Binodh S Desilva

List of Publications by Year
in descending order

65 papers	2,892 citations	304743 22 h-index	168389 53 g-index
74 all docs	74 docs citations	74 times ranked	2562 citing authors

#	Article	IF	Citations
1	Biomarker Assay Validation by Mass Spectrometry. AAPS Journal, 2022, 24, 66.	4.4	6
2	Evaluating a Multiscale Mechanistic Model of the Immune System to Predict Human Immunogenicity for a Biotherapeutic in Phase 1. AAPS Journal, 2019, 21, 94.	4.4	10
3	Report on the AAPS Immunogenicity Guidance Forum. AAPS Journal, 2019, 21, 55.	4.4	14
4	The Journey to AAPS 2020: a Reflection from Strategic Planning to PharmSci 360. AAPS Journal, 2019, 21, 2.	4.4	0
5	Surface plasmon resonance as a tool for ligand-binding assay reagent characterization in bioanalysis of biotherapeutics. Bioanalysis, 2018, 10, 559-576.	1.5	12
6	The Journey to AAPS 2020: a Reflection from Strategic Planning to PharmSci 360. AAPS PharmSciTech, 2018, 19, 3325-3327.	3.3	0
7	Development and validation of a functional cell-based neutralizing antibody assay for ipilimumab. Bioanalysis, 2018, 10, 1273-1287.	1.5	9
8	Concerted application of LCâ€“MS and ligand binding assays to better understand exposure of a large molecule drug. Bioanalysis, 2018, 10, 1261-1272.	1.5	3
9	Bead-extraction and heat-dissociation (BEHD): A novel way to overcome drug and matrix interference in immunogenicity testing. Journal of Immunological Methods, 2018, 462, 34-41.	1.4	17
10	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. Analytica Chimica Acta, 2017, 979, 36-44.	5.4	13
11	Ligand Binding Assays in the Regulated Bioanalytical Laboratory. AAPS Advances in the Pharmaceutical Sciences Series, 2017, , 177-228.	0.6	1
12	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. Journal of Immunological Methods, 2017, 448, 91-104.	1.4	15
13	Characterization of labeled reagents in ligand-binding assays by a surface plasmon resonance biosensor. Bioanalysis, 2017, 9, 193-207.	1.5	8
14	2017 White Paper on recent issues in bioanalysis: a global perspective on immunogenicity guidelines & biomarker assay performance (Part 3 â€“ LBA: immunogenicity, biomarkers and PK assays). Bioanalysis, 2017, 9, 1967-1996.	1.5	47
15	Accelerating Regulated Bioanalysis for Biotherapeutics: Case Examples Using a Microfluidic Ligand Binding Assay Platform. AAPS Journal, 2017, 19, 82-91.	4.4	4
16	Immunoaffinity-coupled MS: best of both technologies. Bioanalysis, 2016, 8, 1543-1544.	1.5	3
17	Antibodyâ€“drug conjugate bioanalysis using LB-LCâ€“MS/MS hybrid assays: strategies, methodology and correlation to ligand-binding assays. Bioanalysis, 2016, 8, 1383-1401.	1.5	33
18	Current Challenges and Potential Opportunities for the Pharmaceutical Sciences to Make Global Impact: An FIP Perspective. Journal of Pharmaceutical Sciences, 2016, 105, 2489-2497.	3.3	20

