

Binodh S Desilva

List of Publications by Year in Descending Order

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The third column is the impact factor (IF) of the journal, and the fourth column is the number of citations of the article.

63

papers

2,395

citations

21

h-index

48

g-index

74

ext. papers

2,688

ext. citations

3.3

avg, IF

3.93

L-index

#	Paper	IF	Citations
63	Biomarker Assay Validation by Mass Spectrometry.. <i>AAPS Journal</i> , 2022 , 24, 66	3.7	2
62	Report on the AAPS Immunogenicity Guidance Forum. <i>AAPS Journal</i> , 2019 , 21, 55	3.7	7
61	Evaluating a Multiscale Mechanistic Model of the Immune System to Predict Human Immunogenicity for a Biotherapeutic in Phase 1. <i>AAPS Journal</i> , 2019 , 21, 94	3.7	6
60	Surface plasmon resonance as a tool for ligand-binding assay reagent characterization in bioanalysis of biotherapeutics. <i>Bioanalysis</i> , 2018 , 10, 559-576	2.1	8
59	Concerted application of LC-MS and ligand binding assays to better understand exposure of a large molecule drug. <i>Bioanalysis</i> , 2018 , 10, 1261-1272	2.1	2
58	Bead-extraction and heat-dissociation (BEHD): A novel way to overcome drug and matrix interference in immunogenicity testing. <i>Journal of Immunological Methods</i> , 2018 , 462, 34-41	2.5	5
57	Development and validation of a functional cell-based neutralizing antibody assay for ipilimumab. <i>Bioanalysis</i> , 2018 , 10, 1273-1287	2.1	3
56	A multiplexed immunocapture liquid chromatography tandem mass spectrometry assay for the simultaneous measurement of myostatin and GDF-11 in rat serum using an automated sample preparation platform. <i>Analytica Chimica Acta</i> , 2017 , 979, 36-44	6.6	8
55	Ligand Binding Assays in the Regulated Bioanalytical Laboratory. <i>AAPS Advances in the Pharmaceutical Sciences Series</i> , 2017 , 177-228	0.5	
54	A systematic study of the effect of low pH acid treatment on anti-drug antibodies specific for a domain antibody therapeutic: Impact on drug tolerance, assay sensitivity and post-validation method assessment of ADA in clinical serum samples. <i>Journal of Immunological Methods</i> , 2017 , 448, 91-104	2.5	11
53	Characterization of labeled reagents in ligand-binding assays by a surface plasmon resonance biosensor. <i>Bioanalysis</i> , 2017 , 9, 193-207	2.1	8
52	2017 White Paper on recent issues in bioanalysis: a global perspective on immunogenicity guidelines & biomarker assay performance (Part 3 - LBA: immunogenicity, biomarkers and PK assays). <i>Bioanalysis</i> , 2017 , 9, 1967-1996	2.1	33
51	Accelerating Regulated Bioanalysis for Biotherapeutics: Case Examples Using a Microfluidic Ligand Binding Assay Platform. <i>AAPS Journal</i> , 2017 , 19, 82-91	3.7	3
50	Antibody-drug conjugate bioanalysis using LB-LC-MS/MS hybrid assays: strategies, methodology and correlation to ligand-binding assays. <i>Bioanalysis</i> , 2016 , 8, 1383-401	2.1	24
49	Current Challenges and Potential Opportunities for the Pharmaceutical Sciences to Make Global Impact: An FIP Perspective. <i>Journal of Pharmaceutical Sciences</i> , 2016 , 105, 2489-2497	3.9	12
48	Validation of an integrated series of ligand-binding assays for the quantitative determination of antibody-drug conjugates in biological matrices. <i>Bioanalysis</i> , 2016 , 8, 519-31	2.1	2
47	Anti-PEG antibody bioanalysis: a clinical case study with PEG-IFN- α 1a and PEG-IFN- α 2a in naive patients. <i>Bioanalysis</i> , 2015 , 7, 1093-106	2.1	25

