Robert A Lionberger

List of Publications by Year
in descending order

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79 papers	3,404 citations	136740 32 h-index	143772 57 g-index
83 all docs	83 docs citations	83 times ranked	3164 citing authors

#	Article	IF	Citations
1	Quality by Design: Concepts for ANDAs. AAPS Journal, 2008, 10, 268-276.	2.2	263
2	Applications of process analytical technology to crystallization processes. Advanced Drug Delivery Reviews, 2004, 56, 349-369.	6.6	262
3	Generic Development of Topical Dermatologic Products: Formulation Development, Process Development, and Testing of Topical Dermatologic Products. AAPS Journal, 2013, 15, 41-52.	2.2	200
4	Bioequivalence Approaches for Highly Variable Drugs and Drug Products. Pharmaceutical Research, 2008, 25, 237-241.	1.7	181
5	High frequency modulus of hard sphere colloids. Journal of Rheology, 1994, 38, 1885-1908.	1.3	178
6	Utility of Physiologically Based Absorption Modeling in Implementing Quality by Design in Drug Development. AAPS Journal, 2011, 13, 59-71.	2.2	117
7	In vitro and in vivo characterizations of PEGylated liposomal doxorubicin. Bioanalysis, 2011, 3, 333-344.	0.6	96
8	Implementation of a Reference-Scaled Average Bioequivalence Approach for Highly Variable Generic Drug Products by the US Food and Drug Administration. AAPS Journal, 2012, 14, 915-924.	2.2	96
9	Low Buffer Capacity and Alternating Motility along the Human Gastrointestinal Tract: Implications for in Vivo Dissolution and Absorption of Ionizable Drugs. Molecular Pharmaceutics, 2017, 14, 4281-4294.	2.3	94
10	FDA Critical Path Initiatives: Opportunities for Generic Drug Development. AAPS Journal, 2008, 10, 103-109.	2.2	90
11	The role of predictive biopharmaceutical modeling and simulation in drug development and regulatory evaluation. International Journal of Pharmaceutics, 2011, 418, 151-160.	2.6	81
12	Pharmacokinetics-Based Approaches for Bioequivalence Evaluation of Topical Dermatological Drug Products. Clinical Pharmacokinetics, 2015, 54, 1095-1106.	1.6	72
13	Novel bioequivalence approach for narrow therapeutic index drugs. Clinical Pharmacology and Therapeutics, 2015, 97, 286-291.	2.3	70
14	A Smoluchowski theory with simple approximations for hydrodynamic interactions in concentrated dispersions. Journal of Rheology, 1997, 41, 399-425.	1.3	69
15	Generic lamotrigine versus brandâ€name <scp>Lamictal</scp> bioequivalence in patients with epilepsy: A field test of the <scp>FDA</scp> bioequivalence standard. Epilepsia, 2015, 56, 1415-1424.	2.6	68
16	Effect of Device Design on the In Vitro Performance and Comparability for Capsule-Based Dry Powder Inhalers. AAPS Journal, 2012, 14, 667-676.	2.2	67
17	Scientific considerations in the review and approval of generic enoxaparin in the United States. Nature Biotechnology, 2013, 31, 220-226.	9.4	67
18	Development of performance matrix for generic product equivalence of acyclovir topical creams. International Journal of Pharmaceutics, 2014, 475, 110-122.	2.6	64

