PDA Technical Documents

PDA BOOKSTORE

No.	TITLE		Paper Version	Digital Version
	PDA Technical Reports			
1	Validation of Moist Heat Sterilization Processes: Cycle Design, Development, Qualification and Ongoing Control	Revised 2007 *(Published 1980)*	01001	43381
3	Validation of Dry Heat Processes Used for Depyrogenation and Sterilization	Revised 2013 *(Published 1981)*		43506
4	Design Concepts For the Validation of a Water for Injection System **(Retired)**	1983		43209
5	Sterile Pharmaceutical Packaging: Compatibility and Stability **(Retired)**	1984		43210
7	Depyrogenation **(Retired)**	1985		43212
9	Review of Commercially Available Particulate Measurement Systems **(Retired)**	1988		43214
10	Parenteral Formulations of Proteins and Peptides: Stability and Stabilizers **(Retired)**	1988		43215
11	Sterilization of Parenterals by Gamma Radiation **(Retired)**	1988		43216
12	Siliconization of Parenteral Drug Packaging Components	1988		43217
13	Fundamentals of an Environmental Monitoring Program	Revised 2014 *(Published 1990)*		43513
14	Validation of Column-Based Chromatography Processes for the Purification of Proteins	Revised 2008 *(Published 1992)*		43220
15	Validation of Tangential Flow Filtration in Biopharmaceutical Applications	Revised 2009 *(Published 1992)*	01015	43221
16	Effects of Gamma Irradiation on Elastomeric Closures **(Retired)**	1992		43222
17	Current Practices in the Validation of Aseptic Processing -- 1992 **(Retired)**	1993		43223
18	Validation of Computer-Related Systems **(Retired)**	1995		43224
19	Rapid/Automated ID Methods Survey **(Retired)**	1990		43225
20	Report on Survey of Current Industry Gowning Practices **(Retired)**	1990		41239
21	Bioburden Recovery Validation **(Retired)**	1990		41258
22	Process Simulation for Aseptically Filled Products	Revised 2011 *(Published 1996)*		43226
23	Industry Survey on Current Sterile Filtration Practices **(Retired)**	1997		43227
24	Current Practices in the Validation of Aseptic Processing **(Retired)**	1997		43228
25	Blend Uniformity Analysis: Validation and In-Process Testing **(Retired)**	1997		43229
26	Sterilizing Filtration of Liquids	Revised 2008 *(Published 1998)*		43230
27	Pharmaceutical Package Integrity	1998		43231
28	Process Simulation Testing for Sterile Bulk Pharmaceutical Chemicals	Revised 2006 *(Published 1998)*		43232
29	Points to Consider for Cleaning Validation	Revised 2012 *(Published 1998)*		43501
30	Parametric Release of Pharmaceuticals and Medical Device Products Terminally Sterilized by Moist Heat	Revised 2012 *(Published 1999)*		43234
31	Validation and Qualification of Computerized Laboratory Data Acquisition Systems **(Retired)**	1999		43235
32	Auditing of Suppliers Providing Computer Products and Services for Regulated Pharmaceutical Operations **(Retired)**	Revised 2004 *(Published 1999)*		43236
33	Evaluation, Validation and Implementation of Alternative and Rapid Microbiological Methods	Revised 2013 *(Published 2000)*		43510
34	Design and Validation of Isolator Systems for the Manufacturing and Testing of Health Care Products	2001	01034	43239
35	A Proposed Training Model for the Microbiological Function in the Pharmaceutical Industry **(Retired)**	2001		43240