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19	Validation of an integrated series of ligand-binding assays for the quantitative determination of antibodyâ€“drug conjugates in biological matrices. Bioanalysis, 2016, 8, 519-531.	1.5	4
20	Development and Fit-for-Purpose Validation of a Soluble Human Programmed Death-1 Protein Assay. AAPS Journal, 2015, 17, 976-987.	4.4	11
21	Detection of drug specific circulating immune complexes from in vivo cynomolgus monkey serum samples. Journal of Immunological Methods, 2015, 416, 124-136.	1.4	17
22	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. Journal of Immunological Methods, 2015, 416, 94-104.	1.4	23
23	Workshop Report: Crystal City Vâ€”Quantitative Bioanalytical Method Validation and Implementation: The 2013 Revised FDA Guidance. AAPS Journal, 2015, 17, 277-288.	4.4	109
24	Anti-PEG antibody bioanalysis: a clinical case study with PEG-IFN-Î»-1a and PEG-IFN-Î±2a in naive patients. Bioanalysis, 2015, 7, 1093-1106.	1.5	28
25	Workshop Report: AAPS Workshop on Method Development, Validation, and Troubleshooting of Ligand-Binding Assays in the Regulated Environment. AAPS Journal, 2015, 17, 1019-1024.	4.4	2
26	Development and validation of a liquid chromatography tandem mass spectrometry assay for the quantitation of a protein therapeutic in cynomolgus monkey serum. Journal of Chromatography B: Analytical Technologies in the Biomedical and Life Sciences, 2015, 988, 81-87.	2.3	11
27	Development and characterization of a free therapeutic ligand binding assay with assistance from kinetics modeling. Journal of Immunological Methods, 2015, 419, 18-24.	1.4	5
28	Development and characterization of antibody reagents to assess anti-PEG IgG antibodies in clinical samples. Bioanalysis, 2015, 7, 1869-1883.	1.5	10
29	Stability assessment in ligand-binding assays: a critical parameter for data integrity. Bioanalysis, 2015, 7, 1315-1317.	1.5	1
30	An integrated multiplatform bioanalytical strategy for antibodyâ€“drug conjugates: a novel case study. Bioanalysis, 2015, 7, 1569-1582.	1.5	29
31	Development of a Generic Anti-PEG Antibody Assay Using BioScaleâ€™s Acoustic Membrane MicroParticle Technology. AAPS Journal, 2015, 17, 1511-1516.	4.4	16
32	Introduction to the Proposals from the Global Bioanalysis Consortium Harmonization Team. AAPS Journal, 2014, 16, 1159-1161.	4.4	5
33	2014 White Paper on recent issues in bioanalysis: a full immersion in bioanalysis (Part 2 â€“ hybrid) Tj ETQq1 1 0.784314 rgBT /Overlo	1.5	45
34	Addressing matrix effects in ligand-binding assays through the use of new reagents and technology. Bioanalysis, 2014, 6, 1059-1067.	1.5	8
35	Targeting an acid labile aspartylâ€“prolyl amide bond as a viable alternative to trypsin digestion to generate a surrogate peptide for LCâ€“MS/MS analysis. Bioanalysis, 2014, 6, 2985-2998.	1.5	7
36	Development and validation of an LCâ€“MS/MS assay for the quantitation of a PEGylated anti-CD28 domain antibody in human serum: overcoming interference from antidrug antibodies and soluble target. Bioanalysis, 2014, 6, 2371-2383.	1.5	19

