Michael J Pikal

List of Publications by Citations

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128 papers	9,559 citations	55 h-index	95 g-index
130 ext. papers	10,260 ext. citations	4.2 avg, IF	6.32 L-index

#	Paper	IF	Citations
128	Design of freeze-drying processes for pharmaceuticals: practical advice. *Pharmaceutical Research*, **2004**, 21, 191-200	4.5	609
127	Rational design of stable lyophilized protein formulations: some practical advice. *Pharmaceutical Research*, **1997**, 14, 969-75	4.5	514
126	Role of thermodynamic, molecular, and kinetic factors in crystallization from the amorphous state. *Journal of Pharmaceutical Sciences*, **2008**, 97, 1329-49	3.9	328
125	Mechanism of protein stabilization by sugars during freeze-drying and storage: native structure preservation, specific interaction, and/or immobilization in a glassy matrix?. *Journal of Pharmaceutical Sciences*, **2005**, 94, 1427-44	3.9	318
124	Characterization of the Time Scales of Molecular Motion in Pharmaceutically Important Glasses. *Journal of Physical Chemistry B*, **1999**, 103, 4113-4121	3.4	304
123	Protein stability during freezing: separation of stresses and mechanisms of protein stabilization. *Pharmaceutical Development and Technology*, **2007**, 12, 505-23	3.4	301
122	Solubility advantage of amorphous pharmaceuticals: I. A thermodynamic analysis. *Journal of Pharmaceutical Sciences*, **2010**, 99, 1254-64	3.9	286
121	The role of electroosmotic flow in transdermal iontophoresis. *Advanced Drug Delivery Reviews*, **2001**, 46, 281-305	18.5	240
120	The collapse temperature in freeze drying: Dependence on measurement methodology and rate of water removal from the glassy phase. *International Journal of Pharmaceutics*, **1990**, 62, 165-186	6.5	224
119	The effects of formulation variables on the stability of freeze-dried human growth hormone. *Pharmaceutical Research*, **1991**, 8, 427-36	4.5	222
118	Mechanisms of protein stabilization in the solid state. *Journal of Pharmaceutical Sciences*, **2009**, 98, 2886-908	3.9	202
117	Determination of end point of primary drying in freeze-drying process control. *AAPS PharmSciTech*, **2010**, 11, 73-84	3.9	175
116	Heat and mass transfer scale-up issues during freeze drying: II. Control and characterization of the degree of supercooling. *AAPS PharmSciTech*, **2004**, 5, e58	3.9	162
115	Solubility advantage of amorphous pharmaceuticals: II. Application of quantitative thermodynamic relationships for prediction of solubility enhancement in structurally diverse insoluble pharmaceuticals. *Pharmaceutical Research*, **2010**, 27, 2704-14	4.5	156
114	Effect of sorbitol and residual moisture on the stability of lyophilized antibodies: Implications for the mechanism of protein stabilization in the solid state. *Journal of Pharmaceutical Sciences*, **2005**, 94, 1445-55	3.9	138
113	Freeze-drying process design by manometric temperature measurement: design of a smart freeze-dryer. *Pharmaceutical Research*, **2005**, 22, 685-700	4.5	136
112	Effect of initial buffer composition on pH changes during far-from-equilibrium freezing of sodium phosphate buffer solutions. *Pharmaceutical Research*, **2001**, 18, 90-7	4.5	126

