FDA Office of Generic Drugs Office of Research & Standards (ORS)
Journal Articles Published by External Collaborators and ORS Staff in Fiscal Year 2017

1. Andhariya JV, Choi S, Wang Y, Zou Y, Burgess DJ, Shen J. Accelerated In Vitro Release Testing Method for Naltrexone Loaded PLGA Microspheres, International Journal of Pharmaceutics 520 2017;79–85.
2. Andhariya JV, Shen J, Choi S, Wang Y, Zou Y, Burgess DJ. Development Of In Vitro-In Vivo Correlation Of Parenteral Naltrexone Loaded Polymeric Microspheres, J Control Release. 2017 Jun 10;255:27-35.
3. Bao Q, Jog R, Shen J, Newman B, Wang Y, Choi S, Burgess D. Physicochemical Attributes And Dissolution Testing Of Ophthalmic Ointments, International Journal of Pharmaceutics. 2017 May;523(1):310-319.
4. Bao Q, Shen J, Jog R, Zhang C, Newman B, Wang Y, Choi S, Burgess D. In Vitro Release Testing Method Development For Ophthalmic Ointments, International Journal of Pharmaceutics. 2017 June;526(1-2):145-156
5. Barton Pai A, Meyer DE, Bales B, Cotero V, Pai MP, Zheng N, Jiang W. Performance Of Redox Active And Chelatable Iron Assays To Determine Labile Iron Release For Intravenous Iron Formulations, Clin Transl Sci. 2017 Feb 3. doi: 10. 1111/cts. 12443.
6. Bhagwat S, Schilling U, Chen MJ, Wei X, Delvadia R, Absar M, Saluja B, Hochhaus G. Predicting Pulmonary Pharmacokinetics from In Vitro Properties of Dry Powder Inhalers, Pharmaceutical Research, 2017; DOI 10. 1007/s11095-017-2235-y.
7. Connarn JN, Flowers S, Kelly M, Luo R, Ward KM, Harrington G, Moncion I, Kamali M, McInnis M, Feng MR, Ellingrod V, Babiskin A, Zhang X, Sun D. Pharmacokinetics and Pharmacogenomics of Bupropion in Three Different Formulations with Different Release Kinetics in Healthy Human Volunteers, The AAPS Journal, 2017;19(5), 1513-1522.
8. Doty AC, Weinstein DG, Hirota K, Olsen KF, Ackermann R, Wang Y, Choi S, Schwendeman SP. Mechanisms of in vivo release of triamcinolone acetonide from PLGA microspheres, J Control Release. 2017 Jun 28;256:19-25.
9. Gagne JJ, Polinski JM, Jiang W, Dutcher S, Xie J, Lii J, Fulchino LA, Kesselheim AS. Outcomes Associated with Generic Drugs Approved using Product-Specific Determinations of Therapeutic Equivalence,2017 Mar;77(4):427-433.
10. Gomeni R, Bressolle-Gomeni FMM, Spencer TJ, Faraone SV, Fang L, Babiskin A. Model-Based Approach for Optimizing Study Design and Clinical Drug Performances of Extended-Release Formulations of Methylphenidate for the Treatment of Attention-Deficit Hyperactivity Disorder, Clin Pharmacol Ther. 2017;doi: 10.
11. González-Sales M, Fang L, Kim MJ, Zhao L. Model Based Assessment of Using Conventional BE Limits to Ensure Safety and Efficacy of Rivaroxaban in Patients Undergoing Hip or Knee Replacement, Journal of Clinical Pharmacology. 2017;doi: 10.
12. Hansen RA, Qian J, Berg R, Linneman J, Seoane-Vazquez E, Dutcher S, Raofi S, Page CD, Peissig P. Comparison Of Generic-To-Brand Switchback Patterns For Generic And Authorized Generic Drugs, Pharmacotherapy. 2017 Apr;37(4):429-437.