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37	Matrix interference in ligand-binding assays: challenge or solution?. Bioanalysis, 2014, 6, 1029-1031.	1.5	6
38	Innovative Use of LC-MS/MS for Simultaneous Quantitation of Neutralizing Antibody, Residual Drug, and Human Immunoglobulin G in Immunogenicity Assay Development. Analytical Chemistry, 2014, 86, 2673-2680.	6.5	38
39	Specific Method Validation and Sample Analysis Approaches for Biocomparability Studies of Denosumab Addressing Method and Manufacture Site Changes. AAPS Journal, 2013, 15, 70-77.	4.4	2
40	Rapid development of multiple â€˜fit-for-purposeâ€™ assays on an automatic microfluidic system using a streamlined process in support of early biotherapeutics discovery programs. Bioanalysis, 2013, 5, 1751-1763.	1.5	6
41	Fully Validated LC-MS/MS Assay for the Simultaneous Quantitation of Coadministered Therapeutic Antibodies in Cynomolgus Monkey Serum. Analytical Chemistry, 2013, 85, 9859-9867.	6.5	74
42	Laboratory automation of high-quality and efficient ligand-binding assays for biotherapeutic drug development. Bioanalysis, 2013, 5, 1635-1648.	1.5	7
43	A generic template for automated bioanalytical ligand-binding assays using modular robotic scripts in support of discovery biotherapeutic programs. Bioanalysis, 2013, 5, 1735-1750.	1.5	4
44	Bioanalysis of biomarkers for drug development. Bioanalysis, 2012, 4, 2425-2426.	1.5	6
45	Assessment of Incurred Sample Reanalysis for Macromolecules to Evaluate Bioanalytical Method Robustness: Effects from Imprecision. AAPS Journal, 2011, 13, 291-298.	4.4	11
46	Bioanalytical considerations in the comparability assessment of biotherapeutics. Bioanalysis, 2011, 3, 613-622.	1.5	9
47	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. AAPS Journal, 2010, 12, 576-585.	4.4	58
48	A strategy for improving comparability across sites for ligand binding assays measuring therapeutic proteins. Journal of Pharmaceutical and Biomedical Analysis, 2010, 53, 729-734.	2.8	10
49	Applications of a planar electrochemiluminescence platform to support regulated studies of macromolecules: Benefits and limitations in assay range. Journal of Pharmaceutical and Biomedical Analysis, 2010, 51, 626-632.	2.8	11
50	Novel approaches using alkaline or acid/guanidine treatment to eliminate therapeutic antibody interference in the measurement of total target ligand. Journal of Pharmaceutical and Biomedical Analysis, 2010, 51, 1128-1133.	2.8	20
51	Strategies to minimize variability and bias associated with manual pipetting in ligand binding assays to assure data quality of protein therapeutic quantification. Journal of Pharmaceutical and Biomedical Analysis, 2010, 53, 623-630.	2.8	36
52	Bioanalytical method requirements and statistical considerations in incurred sample reanalysis for macromolecules. Bioanalysis, 2010, 2, 1587-1596.	1.5	9
53	Application of multi-factorial design of experiments to successfully optimize immunoassays for robust measurements of therapeutic proteins. Journal of Pharmaceutical and Biomedical Analysis, 2009, 49, 311-318.	2.8	48
54	Tartrate-resistant acid phosphatase (TRACP 5b): A biomarker of bone resorption rate in support of drug development: Modification, validation and application of the BoneTRAPÂ® kit assay. Journal of Pharmaceutical and Biomedical Analysis, 2009, 49, 1203-1212.	2.8	19

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55	Experimental and statistical approaches in method cross-validation to support pharmacokinetic decisions. Journal of Pharmaceutical and Biomedical Analysis, 2009, 49, 613-618.	2.8	13
56	â€œFit-for-Purposeâ€•Method Validation and Application of a Biomarker (C-terminal Telopeptides of Type 1) Tj ETQq0 0 0 rgBT /Overloc	4.4	35
57	Key elements of bioanalytical method validation for macromolecules. AAPS Journal, 2007, 9, E156-E163.	4.4	130
58	Bioanalytical Method Validation for Macromolecules in Support of Pharmacokinetic Studies. Pharmaceutical Research, 2005, 22, 1425-1431.	3.5	100
59	Suppression of angiogenesis and tumor growth by selective inhibition of angiopoietin-2. Cancer Cell, 2004, 6, 507-516.	16.8	689
60	Recommendations for the Bioanalytical Method Validation of Ligand-Binding Assays to Support Pharmacokinetic Assessments of Macromolecules. Pharmaceutical Research, 2003, 20, 1885-1900.	3.5	551
61	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. Applied Biochemistry and Biotechnology, 2000, 83, 195-208.	2.9	4
62	Synthesis of Bifunctional Antibodies for Immunoassays. Methods, 2000, 22, 33-43.	3.8	7
63	Development of a Cell Culture System To Study Antibody Convection in Tumors. Journal of Pharmaceutical Sciences, 1997, 86, 858-864.	3.3	2
64	Solid phase synthesis of bifunctional antibodies. Journal of Immunological Methods, 1995, 188, 9-19.	1.4	9
65	Analytical Considerations for Immunoassays for Macromolecules. , 0, , 573-584.		1