111	The stability of insulin in crystalline and amorphous solids: observation of greater stability for the amorphous form. *Pharmaceutical Research*, **1997**, 14, 1379-87	4.5	122
110	Heat and mass transfer scale-up issues during freeze-drying, I: atypical radiation and the edge vial effect. *AAPS PharmSciTech*, **2003**, 4, E14	3.9	122
109	Dynamics of pharmaceutical amorphous solids: the study of enthalpy relaxation by isothermal microcalorimetry. *Journal of Pharmaceutical Sciences*, **2002**, 91, 1853-62	3.9	121
108	The challenge of drying method selection for protein pharmaceuticals: product quality implications. *Journal of Pharmaceutical Sciences*, **2007**, 96, 1886-916	3.9	119
107	A spectroscopic investigation of hydrogen bond patterns in crystalline and amorphous phases in dihydropyridine calcium channel blockers. *Pharmaceutical Research*, **2002**, 19, 477-83	4.5	119
106	Interpretation of relaxation time constants for amorphous pharmaceutical systems. *Journal of Pharmaceutical Sciences*, **2000**, 89, 417-27	3.9	116
105	Calorimetric investigation of the structural relaxation of amorphous materials: evaluating validity of the methodologies. *Journal of Pharmaceutical Sciences*, **2005**, 94, 948-65	3.9	115
104	The role of electroosmotic flow in transdermal iontophoresis. *Advanced Drug Delivery Reviews*, **1992**, 9, 201-237	18.5	111
103	Stabilization of proteins in solid form. *Advanced Drug Delivery Reviews*, **2015**, 93, 14-24	18.5	107
102	Evaluation of tunable diode laser absorption spectroscopy for in-process water vapor mass flux measurements during freeze drying. *Journal of Pharmaceutical Sciences*, **2007**, 96, 1776-93	3.9	105
101	Transport mechanisms in iontophoresis. II. Electroosmotic flow and transference number measurements for hairless mouse skin. *Pharmaceutical Research*, **1990**, 7, 213-21	4.5	105
100	Transport mechanisms in iontophoresis. I. A theoretical model for the effect of electroosmotic flow on flux enhancement in transdermal iontophoresis. *Pharmaceutical Research*, **1990**, 7, 118-26	4.5	104
99	Lyophilized Drug Product Cake Appearance: What Is Acceptable?. *Journal of Pharmaceutical Sciences*, **2017**, 106, 1706-1721	3.9	96
98	Aqueous solubility of crystalline and amorphous drugs: Challenges in measurement. *Pharmaceutical Development and Technology*, **2011**, 16, 187-200	3.4	94
97	Transport mechanisms in iontophoresis. III. An experimental study of the contributions of electroosmotic flow and permeability change in transport of low and high molecular weight solutes. *Pharmaceutical Research*, **1990**, 7, 222-9	4.5	94
96	Drying-induced variations in physico-chemical properties of amorphous pharmaceuticals and their impact on stability (I): stability of a monoclonal antibody. *Journal of Pharmaceutical Sciences*, **2007**, 96, 1983-2008	3.9	90
95	Freeze-Drying of Proteins. *ACS Symposium Series*, **1994**, 120-133	0.4	89
94	Study of the individual contributions of ice formation and freeze-concentration on isothermal stability of lactate dehydrogenase during freezing. *Journal of Pharmaceutical Sciences*, **2008**, 97, 798-814	3.9	87

