporine Ophthalmic Emulsion Bioavailability and Tear Film Breakup Time*. Journal of Pharmaceutical Sciences. (2019) **108**(1):620–629. DOI: [10.1016/j.xphs.2018.10.034](https://doi.org/10.1016/j.xphs.2018.10.034). PMID: [30385283](https://pubmed.ncbi.nlm.nih.gov/30385283/).
62. Walenga, R., Babiskin, A., Zhao, L. *In Silico Methods for Development of Generic Drug-Device Combination Orally Inhaled Drug Products*. CPT Pharmacometrics Syst Pharmacol. (2019) **8**(6):359–370. DOI: [10.1002/psp4.12413](https://doi.org/10.1002/psp4.12413). PMID: [31044532](https://pubmed.ncbi.nlm.nih.gov/31044532/).
63. 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/).
64. Wei X, Hindle M, Kaviratna A, Huynh BK, Delvadia RR, Sandell D, Byron PR. *In vitro tests for aerosol deposition. VI: realistic testing with different mouth–throat models and in vitro–in vivo correlations for a dry powder inhaler, metered dose inhaler, and soft mist inhaler*. J Aerosol Med Pulm Drug Deliv. (2018) **31**(6):358–71. DOI: [10.1089/jamp.2018.1454](https://doi.org/10.1089/jamp.2018.1454). PMID: [29878859](https://pubmed.ncbi.nlm.nih.gov/29878859/).
65. Willet, D.R., Yilmaz, H., Wokovich, A.M., Rodriguez, J.D., *Low-Frequency Raman Mapping and Multivariate Image Analysis for Complex Drug Products*, American Pharma. Rev., 19, 2019.
66. Woo, J., Luan, J., Li, Z., Grosser, S., Peters, J., and Chazin, H. *Abbreviated New Drug Applications: Generic Drug User Fee Amendments Act Analysis of Application Quality Metrics*. Therapeutic Innovation and Regulatory Science. (2018) **53**(5):696–700. DOI: [10.1177/2168479018806192](https://doi.org/10.1177/2168479018806192). PMID: [30360656](https://pubmed.ncbi.nlm.nih.gov/30360656/).
67. Xu, X., Siddiqui, A., Mohammad, A., Srinivasan, C., Rahman, Z., Korang-Yeboah, M., Feng, X., Khan, M., Ashraf, M. *Evaluation of Abuse-Deterrent Characteristics of Tablets Prepared via Hot-melt Extrusion*. AAPS PharmSciTech (2019) **20**:230. DOI: [10.1208/s12249-019-1448-2](https://doi.org/10.1208/s12249-019-1448-2). PMID: [31227939](https://pubmed.ncbi.nlm.nih.gov/31227939/).
68. Yuan, D., He, H., Wu, Y., Fan, J., and Cao, Y. *Physiologically Based Pharmacokinetic Modeling of Nanoparticles*. J. Pharm. Sci. (2019) **108**:58–72. DOI: [10.1016/j.xphs.2018.10.037](https://doi.org/10.1016/j.xphs.2018.10.037). PMID:[30385282](https://pubmed.ncbi.nlm.nih.gov/30385282/).
69. Zeng, K., Boyne, M.T., Toby, T.K., Ruzicka, R. *Impurity Characterization and Quantification by Liquid Chromatography–High-resolution Mass Spectrometry*. Peptide Therapeutics: Strategy and Tactics for Chemistry, Manufacturing and Controls. (2019) 313–342. DOI: [10.1039/9781788016445-00313](https://doi.org/10.1039/9781788016445-00313).
70. Zhao, L., Kim, MJ., Zhang, L., and Lionberger, R. *Generating Model Integrated Evidence for Generic Drug Development and Assessment*. Clin Pharmacol Ther. (2019) **105**(2):338–349. DOI: [10.1002/cpt.1282](https://doi.org/10.1002/cpt.1282). PMID: [30414386](https://pubmed.ncbi.nlm.nih.gov/30414386/).
71. Zhao, L., Seo, P., Lionberger, R. *Current Scientific Considerations to Verify Physiologically-Based Pharmacokinetic Models and Their Implications for Locally Acting Products*. CPT:

Pharmacometrics & Systems Pharmacology. (2019) **8**(6):347-351. DOI [10.1002/psp4.12421](https://doi.org/10.1002/psp4.12421).
PMID: [31355547](https://pubmed.ncbi.nlm.nih.gov/31355547/).