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36	Current Practices in the Validation of Aseptic Processing – 2001 **(Retired)**	2002		43241
38	Manufacturing Chromatography Systems Postapproval Changes (ChromPAC): Chemistry, Manufacturing, and Controls Documentation	2006		43315
39	Guidance for Temperature-Controlled Medicinal Products — Maintaining the Quality of Temperature-Sensitive Medicinal Products through the Transportation Environment	2021		43556
40	Sterilization Filtration of Gases	2005	01040	43314
41	Virus Filtration	2008	01041	43313
42	Process Validation of Protein Manufacturing	2005	01042	43311
43	Identification and Classification of Nonconformities in Molded and Tubular Glass Containers for Pharmaceutical Manufacturing: Covering Ampoules, Bottles, Cartridges, Syringes and Vials	Revised 2013 (Published 2007)		43508
44	Quality Risk Management for Aseptic Processes	2008	01044	43410
45	Filtration of Liquids Using Cellulose-Based Depth Filters	2008		43422
46	Last Mile: Guidance for Good Distribution Practices for Pharmaceutical Products to the End User	2009	01046	43485
47	Preparation of Virus Spikes Used for Virus Clearance Studies	2010		43486
48	Moist Heat Sterilizer Systems: Design, Commissioning, Operation, Qualification and Maintenance	2010		43487
49	Points to Consider for Biotechnology Cleaning Validation	2010		43488
50	Alternative Methods for Mycoplasma Testing	2010		43489
51	Biological Indicators for Gas and Vapor-Phase Decontamination Processes: Specification, Manufacture, Control and Use	2010		43490
52	Guidance for Good Distribution Practices (GDPs) For the Pharmaceutical Supply Chain	2011		43491
53	Guidance for Industry: Stability Testing to Support Distribution of New Drug Products	2011		43492
54	Implementation of Quality Risk Management For Pharmaceutical and Biotechnology Manufacturing Operations	2012		43493
54-2	Implementation of Quality Risk Management for Pharmaceutical and Biotechnology Manufacturing Operations Annex 1: Case Study Examples for Quality Risk Management in Packaging and Labeling	2013		43504
54-3	Implementation of Quality Risk Management for Pharmaceutical and Biotechnology Manufacturing Operations Annex 2: Case Studies in the Manufacturing of Pharmaceutical Drug Products	2013		43511
54-4	Implementation of Quality Risk Management for Pharmaceutical and Biotechnology Manufacturing Operations Annex 3: Case Studies in the Manufacturing of Biotechnological Bulk Drug Substances	2014		43518
55	Detection and Mitigation of 2,4,6-Tribromoanisole and 2,4,6-Trichloroanisole Taints and Odors in the Pharmaceutical and Consumer Healthcare Industries	2012		43494
56	Application of Phase-Appropriate Quality System and cGMP to the Development of Therapeutic Protein Drug Substance (API or Biological Active Substance)	Revised 2016 (Published 2012)		43530
57	Analytical Method Validation and Transfer for Biotechnology Products	2012		43497
57-2	Analytical Method Development and Qualification for Biotechnology Products	2015		43519
58	Risk Management for Temperature-Controlled Distribution	2012		43499
59	Utilization of Statistical Methods for Production Monitoring	2012		43500
60	Process Validation: A Lifecycle Approach	2013		43502
60-2	Process Validation: A Lifecycle Approach Annex 1: Oral Solid Dosage/Semisolid Dosage Forms	2017		43532

