

Container Closure Integrity: Regulations, Test Methods, Application - References

Instructors

Coralie Richard, Ph.D.; Eli Lilly and Company; coralie.richard@lilly.com

Allison Dill, Ph.D.; Eli Lilly and Company; dillal@lilly.com

With significant contribution from Dr. Dana M. Guazzo PhD, RxPax, LLC, dguazzo@rxpax.com



References

- Destry M. Sullivan, Container Closure Integrity Testing Expectations from a CBER Perspective, PDA Packaging Conference, May 20-May21, 2014, Washington DC.
- Federal Food, Drug, and Cosmetic Act (FD&C Act), United States Code, Title 21.
- US FDA (1999). Guidance for Industry: Container Closure Systems for Packaging Human Drugs and Biologics.
- ICH Q8(R2) (2009) Pharmaceutical Development.
- US FDA (1994). Guidance for Industry for the Submission Documentation for Sterilization Process Validation in Applications for Human and Veterinary Drug Products.
- EU Guideline to Good Manufacturing Practice (2008). Medicinal Products for Human and Veterinary Use, Annex 1. Manufacturer of Sterile Medicinal Products.
- US FDA (2004). Guidance for Industry Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice.
- US State Food and Drug Administration (2008). Container and Closure System Integrity Testing in Lieu of Sterility Testing as a Component of the Stability Protocol for Sterile Products.
- ICH Q5C Guidance for the industry “Quality of Biotechnological products: Stability testing of Biotechnological / Biological products”.
- PDA Technical Report 27 (TR 27) : Pharmaceutical Package Integrity.
- PDA Technical Report 86 (TR 86): Industry Challenges and Current Technologies for Pharmaceutical Package Integrity Testing
- USP<1207> Package integrity evaluation – Sterile products.

References

- Lee Kirsch, et al, PDA J Pharm Sci & Technol, Vol. 51, No. 5, 1997.
- Dana Guazzo, presentation “Sterile Product Integrity Testing”, May 17, 2010.
- Jackson CN, Sherlock CN, Moore PO, Nondestructive Testing Handbook, 3rd ed. Vol 1 Leak Testing, American Society for Nondestructive Testing, Inc. 1998.
- H. Wolf, T. Stauffer, S-Chen Chen, et al, PDA J Pharm Sci & Technol., 63, 2009, p. 489 – 498.
- D. Paskiet, R. Asselta. “Qualifying Integral Container Closure Systems Employing Advanced Measurement Techniques”.
- V. Pethe, Microleak detection in flexible containers and its correlation to microbial ingress probability, PDA Europe Parenteral Packaging Conference, Brussels, Belgium, March 12, 2014.
- S. Orosz, D. Guazzo, Glass vial finish defects - Leak detection and product risk assessment, PSIG session of the PDA Annual Meeting, Orlando, FL, March 16, 2010.
- J. Patel, B. Mulhall, H.Wolf, et al, PDA J Pharm Sci & Tech, 65, Sep/Oct 2011 p. 486 – 505.
- M. Whitlow, CCIT flexible foil packaging, PDA Europe Parenteral Packaging Conference, Brussels, Belgium, March 12, 2014.
- L. Li, Container Closure Integrity Testing Method Development and Validation for Pre-filled Syringes, PDA Universe of Pre-filled Syringes and Injection Devices, Las Vegas, NV, Oct 16, 2012.
- P. Buus, R. Damgaard, High voltage leak detection (HVLD) of flexible container, PDA Europe Parenteral Packaging Conference, Brussels, Belgium, March 12, 2014.

References

- J. Ludwig, et al, J Parenteral Sci & Technol, 47, 5, 1993, p. 211, and 49, 5, 1995, p. 253.
- H. Wolf, D. Guazzo, ASTM Standard Test Method for Nondestructive Airborne Ultrasound Seal Integrity Test for Flexible Packages, ASTM F02 Committee meeting, April 18, 2007.
- D. Guazzo, Container closure integrity challenges unique to prefilled syringes and cartridges, PDA 7th.
- J. Young, B. Zurawlow. Optimized CCI Test Method Dev. and Val. Approaches, PDA Europe Parenteral Packaging Conference, Frankfurt, Germany, 4 March 2015.
- Lenox Laser website (last accessed on 16-Oct-2017)
<https://lenoxlaser.com/resources/calculators/orifice-calculator/>
- Jackson CN, Sherlock CN, Moore PO, Nondestructive Testing Handbook, 3rd ed. Vol 1 Leak Testing, American Society for Nondestructive Testing, Inc. 1998.
- “Container Closure Integrity Testing – Practical Aspects and Approaches in the Pharmaceutical Industry” PDA J. Pharma. Sci. Technol. 2017 Mar-Apr;71(2):147-162
- Sarah S Peláez, Hanns-Christian Mahler, Christoph Herdlitschka, et al. PDA Journal of Pharmaceutical Science and Technology 2019. “Comparing Physical Container Closure Integrity Test Methods and Artificial Leak Methodologies.”