46	Workshop Report: AAPS Workshop on Method Development, Validation, and Troubleshooting of Ligand-Binding Assays in the Regulated Environment. <i>AAPS Journal</i> , 2015 , 17, 1019-24	3.7	2
45	Development and validation of a liquid chromatography tandem mass spectrometry assay for the quantitation of a protein therapeutic in cynomolgus monkey serum. <i>Journal of Chromatography B: Analytical Technologies in the Biomedical and Life Sciences</i> , 2015 , 988, 81-7	3.2	9
44	Development and characterization of a free therapeutic ligand binding assay with assistance from kinetics modeling. <i>Journal of Immunological Methods</i> , 2015 , 419, 18-24	2.5	5
43	Development and characterization of antibody reagents to assess anti-PEG IgG antibodies in clinical samples. <i>Bioanalysis</i> , 2015 , 7, 1869-83	2.1	9
42	Stability assessment in ligand-binding assays: a critical parameter for data integrity. <i>Bioanalysis</i> , 2015 , 7, 1315-7	2.1	1
41	An integrated multiplatform bioanalytical strategy for antibody-drug conjugates: a novel case study. <i>Bioanalysis</i> , 2015 , 7, 1569-82	2.1	25
40	Development of a Generic Anti-PEG Antibody Assay Using BioScale [®] Acoustic Membrane MicroParticle Technology. <i>AAPS Journal</i> , 2015 , 17, 1511-6	3.7	15
39	Development and Fit-for-Purpose Validation of a Soluble Human Programmed Death-1 Protein Assay. <i>AAPS Journal</i> , 2015 , 17, 976-87	3.7	8
38	Detection of drug specific circulating immune complexes from in vivo cynomolgus monkey serum samples. <i>Journal of Immunological Methods</i> , 2015 , 416, 124-36	2.5	15
37	Development and characterization of a pre-treatment procedure to eliminate human monoclonal antibody therapeutic drug and matrix interference in cell-based functional neutralizing antibody assays. <i>Journal of Immunological Methods</i> , 2015 , 416, 94-104	2.5	18
36	Workshop report: Crystal City V--quantitative bioanalytical method validation and implementation: the 2013 revised FDA guidance. <i>AAPS Journal</i> , 2015 , 17, 277-88	3.7	91
35	Development and validation of an LC-MS/MS assay for the quantitation of a PEGylated anti-CD28 domain antibody in human serum: overcoming interference from antidrug antibodies and soluble target. <i>Bioanalysis</i> , 2014 , 6, 2371-83	2.1	18
34	Matrix interference in ligand-binding assays: challenge or solution?. <i>Bioanalysis</i> , 2014 , 6, 1029-31	2.1	6
33	Innovative use of LC-MS/MS for simultaneous quantitation of neutralizing antibody, residual drug, and human immunoglobulin G in immunogenicity assay development. <i>Analytical Chemistry</i> , 2014 , 86, 2673-80	7.8	33
32	2014 White Paper on recent issues in bioanalysis: a full immersion in bioanalysis (Part 2 - hybrid LBA/LCMS, ELN & regulatory agencies input). <i>Bioanalysis</i> , 2014 , 6, 3237-49	2.1	36
31	Addressing matrix effects in ligand-binding assays through the use of new reagents and technology. <i>Bioanalysis</i> , 2014 , 6, 1059-67	2.1	7
30	Targeting an acid labile aspartyl-prolyl amide bond as a viable alternative to trypsin digestion to generate a surrogate peptide for LC-MS/MS analysis. <i>Bioanalysis</i> , 2014 , 6, 2985-98	2.1	6
29	Specific method validation and sample analysis approaches for biocomparability studies of denosumab addressing method and manufacture site changes. <i>AAPS Journal</i> , 2013 , 15, 70-7	3.7	2