93	Solubility advantage of amorphous pharmaceuticals, part 3: Is maximum solubility advantage experimentally attainable and sustainable?. *Journal of Pharmaceutical Sciences*, **2011**, 100, 4349-56	3.9	86
92	Coupling between chemical reactivity and structural relaxation in pharmaceutical glasses. *Pharmaceutical Research*, **2006**, 23, 2254-68	4.5	86
91	The effect of stabilizers and denaturants on the cold denaturation temperatures of proteins and implications for freeze-drying. *Pharmaceutical Research*, **2005**, 22, 1167-75	4.5	86
90	Interpretation of relaxation time constants for amorphous pharmaceutical systems. *Journal of Pharmaceutical Sciences*, **2000**, 89, 417	3.9	84
89	Stability testing of pharmaceuticals by high-sensitivity isothermal calorimetry at 25°C: cephalosporins in the solid and aqueous solution states. *International Journal of Pharmaceutics*, **1989**, 50, 233-252	6.5	83
88	Impact of sucrose level on storage stability of proteins in freeze-dried solids: II. Correlation of aggregation rate with protein structure and molecular mobility. *Journal of Pharmaceutical Sciences*, **2009**, 98, 3145-66	3.9	82
87	Drying-induced variations in physico-chemical properties of amorphous pharmaceuticals and their impact on Stability II: stability of a vaccine. *Pharmaceutical Research*, **2007**, 24, 715-27	4.5	82
86	Solid state chemistry of proteins: II. The correlation of storage stability of freeze-dried human growth hormone (hGH) with structure and dynamics in the glassy solid. *Journal of Pharmaceutical Sciences*, **2008**, 97, 5106-21	3.9	80
85	Freeze-drying of mannitol-trehalose-sodium chloride-based formulations: the impact of annealing on dry layer resistance to mass transfer and cake structure. *Pharmaceutical Development and Technology*, **2004**, 9, 85-95	3.4	77
84	Reduced pressure ice fog technique for controlled ice nucleation during freeze-drying. *AAPS PharmSciTech*, **2009**, 10, 1406-11	3.9	67
83	Prediction of the onset of crystallization of amorphous sucrose below the calorimetric glass transition temperature from correlations with mobility. *Journal of Pharmaceutical Sciences*, **2007**, 96, 1258-69	3.9	66
82	Emerging freeze-drying process development and scale-up issues. *AAPS PharmSciTech*, **2011**, 12, 372-8	3.9	63
81	Prediction of onset of crystallization from experimental relaxation times. II. Comparison between predicted and experimental onset times. *Journal of Pharmaceutical Sciences*, **2008**, 97, 455-72	3.9	63
80	Heat and mass transfer scale-up issues during freeze-drying, III: control and characterization of dryer differences via operational qualification tests. *AAPS PharmSciTech*, **2006**, 7, E39	3.9	63
79	Choked flow and importance of Mach I in freeze-drying process design. *Chemical Engineering Science*, **2010**, 65, 5716-5727	4.4	62
78	Predictions of onset of crystallization from experimental relaxation times I-correlation of molecular mobility from temperatures above the glass transition to temperatures below the glass transition. *Pharmaceutical Research*, **2006**, 23, 2277-90	4.5	58
77	A pragmatic test of a simple calorimetric method for determining the fragility of some amorphous pharmaceutical materials. *Pharmaceutical Research*, **1998**, 15, 762-7	4.5	57
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73	The effect of temperature on hydrogen bonding in crystalline and amorphous phases in dihydropyrine calcium channel blockers. *Pharmaceutical Research*, **2002**, 19, 484-90	4.5	55
72	Impact of sucrose level on storage stability of proteins in freeze-dried solids: I. Correlation of protein-sugar interaction with native structure preservation. *Journal of Pharmaceutical Sciences*, **2009**, 98, 3131-44	3.9	54
71	Role of mechanical stress in crystallization and relaxation behavior of amorphous indomethacin. *Journal of Pharmaceutical Sciences*, **2008**, 97, 4446-58	3.9	54
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69	Measurement of the kinetics of protein unfolding in viscous systems and implications for protein stability in freeze-drying. *Pharmaceutical Research*, **2005**, 22, 1176-85	4.5	50
68	Use of manometric temperature measurement (MTM) and SMART freeze dryer technology for development of an optimized freeze-drying cycle. *Journal of Pharmaceutical Sciences*, **2007**, 96, 3402-18	3.9	49
67	Lyophilization process design space. *Journal of Pharmaceutical Sciences*, **2013**, 102, 3883-7	3.9	46
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63	Non-invasive product temperature determination during primary drying using tunable diode laser absorption spectroscopy. *Journal of Pharmaceutical Sciences*, **2009**, 98, 3406-18	3.9	41
62	Solid state chemistry of proteins: I. glass transition behavior in freeze dried disaccharide formulations of human growth hormone (hGH). *Journal of Pharmaceutical Sciences*, **2007**, 96, 2765-76	3.9	39
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60	The study of phase separation in amorphous freeze-dried systems. Part I: Raman mapping and computational analysis of XRPD data in model polymer systems. *Journal of Pharmaceutical Sciences*, **2011**, 100, 206-22	3.9	38
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57	Freeze-Drying Process Development and Scale-Up: Scale-Up of Edge Vial Versus Center Vial Heat Transfer Coefficients, K. *Journal of Pharmaceutical Sciences*, **2016**, 105, 3333-3343	3.9	37
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55	Investigation of drying stresses on proteins during lyophilization: differentiation between primary and secondary-drying stresses on lactate dehydrogenase using a humidity controlled mini freeze-dryer. *Journal of Pharmaceutical Sciences*, **2007**, 96, 61-70	3.9	36
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45	Evaluation of manometric temperature measurement, a process analytical technology tool for freeze-drying: part II measurement of dry-layer resistance. *AAPS PharmSciTech*, **2006**, 7, 93	3.9	29
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40	Effect of Controlled Ice Nucleation on Stability of Lactate Dehydrogenase During Freeze-Drying. *Journal of Pharmaceutical Sciences*, **2018**, 107, 824-830	3.9	26