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61	Steam In Place	2013		43503
62	Recommended Practices for Manual Aseptic Processes	2013		43505
63	Quality Requirements for the Extemporaneous Preparation of Clinical Trial Materials	2013		43507
64	Active Temperature-Controlled Systems: Qualification Guidance	2013		43509
65	Technology Transfer	2014		43514
66	Application of Single-Use Systems in Pharmaceutical Manufacturing	2014		43515
67	Exclusion of Objectionable Microorganisms from Nonsterile Pharmaceuticals, Medical Devices, and Cosmetics	2014		43516
68	Risk-Based Approach for Prevention and Management of Drug Shortages	2014		43517
69	Bioburden and Biofilm Management in Pharmaceutical Manufacturing Operations	2015		43521
70	Fundamentals of Cleaning and Disinfection Programs for Aseptic Manufacturing Facilities	2015		43522
71	Emerging Methods for Virus Detection	2015		43523
72	Passive Thermal Protection Systems for Global Distribution: Qualification and Operational Guidance	2015		43524
73	Prefilled Syringe User Requirements for Biotechnology Applications	2015		43525
74	Reprocessing of Biopharmaceuticals	2016		43526
75	Consensus Method for Rating 0.1μm Mycoplasma Reduction Filters	2016		43528
76	Identification and Classification of Visible Nonconformities in Elastomeric Components and Aluminum Seals for Parenteral Packaging	2016		43529
77	The Manufacture of Sterile Pharmaceutical Products Using Blow-Fill-Seal Technology	2017		43531
54-5	Quality Risk Management for the Design, Qualification, and Operation of Manufacturing Systems	2017		43533
78	Particulate Matter in Oral Dosage Forms	2017		43535
79	Particulate Matter Control in Difficult to Inspect Parenterals	2018		43536
80	Data Integrity Management System for Pharmaceutical Laboratories	2018		43537
81	Cell-Based Therapy Control Strategy	2019		43538
82	Low Endotoxin Recovery	2019		43539
83	Virus Contamination in Biomanufacturing: Risk Mitigation, Preparedness, and Response	2019		43541
54-6	Formalized Risk Assessment for Excipients	2019		43542
84	Integrating Data Integrity Requirements into Manufacturing & Packing Operations	2020		43547
13-2	Fundamentals of an Environmental Monitoring Program Annex 1	2020		43549
60-3	Process Validation: A Lifecycle Approach Annex 2: Biopharmaceutical Drug Substances Manufacturing	2021		43551
85	Enhanced Test Methods for Visible Particle Detection and Enumeration on Elastomeric Closures and Glass Containers	2021		43552
86	Industry Challenges and Current Technologies for Pharmaceutical Package Integrity Testing	2021		43553
87	Current Best Practices for Pharmaceutical Glass Vial Handling and Processing	2021		43555

TITLE		Paper Version	Digital Version
PDA Points to Consider Paper			
Points to Consider for Aseptic Processing - PDA Journal of Pharmaceutical Science and Technology: 2003 Supplement Volume 57 Issue 2	**2003**		42148
Points to Consider for Aseptic Processing: Part 1, January 2015	**2015**		43520
Points to Consider for Aseptic Processing: Part 2, May 2016	**2016**		43527
Points to Consider for Aging Facilities	**2017**		43534
Points to Consider for the Aseptic Processing of Sterile Pharmaceutical Products in Isolators	**2020**		43543
Points to Consider for Sensitivity to Oxidation by Peroxide	**2020**		43544
Points to Consider for Risks Associated with Sterilizing Grade Filters and Sterilizing Filtration	**2020**		43545
Points to Consider for Implementation of Pre-Use Post-Sterilization Integrity Testing	**2020**		43546
Points to Consider in Remote and Hybrid GMP/GDP Inspections	**2021**		43554

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PDA Surveys			
Risk Mitigation of Tribromoanisole (TBA)/Trichloroanisole (TCA) Taints and Odors: A Pharmaceutical Industry Benchmarking Survey	**2011**		45000
Business Case for Pharmaceutical Quality	**2012**		45001
Glass Quality: 2011 and 2012 Results and Comparison	**2013**		45002
2013 PDA Objectionable Microorganisms for Nonsterile Pharmaceutical, Consumer Health, Medical Devices, Dietary Supplement and Cosmetic Products	**2014**		45003
2014 PDA Process Validation Survey	**2014**		45004
2014 Quality Culture Metrics	**2015**		45005
2014 Visual Inspection	**2015**		45006
2015 Particulate Matter in Oral Dosage Forms	**2016**		45007
2015 Particulate Matter in Difficult to Inspect Parenterals	**2016**		45008
2015 Aging Facilities	**2016**		45009
2017 PDA Aseptic Processing Survey	**2017**		45010
2017 PDA PUPSIT Survey	**2017**		45011
2017 PDA Glass Quality Survey	**2018**		45012
2019 Technology Transfer Industry Survey	**2019**		45013
2019 Sterile Lyophilized Drug Product Loading Survey	**2019**		45014
2019 PDA Traceability of Primary Packaging Survey	**2020**		45015
2021 Post-Approval Change Issues and Impacts Survey	**2021**		45016
2020 Particulate Matter in Flexible Containers Survey	**2021**		45017