13. Irwin JJ, Pottel J, Zou L, Wen H, Zuk S, Zhang X, Sterling T, Shoichet BK, Lionberger R, Giacomini KM. A Molecular Basis For Innovation In Drug Excipients, Clin Pharmacol Ther. 2017;101(3):320-323.
14. Kannan R, Chen ZJ, Singh N, Przekwas A, Delvadia R, Tian G, Walenga R. Pharmaceutical Aerosols Deposition Patterns From A Dry Powder Inhaler: Euler Lagrangian Prediction And Validation, Med Eng Phys. 2017;42:35-47.
15. Kesselheim AS, Gagne JJ, Franklin JM, Eddings W, Fulchino LA, Campbell EG. Do patients trust the FDA? A survey assessing how patients view generic drugs approved via product-specific regulatory pathways, Pharmacoepidemiol Drug Saf. 2017;26(6):694-701.
16. Leal LB, Cordery SF, Delgado-Charro MB, Bunge AL, Guy RH. Bioequivalence Methodologies For Topical Drug Products: In Vitro And Ex Vivo Studies With A Corticosteroid And An Anti Fungal Drug, Pharm Res. 2017 Apr;34(4):730-737. doi: 10. 1007/s11095-017-2099-1.
17. Matsui K, Tsume Y, Takeuchi S, Searls A, Amidon GL. Utilization of Gastrointestinal Simulator, and in vivo predictive dissolution methodology, coupled with computational approach to forecast oral absorption of dipyridamole, Mol Pharm. 2017;14(4):1181-1189.
18. Rahman MM, Alatawi Y, Cheng N, Qian J, Plotkina AV, Peissig PL, Berg RL, Page D, Hansen RA. Comparison of brand versus generic antiepileptic drug adverse event reporting rates in the U. S, Food and Drug Administration Adverse Event Reporting System (FAERS). 2017;135:71-78.
19. Romanelli RJ, Nimbal V, Dutcher SK, Pu X, Segal JB. Provider and Patient Determinants of Generic Levothyroxine Prescribing: An Electronic Health Records-Based Study, Ann Pharmacother. 2017;51(8):640-648.
20. Sheth P, Sandell D, Conti DS, Holt JT, Hickey AJ, Saluja B. Influence Of Formulation Factors On The Aerosol Performance Of Suspension And And Solution Metered Dose Inhalers: A Systematic Approach, The AAPS Journal, Research Article, 07 June 2017, DOI: 10. 1208/s12248-017-0095-3.
21. Shin S, Ghosh P, Newman B, Hammell D, Raney S, Hassan H. On the Road to Development of an in Vitro Permeation Test Model to Compare Heat Effects on Transdermal Delivery Systems: Exploratory Studies with Nicotine and Fentanyl, Pharm Res. 2017 Sep;34(9):1817-1830. doi: 10. 1007/s11095-017-2189-0.
22. Trasi N, Purohit H, Wen H, Sun D, Taylor L. Non-Sink Dissolution Behavior And Solubility Limit Of Commercial Tacrolimus Amorphous Formulation, Journal of Pharmaceutical Sciences. 2017;106:264-272.
23. Tsume Y, Matsui K, Searls AL, Takeuchi S, Amidon GE, Sun D, Amidon GL. The impact of supersaturation level for oral absorption of BCS class IIb drugs, dipyridamole and ketoconazole, using in vivo predictive dissolution system: Gastrointestinal Simulator (GIS), Eur J Pharm Sci. 2017;102:126-39.
24. Wang J, Lee GY, Kennard R, Barillaro G, Bisiewicz RH, Cortez Lemus NA, Cao XC, Anglin EJ, Park JS, Potocny A, Bernhard D, Li J, Sailor MJ. Engineering The Properties Of Polymer Photonic Crystals With Mesoporous Silicon Templates, Chem. Mater. 2017;29:1263-1272; DOI: 10. 1021/acs. chemmater. 6b04670.
25. Wang Y, Qu W, Choi S. FDA's Regulatory Science Program for Generic PLA/PLGA-Based Drug Products, American Pharmaceutical Review.

26. Yousef S, Mohammed Y, Namjoshi S, Grice J, Sakran W, Roberts M. Mechanistic Evaluation Of Hydration Effects On The Human Epidermal Permeation Of Salicylate Esters, AAPS J. 2017;19(1):180-190.
27. Yu A, Baker JR, Fioritto AF, Wang Y, Luo R, Li S, Wen B, Bly M, Tsume Y, Koenigsknecht MJ, Zhang X, Lionberger R, Amidon GL, Hasler WL, Sun D. Measurement Of In Vivo Gastrointestinal Release And Dissolution Of Three Locally Acting Mesalamine Formulations In Regions Of The Human Gastrointestinal Tract, Mol Pharm. 2017;14(2):345-358.
28. Yuan W, Kuai R, Dai Z, Yuan Y, Zheng N, Jiang W, Noble C, Hayes M, Szoka FC, Schwendeman A. Development of a Flow-Through USP-4 Apparatus Drug Release Assay to Evaluate Doxorubicin Liposomes, AAPS J. 2017;19(1):150-160.
29. Zhang Q, Murawsky M, LaCount T, Hao J, Kasting GB, Newman B, Ghosh P, Raney SG, Li SK. Characterization Of Temperature Profiles In Skin And Transdermal Delivery System When Exposed To Temperature Gradients In Vivo And In Vitro, Pharm Res. 2017;34:1491–1504 DOI 10. 1007/s11095-017-2171-x.