28	Rapid development of multiple fit-for-purpose assays on an automatic microfluidic system using a streamlined process in support of early biotherapeutics discovery programs. <i>Bioanalysis</i> , 2013 , 5, 1751-63 ¹	2.1	5
27	Fully validated LC-MS/MS assay for the simultaneous quantitation of coadministered therapeutic antibodies in cynomolgus monkey serum. <i>Analytical Chemistry</i> , 2013 , 85, 9859-67	7.8	66
26	Laboratory automation of high-quality and efficient ligand-binding assays for biotherapeutic drug development. <i>Bioanalysis</i> , 2013 , 5, 1635-48	2.1	7
25	A generic template for automated bioanalytical ligand-binding assays using modular robotic scripts in support of discovery biotherapeutic programs. <i>Bioanalysis</i> , 2013 , 5, 1735-50	2.1	4
24	Bioanalysis of biomarkers for drug development. <i>Bioanalysis</i> , 2012 , 4, 2425-6	2.1	4
23	Assessment of incurred sample reanalysis for macromolecules to evaluate bioanalytical method robustness: effects from imprecision. <i>AAPS Journal</i> , 2011 , 13, 291-8	3.7	7
22	Bioanalytical considerations in the comparability assessment of biotherapeutics. <i>Bioanalysis</i> , 2011 , 3, 613-22	2.1	9
21	Bioanalytical method requirements and statistical considerations in incurred sample reanalysis for macromolecules. <i>Bioanalysis</i> , 2010 , 2, 1587-96	2.1	8
20	Ligand-binding mass spectrometry to study biotransformation of fusion protein drugs and guide immunoassay development: strategic approach and application to peptibodies targeting the thrombopoietin receptor. <i>AAPS Journal</i> , 2010 , 12, 576-85	3.7	50
19	A strategy for improving comparability across sites for ligand binding assays measuring therapeutic proteins. <i>Journal of Pharmaceutical and Biomedical Analysis</i> , 2010 , 53, 729-34	3.5	9
18	Applications of a planar electrochemiluminescence platform to support regulated studies of macromolecules: benefits and limitations in assay range. <i>Journal of Pharmaceutical and Biomedical Analysis</i> , 2010 , 51, 626-32	3.5	11
17	Novel approaches using alkaline or acid/guanidine treatment to eliminate therapeutic antibody interference in the measurement of total target ligand. <i>Journal of Pharmaceutical and Biomedical Analysis</i> , 2010 , 51, 1128-33	3.5	20
16	Strategies to minimize variability and bias associated with manual pipetting in ligand binding assays to assure data quality of protein therapeutic quantification. <i>Journal of Pharmaceutical and Biomedical Analysis</i> , 2010 , 53, 623-30	3.5	25
15	Application of multi-factorial design of experiments to successfully optimize immunoassays for robust measurements of therapeutic proteins. <i>Journal of Pharmaceutical and Biomedical Analysis</i> , 2009 , 49, 311-8	3.5	40
14	Tartrate-resistant acid phosphatase (TRACP 5b): a biomarker of bone resorption rate in support of drug development: modification, validation and application of the BoneTRAP kit assay. <i>Journal of Pharmaceutical and Biomedical Analysis</i> , 2009 , 49, 1203-12	3.5	16
13	Experimental and statistical approaches in method cross-validation to support pharmacokinetic decisions. <i>Journal of Pharmaceutical and Biomedical Analysis</i> , 2009 , 49, 613-8	3.5	12
12	"Fit-for-purpose" method validation and application of a biomarker (C-terminal telopeptides of type 1 collagen) in denosumab clinical studies. <i>AAPS Journal</i> , 2009 , 11, 385-94	3.7	31
11	Key elements of bioanalytical method validation for macromolecules. <i>AAPS Journal</i> , 2007 , 9, E156-63	3.7	106

10	Bioanalytical method validation for macromolecules in support of pharmacokinetic studies. <i>Pharmaceutical Research</i> , 2005 , 22, 1425-31	4.5	84
9	Suppression of angiogenesis and tumor growth by selective inhibition of angiotensin-2. <i>Cancer Cell</i> , 2004 , 6, 507-16	24.3	601
8	Recommendations for the bioanalytical method validation of ligand-binding assays to support pharmacokinetic assessments of macromolecules. <i>Pharmaceutical Research</i> , 2003 , 20, 1885-900	4.5	461
7	Catalytic antibodies for complex reactions: hapten design and the importance of screening for catalysis in the generation of catalytic antibodies for the NDA/CN reaction. <i>Applied Biochemistry and Biotechnology</i> , 2000 , 83, 195-206; discussion 206-8, 297-313	3.2	3
6	Synthesis of bifunctional antibodies for immunoassays. <i>Methods</i> , 2000 , 22, 33-43	4.6	7
5	Development of a cell culture system to study antibody convection in tumors. <i>Journal of Pharmaceutical Sciences</i> , 1997 , 86, 858-64	3.9	2
4	Solid phase synthesis of bifunctional antibodies. <i>Journal of Immunological Methods</i> , 1995 , 188, 9-19	2.5	8
3	Validation of Ligand-Binding Assays to Support Pharmacokinetic Assessments of Biotherapeutics 81-110		1
2	Analytical Considerations for Immunoassays for Macromolecules 573-584		1
1	Analytical Considerations for Immunoassays for Macromolecules 1		