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19	Current Challenges in Bioequivalence, Quality, and Novel Assessment Technologies for Topical Products. Pharmaceutical Research, 2014, 31, 837-846.	1.7	61
20	Modeling and Simulation of the Effect of Proton Pump Inhibitors on Magnesium Homeostasis. 1. Oral Absorption of Magnesium. Molecular Pharmaceutics, 2012, 9, 3495-3505.	2.3	60
21	Generic Development of Topical Dermatologic Products, Part II: Quality by Design for Topical Semisolid Products. AAPS Journal, 2013, 15, 674-683.	2.2	57
22	In Vivo Predictive Dissolution (IPD) and Biopharmaceutical Modeling and Simulation: Future Use of Modern Approaches and Methodologies in a Regulatory Context. Molecular Pharmaceutics, 2017, 14, 1307-1314.	2.3	48
23	International Guidelines for Bioequivalence of Locally Acting Orally Inhaled Drug Products: Similarities and Differences. AAPS Journal, 2015, 17, 546-557.	2.2	46
24	In Vivo Dissolution and Systemic Absorption of Immediate Release Ibuprofen in Human Gastrointestinal Tract under Fed and Fasted Conditions. Molecular Pharmaceutics, 2017, 14, 4295-4304.	2.3	46
25	A Bioequivalence Approach for Generic Narrow Therapeutic Index Drugs: Evaluation of the Reference-Scaled Approach and Variability Comparison Criterion. AAPS Journal, 2015, 17, 891-901.	2.2	45
26	Generating Model Integrated Evidence for Generic Drug Development and Assessment. Clinical Pharmacology and Therapeutics, 2019, 105, 338-349.	2.3	45
27	Innovative approaches for demonstration of bioequivalence: the US FDA perspective. Therapeutic Delivery, 2013, 4, 725-740.	1.2	40
28	Measurement of in vivo Gastrointestinal Release and Dissolution of Three Locally Acting Mesalamine Formulations in Regions of the Human Gastrointestinal Tract. Molecular Pharmaceutics, 2017, 14, 345-358.	2.3	39
29	Viscosity of bimodal and polydisperse colloidal suspensions. Physical Review E, 2002, 65, 061408.	0.8	35
30	Pharmaceutical Equivalence by Design for Generic Drugs: Modified-Release Products. Pharmaceutical Research, 2011, 28, 1445-1453.	1.7	32
31	Use of Partial AUC to Demonstrate Bioequivalence of Zolpidem Tartrate Extended Release Formulations. Pharmaceutical Research, 2012, 29, 1110-1120.	1.7	32
32	Using Partial Area for Evaluation of Bioavailability and Bioequivalence. Pharmaceutical Research, 2011, 28, 1939-1947.	1.7	31
33	Effectiveness of nonequilibrium closures for the many body forces in concentrated colloidal dispersions. Journal of Chemical Physics, 1997, 106, 402-416.	1.2	30
34	Clinical, Pharmacokinetic, and In Vitro Studies to Support Bioequivalence of Ophthalmic Drug Products. AAPS Journal, 2016, 18, 1032-1038.	2.2	30
35	Impact of P-Glycoprotein-Mediated Intestinal Efflux Kinetics on Oral Bioavailability of P-Glycoprotein Substratesâ€. Molecular Pharmaceutics, 2004, 1, 455-465.	2.3	27
36	Effects of Device and Formulation on In Vitro Performance of Dry Powder Inhalers. AAPS Journal, 2012, 14, 400-409.	2.2	25

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37	Spreadability Measurements to Assess Structural Equivalence (Q3) of Topical Formulationsâ€"A Technical Note. AAPS PharmSciTech, 2008, 9, 84-86.	1.5	24
38	Gastric emptying and intestinal appearance of nonabsorbable drugs phenol red and paromomycin in human subjects: A multi-compartment stomach approach. European Journal of Pharmaceutics and Biopharmaceutics, 2018, 129, 162-174.	2.0	24
39	Microscopic Theories of the Rheology of Stable Colloidal Dispersions. Advances in Chemical Physics, 2007, , 399-474.	0.3	23
40	Use of Partial Area under the Curve Metrics to Assess Bioequivalence of Methylphenidate Multiphasic Modified Release Formulations. AAPS Journal, 2012, 14, 925-926.	2.2	22
41	IntegratingIn Vitro, Modeling, andIn VivoApproaches to Investigate Warfarin Bioequivalence. CPT: Pharmacometrics and Systems Pharmacology, 2017, 6, 523-531.	1.3	22
42	Application of Mechanistic Ocular Absorption Modeling and Simulation to Understand the Impact of Formulation Properties on Ophthalmic Bioavailability in Rabbits: a Case Study Using Dexamethasone Suspension. AAPS Journal, 2019, 21, 65.	2.2	22
43	US FDA Question-Based Review for Generic Drugs: A New Pharmaceutical Quality Assessment System. Journal of Generic Medicines, 2007, 4, 239-246.	0.0	21
44	Linking the Gastrointestinal Behavior of Ibuprofen with the Systemic Exposure between and within Humansâ€"Part 1: Fasted State Conditions. Molecular Pharmaceutics, 2018, 15, 5454-5467.	2.3	21
45	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, 620-629.	1.6	21
46	Modeling and Simulation of Biopharmaceutical Performance. Clinical Pharmacology and Therapeutics, 2014, 95, 480-482.	2.3	20
47	Current Scientific Considerations to Verify Physiologicallyâ€Based Pharmacokinetic Models and Their Implications for Locally Acting Products. CPT: Pharmacometrics and Systems Pharmacology, 2019, 8, 347-351.	1.3	20
48	Innovation for Generic Drugs: Science and Research Under the Generic Drug User Fee Amendments of 2012. Clinical Pharmacology and Therapeutics, 2019, 105, 878-885.	2.3	20
49	Shear thinning of colloidal dispersions. Journal of Rheology, 1998, 42, 843-863.	1.3	19
50	CDER Risk Assessment Exercise to Evaluate Potential Risks from the Use of Nanomaterials in Drug Products. AAPS Journal, 2013, 15, 623-628.	2.2	18
51	A Stability Analysis of a Modified Version of the Chi-Square Ratio Statistic: Implications for Equivalence Testing of Aerodynamic Particle Size Distribution. AAPS Journal, 2013, 15, 1-9.	2.2	17
52	Modelâ€Informed Drug Development and Review for Generic Products: Summary of FDA Public Workshop. Clinical Pharmacology and Therapeutics, 2018, 104, 27-30.	2.3	17
53	Confidence in Generic Drug Substitution. Clinical Pharmacology and Therapeutics, 2013, 94, 438-440.	2.3	16
54	Scientific Considerations for the Review and Approval of First Generic Mometasone Furoate Nasal Suspension Spray in the United States from the Bioequivalence Perspective. AAPS Journal, 2019, 21, 14.	2.2	13

