11.0 References

- 1. Carter, J. R.; Levy, R. V. Microbial Retention Testing in the Validation of Sterilizing 1. Filtration. In Filtration in the Biopharmaceutical Industry; Meltzer, T. H., Jornitz, M. W., Eds.; Marcel Dekker: New York, 1998.
- 2. Akers, J. A. Microbial Considerations in the Selection and Validation of Filter Sterilization. In Filtration and Purification in the Biopharmaceutical Industry; Meltzer, T. H., Jornitz, M. W., Eds.; Informa Healthcare: New York, 2008.
- Mittelman, M. W.; Jornitz M.; Meltzer, T. Bacterial Cell Size and Surface Charge Characteristics Relevant to Filter Validation Studies. PDA J. 15. Meltzer, T. H. Some Observations Concerning Pharm. Sci. Technol. 1998, 52, 37-42.
- 4. Sundaram, S.; Auriemma, M.; Howard G.H., Jr.; Brandwein, H.; Leo, F. Application of Membrane Filtration for Removal of Diminutive Bioburden Organisms in Pharmaceutical Products and Processes. PDA J. Pharm. Sci. Technol. 1999, 53, 186-201.
- Bowman, F. W.; Holdowsky, S. Production and Control of a Stable Penicillinase. Antibiot. Chemother, 1960, 10, 508.
- Committee D19, F838-05 Standard Test Method for Determining Bacterial Retention of Membrane Filters Utilized for Liquid Filtration. American Society for Testing and Materials International (ASTM): 2005.
- 7. Aseptic Processing of Health Care Products Part 2: Filtration, 3 Terms and Definitions 13408-2:2003(E). ISO: 2003.
- 8. Tanny, G. B.; Strong, D. K.; Presswood, W. G.; Meltzer, T. H. Adsorptive Retention of Pseudomonas diminuta by Membrane Filters. J. Parent. Drug Assoc. 1979, 33, 40-51.
- 9. Howard, G.; Duberstein, R. A Case of Penetration of 0.2µm Rated Membrane Filters by Bacteria. J. Parent. Drug Assoc. 1980, 34, 93-102.
- 10. Meeker, J.T.; Hickey, E.W.; Martin, J.M.; Howard, Jr., G. Technical Note: A Quantitative Method for Challenging 0.1 mm Rated Filters with A. laidlawii, Biopharm Intl. 1992, (March), 30.
- 11. Roche, K.L.; Levy, R. V. Methods Used to Validate Microporous Membranes for the Removal of Mycoplasma. BioPharm Intl. 1993, (May), 22-33.

- 12. Mouwen, H. C.; Meltzer, T. H. Sterilizing Filters: Pore-Size Distribution and the 1x107/ cm2 Challenge. Pharm. Technol. 1993, 7, 28-35.
- 13. Carter, J. Evaluation of Recovery Filters for Use in Bacterial Retention Testing of Sterilizing-Grade Filters. PDA J. Pharm. Sci. Technol. 1996, 50, 147-163.
- 14. The Rules Governing Medicinal products in the European Union, Volume 4. Medicinal Products for Human and Veterinary Use: Good Manufacturing Practices. Annex 1 Manufacture of Sterile Medicinal Products, 2003.
- Filter Validations. Proceedings of the PDA Second International Congress, Basel, Switzerland, 1993.
- 16. Current Good Manufacturing Practice for Finished Pharmaceuticals. Code of Federal Regulations, Part 211, Title 21, 2007.
- 17. Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs. Code of Federal Regulations. Part 210, Title 21, 2006
- 18. <88> Biological Reactivity Tests, In Vivo. USP 31/NF 26. The United States Pharmacopeia Convention: Rockville, MD, 2007.
- 19. <87> Biological Reactivity Tests, In Vitro. USP 31-NF 26. The United States Pharmacopeia Convention: Rockville, MD, 2007.
- 20. Current Good Manufacturing Practice for Substances Prohibited from Use in Human Food. Code of Federal Regulations, Part 189, Title 21, 2007.
- 21. Current Good Manufacturing Practice Requirements for Specific Cosmetic Products. Code of Federal Regulations, Part 700, Title 21,
- 22. Note for Guidance on Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products, Section 6.4, Tallow Derivatives (EMEA/410/01 Revision 2). European Medicines Agency: 2004.
- 23. Stone, T.; Goel, V.; Leszczak, J.; Chrai, S. Model Stream Approach: Defining Worst Case Conditions. Pharm. Technol., 1996, 20(22), 34-51.