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38	Optical coherence tomography-based freeze-drying microscopy. *Biomedical Optics Express*, **2012**, 3, 55-63	3.5	25
37	Reliable determination of freeze-concentration using DSC. *Thermochimica Acta*, **2005**, 425, 149-163	2.9	24
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35	Chemical stability of amorphous materials: specific and general media effects in the role of water in the degradation of freeze-dried zoniporide. *Journal of Pharmaceutical Sciences*, **2012**, 101, 3110-23	3.9	20
34	The study of amorphous phase separation in a model polymer phase-separating system using Raman microscopy and a low-temperature stage: effect of cooling rate and nucleation temperature. *Journal of Pharmaceutical Sciences*, **2011**, 100, 1362-76	3.9	20
33	Different measures of molecular mobility: comparison between calorimetric and thermally stimulated current relaxation times below Tg and correlation with dielectric relaxation times above Tg. *Journal of Pharmaceutical Sciences*, **2008**, 97, 4498-515	3.9	20
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31	Impact of critical process and formulation parameters affecting in-process stability of lactate dehydrogenase during the secondary drying stage of lyophilization: a mini freeze dryer study. *Journal of Pharmaceutical Sciences*, **2007**, 96, 2242-50	3.9	19
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29	Stability of Freeze-Dried Protein Formulations: Contributions of Ice Nucleation Temperature and Residence Time in the Freeze-Concentrate. *Journal of Pharmaceutical Sciences*, **2020**, 109, 1896-1904	3.9	18
28	Effect of sugars on the molecular motion of freeze-dried protein formulations reflected by NMR relaxation times. *Pharmaceutical Research*, **2011**, 28, 3237-47	4.5	18
27	The glass transition and sub-T(g)-relaxation in pharmaceutical powders and dried proteins by thermally stimulated current. *Journal of Pharmaceutical Sciences*, **2009**, 98, 81-93	3.9	18
26	Freeze-drying in novel container system: Characterization of heat and mass transfer in glass syringes. *Journal of Pharmaceutical Sciences*, **2010**, 99, 3188-204	3.9	18
25	Investigations on polyplex stability during the freezing step of lyophilization using controlled ice nucleation--the importance of residence time in the low-viscosity fluid state. *Journal of Pharmaceutical Sciences*, **2013**, 102, 929-46	3.9	17
24	The impact of thermal treatment on the stability of freeze dried amorphous pharmaceuticals: I. Dimer formation in sodium ethacrynate. *Journal of Pharmaceutical Sciences*, **2010**, 99, 663-82	3.9	17
23	A test of the onsager reciprocal relations and a discussion of the ionic isothermal vector transport coefficientsl Ij for aqueous AgNO3 at 25C. *Journal of Solution Chemistry*, **1972**, 1, 111-130	1.8	17
22	Effects of annealing on enthalpy relaxation in lyophilized disaccharide formulations: mathematical modeling of DSC curves. *Journal of Pharmaceutical Sciences*, **2008**, 97, 3084-99	3.9	16

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18	Freezing of Aqueous Solutions and Chemical Stability of Amorphous Pharmaceuticals: Water Clusters Hypothesis. *Journal of Pharmaceutical Sciences*, **2019**, 108, 36-49	3.9	13
17	Determination and comparison of Hittorf and cell transference numbers for aqueous silver nitrate solutions at 25.deg.. *The Journal of Physical Chemistry*, **1970**, 74, 1337-1344		12
16	Addition of Monovalent Electrolytes to Improve Storage Stability of Freeze-Dried Protein Formulations. *Journal of Pharmaceutical Sciences*, **2016**, 105, 530-541	3.9	11
15	Impact of Natural Variations in Freeze-Drying Parameters on Product Temperature History: Application of Quasi Steady-State Heat and Mass Transfer and Simple Statistics. *AAPS PharmSciTech* , **2018**, 19, 2828-2842	3.9	11
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13	Solid state chemistry of proteins IV. What is the meaning of thermal denaturation in freeze dried proteins?. *Journal of Pharmaceutical Sciences*, **2009**, 98, 1387-99	3.9	9
12	Simultaneous measurement of water desorption isotherm and heats of water desorption of proteins using perfusion isothermal microcalorimetry. *Journal of Pharmaceutical Sciences*, **2007**, 96, 1974-82	3.9	9
11	Chemistry in solid amorphous matrices: Implication for biostabilization257-272		7
10	Dynamics in Polysaccharide Glasses and Their Impact on the Stability of Encapsulated Flavors. *Food Biophysics*, **2016**, 11, 20-33	3.2	6
9	Carbon-deuterium rotational-echo double-resonance NMR spectroscopy of lyophilized aspartame formulations. *Journal of Pharmaceutical Sciences*, **2012**, 101, 283-90	3.9	6
8	Applications of the Tunable Diode Laser Absorption Spectroscopy: In-Process Estimation of Primary Drying Heterogeneity and Product Temperature During Lyophilization. *Journal of Pharmaceutical Sciences*, **2019**, 108, 416-430	3.9	6
7	Protein Internal Dynamics Associated With Pre-System Glass Transition Temperature Endothermic Events: Investigation of Insulin and Human Growth Hormone by Solid State Hydrogen/Deuterium Exchange. *Journal of Pharmaceutical Sciences*, **2016**, 105, 3290-3295	3.9	5
6	Freeze drying properties of some oligonucleotides. *Pharmaceutical Development and Technology*, **2001**, 6, 151-7	3.4	4
5	Lyophilization of Therapeutic Proteins in Vials: Process Scale-Up and Advances in Quality by Design **2015**, 121-156		1
4	Stabilization of Lyophilized Pharmaceuticals by Control of Molecular Mobility: Impact of Thermal History **2010**, 521-548		1

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2	THE FREEZE DRYING PROCESS **2019**, 293-309		
1	The Freeze-Drying Process: The Use of Mathematical Modeling in Process Design, Understanding, and Scale-Up801-817		