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55	Generic omeprazole delayed-release capsules: in vitro performance evaluations. Drug Development and Industrial Pharmacy, 2009, 35, 917-921.	0.9	12
56	A Sensitivity Analysis of the Modified Chi-square Ratio Statistic for Equivalence Testing of Aerodynamic Particle Size Distribution. AAPS Journal, 2013, 15, 465-476.	2.2	12
57	A Molecular Basis for Innovation in Drug Excipients. Clinical Pharmacology and Therapeutics, 2017, 101, 320-323.	2.3	12
58	Linking the Gastrointestinal Behavior of Ibuprofen with the Systemic Exposure between and within Humansâ€"Part 2: Fed State. Molecular Pharmaceutics, 2018, 15, 5468-5478.	2.3	12
59	Equivalence Testing of Complex Particle Size Distribution Profiles Based on Earth Moverâ€™s Distance. AAPS Journal, 2018, 20, 62.	2.2	11
60	Analysis of Bead Sizes for MR Capsules Labeled for Sprinkle. AAPS PharmSciTech, 2010, 11, 1508-1510.	1.5	9
61	Predictive Analysis of First Abbreviated New Drug Application Submission for New Chemical Entities Based on Machine Learning Methodology. Clinical Pharmacology and Therapeutics, 2019, 106, 174-181.	2.3	9
62	Bioequivalence for Liposomal Drug Products. AAPS Advances in the Pharmaceutical Sciences Series, 2014, , 275-296.	0.2	7
63	Application of the Modified Chi-Square Ratio Statistic in a Stepwise Procedure for Cascade Impactor Equivalence Testing. AAPS Journal, 2015, 17, 370-379.	2.2	7
64	In Vivo Predictive Dissolution and Simulation Workshop Report: Facilitating the Development of Oral Drug Formulation and the Prediction of Oral Bioperformance. AAPS Journal, 2018, 20, 100.	2.2	7
65	Research and Education Needs for Complex Generics. Pharmaceutical Research, 2021, 38, 1991-2001.	1.7	7
66	Modeling and mechanistic approaches for oral absorption: quality by design in action. Therapeutic Delivery, 2012, 3, 147-150.	1.2	6
67	Use of Partial Area Under the Curve in Bioavailability or Bioequivalence Assessments: A Regulatory Perspective. Clinical Pharmacology and Therapeutics, 2021, 110, 880-887.	2.3	5
68	Generic Drugs: Expanding Possibilities for Clinical Pharmacology. Clinical Pharmacology and Therapeutics, 2019, 105, 278-281.	2.3	4
69	Factors that have an Impact on Abbreviated New Drug Application (ANDA) Submissions. Therapeutic Innovation and Regulatory Science, 2020, 54, 1372-1381.	0.8	4
70	Decision Science for Generic Drug Development and Review. Journal of Clinical Pharmacology, 2019, 59, 1249-1251.	1.0	3
71	Completeness Assessment of Type II Active Pharmaceutical Ingredient Drug Master Files under Generic Drug User Fee Amendment: Review Metrics and Common Incomplete Items. AAPS Journal, 2014, 16, 1132-1141.	2.2	2
72	Generics 2030: Where Are We Heading in 2030 for Generic Drug Science, Research, and Regulation?. Clinical Pharmacology and Therapeutics, 2020, 107, 1293-1295.	2.3	2

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73	Particle size affects pharmacokinetics of milled oxycodone hydrochloride tablet products following nasal insufflation in nondependent, recreational opioid users. Clinical and Translational Science, 2021, 14, 1977-1987.	1.5	2
74	Association of partial systemic exposure and abuse potential for opioid analgesics with abuse deterrence labeling claims supporting product-specific guidance. EClinicalMedicine, 2021, 41, 101135.	3.2	2
75	Bioavailability and Bioequivalence. , 2008, , 262-289.		2
76	Associated and polymerically stabilized dispersions. , 1999, , .		0
77	Regulatory Aspects of Dissolution for Low Solubility Drug Products. , 2008, , 101-112.		0
78	PATTERNS OF BIOEQUIVALENCE RECOMMENDATIONS AND TRENDS OF ABBREVIATED NEW DRUG APPLICATIONS APPROVAL OVER TIME. Value in Health, 2016, 19, A286.	0.1	0
79	Regulatory Aspects of Microdialysis: A United States Food and Drug Administration Perspective. AAPS Advances in the Pharmaceutical Sciences Series, 2013, , 67-80.	0.2	0