- 24. Reif, O.W. Extractables and Compatibilities of Filters. In Filtration in the Biopharmaceutical Industry; Meltzer, T. H., Jornitz, M. W., Eds.; Marcel Dekker: New York, 1998.
- 25. Clarke, M. E.; Zahka, J. Understanding Membrane Plugging Mechanisms, Microelectronics Application Note MAL 116. Mykrolis, 2000, White Paper. 1-22.
- 26. Fennington, Jr. G. J.; Howard, Jr. G. Preparation and Evaluation of Bacterial Stocks for Filter Validation. PDA J. Pharm. Sci. Technol. 1997, 51,
- 27. Leahy, T. J.; Sullivan, M. Validation of Bacterial Retention Capabilities of Membrane Filters. Pharm. Technol. 1978, 2(11), 64-75.
- 28. Meltzer, T. H. Filtration in the Pharmaceutical Industry; Meltzer, T. H., Jornitz, M.W., Eds.; Marcel Dekker: New York, 1987.
- 29. Sundaram S.; Brantley, J.D.; Howard, Jr. G.; Brandwein, H. Considerations on Using 'Bubble Point' Type Tests as Filter Integrity Tests, Part I. Pharm. Technol. 2000, 24(9), 90-115.
- 30. Sundaram S.; Brantley, J.D.; Howard, Jr. G.; Brandwein, H. Part II: Effect of Filter Area on 'Bubble Point' Measurements and Implications for the Use of 'Bubble Point' Type Tests as Correlated Tests. Pharm. Technol. 2000, 24(10), 108-136.
- 31. Pall, D. B.; Kirnbauer, E. A. Bacteria Removal Prediction in Membrane Filters. Presented at 52nd Colloid and Surface Science Symposium, University of Tennessee, Knoxville, TN, June
- 32. Reti, A. R. An Assessment of Test Criteria for Evaluation the Performance and Integrity of Sterilizing Filters. Bull. Parent. Drug Assoc. 1977, 44. Sterilization of Health Care Products - Radiation -31, 187-193.
- 33. Jornitz, M. W.; Brose D. J.; Meltzer, T. H. Experimental Evaluation of Diffusive Airflow Integrity Testing, PDA J. Pharm. Sci. Technol. 1998, 5, 46-49.
- 34. Guidance for Industry Sterile Drug Products Produced by Aseptic Processing-Current Good Manufacturing Practice; Guideline on Sterile Drug Products Produced by Aseptic Processing, U.S. Food and Drug Administration: 2004,

- 35. Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use, Annex 1, Manufacture of Sterile Medicinal Products (Vol. 4) European Union: 2003.
- 36. Jornitz, M. W., Trotter, A. M., Meltzer, T. H. Integrity Testing. In Filtration in the Biopharmaceutical Industry; Meltzer, T. H., Jornitz, M. W., Eds.; Marcel Dekker: New York, 1998.
- 37. Trotter, A. M.; Meltzer, T. H., et al. Investigation of a Filter Structure by Microbial Retention Studies: A Synthesis and Elaboration of Prior Findings. PDA J. Pharm. Sci. Technol. 2001, 55,
- 38. Agalloco, J. P. Steam Sterilization-In-Place Technology. PDA J. Pharm. Sci. Technol. 1990, 44, 253-256.
- 39. Technical Report No. 1 (Revised 2007): Moist Heat Sterilization Processes: Cycle Design, Development, Qualification and Ongoing Control; Parenteral Drug Association: Bethesda, MD, 2007.
- 40. Myers, T.; Chrai, S. Steam-In-Place Sterilization of Cartridge Filters In-Line with a Receiving Tank. J. Parent. Sci. Tech. 1982, 36, 108-112.
- 41. Steere, W.; Meltzer, T. H. Operational Considerations in the Steam Sterilization of Cartridge Filters. Pharm. Technol. 1993, 9, 98-
- 42. Sterilization of Health Care Products Radiation, Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices, 11137-1:2006. ANSI/AAMI/ ISO: 2006
- 43. Sterilization of Health Care Products Radiation -Part 2: Establishing the Sterilization Dose, 11137-2:2006. ANSI/AAMI/ISO: 2006.
- Part 3: Guidance on Dosimetric Aspects, 11137-3:2006. ANSI/AAMI/ISO: 2006.
- 45. Note for Guidance on Development Pharmaceutics (CPMP (CPMP/QWP/155/96), European Medicines Agency: 1998.
- 46. Decision Tree for Selection of Sterilisation Methods (CPMP/QWP/054/98 Corr.), Annex to Note for Guidance on Development Pharmaceutics (CPMP/QWP/155/96). European Medicines Agency: 2000.

- 47. ANSI. Sterilization of Health Care Products -Radiation Sterilization - Substantiation of a Selected Sterilization Dose - Method VDmax, AMI TIR33: 2005 2.
- 48. ANSI/AAMI/ISO. Medical devices · Validation and Routine Control of Ethylene Oxide Sterilization,
- 49. BPSA Guidelines and Standards Committee. Bio 53. Jornitz, M. W., et al. Filter Integrity Testing in Process Systems Alliance Component Quality Test Matrices. BioProcess Intl., 2007, 5(4), 52-57.
- 50. Hofmann, F. Integrity Testing of Microfiltration Membranes, J. Parent. Sci. Tech., 1984, 148-159.
- 51. Emory, S. F. Principles of Integrity-Testing Hydrophilic Microporous Membrane Filters, Part I, II. Pharm. Technol. 1989, 9, 68-77; 10,
- 52. Jornitz, M. W., et al. Filter Integrity Testing in Liquid Applications, Revisited, Part 1. Pharm. Technol. 2001, October, 34-50.
- Liquid Applications, Revisited, Part 2. Pharm. Technol. 2001, October, 24-35.

Terms of Usage

An Authorized User of the electronic PDA Technical Report is a PDA Member in good standing or the purchaser of the Technical

Authorized Users are permitted to do the following:

- · Search and view the content of the PDA Technical Report
- · Download the PDA Technical Report for the individual use of an Authorized User
- · Print the PDA Technical Report for the individual use of an Authorized User
- · Make a reasonable number of photocopies of a printed PDA Technical Report for the individual use of an Authorized User

Authorized Users are not permitted to do the following:

- · Allow anyone other than an Authorized User to use or access the PDA Technical Report
- · Display or otherwise make any information from the PDA Technical Report available to anyone other than an Authorized User
- · Post articles from the PDA Technical Report on Web sites, either available on the Internet or an Intranet, or in any form of online publications without a license from PDA, Inc.
- · Transmit electronically, via e-mail or any other file transfer protocols, any portion of the PDA Technical Report
- · Create a searchable archive of any portion of the PDA Technical Report
- · Use robots or intelligent agents to access, search and/or systematically download any portion of the PDA Technical Report
- · Sell, re-sell, rent, lease, license, sublicense, assign or otherwise transfer the use of the PDA Technical Report or its content
- · Use or copy the PDA Technical Report for document delivery, fee-for-service use, or bulk reproduction or distribution of materials in any form, or any substantially similar commercial purpose
- · Alter, modify, repackage or adapt any portion of the PDA Technical Report
- · Make any edits or derivative works with respect to any portion of the PDA Technical Report including any text or graphics
- · Delete or remove in any form or format, including on a printed article or photocopy, any copyright information or notice contained in the PDA Technical Report
- · Combine any portion of the PDA Technical Report with any other material

To License or purchase Reprints or Hardcopies

- · Licensing: Site licenses and licenses to distribute PDA Technical Reports can be obtained for a fee. To learn more about licensing options and rates, please contact: Janny Chua, Publications Manager, +1 (301) 656-5900, ext. 133. Written correspondence can be sent to: PDA, Inc. Attn: Janny Chua, 4350 East West Highway, Suite 150, Bethesda, MD 20814.
- · Reprints: Reprints of PDA Technical Reports can be purchased for a fee. To order reprints, please contact: Janny Chua, Publications Manager, +1 (301) 656-5900, ext. 133. Written correspondence can be sent to: PDA, Inc. Attn: Janny Chua, 4350 East West Highway, Suite 150, Bethesda, MD 20814.
- · Hardcopies: Hardcopies of PDA Technical Reports are available on demand for a fee. The PDA membership benefits include discounted pricing for printed copies of PDA Technical Reports. Go to www.pda.org/bookstore to order a hardcopy. PDA members will need their PDA identification number and password to receive the discount.