

Container Closure Integrity: Regulations, Test Methods, Application

References

Instructors

Brandon Zurawlow; Containsure; bz@containsure.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



Basel Switzerland, February 27 - 28, 2020

CONNECTING
PEOPLE
SCIENCE AND
REGULATION®

- 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
- USP<1207> Package integrity evaluation – Sterile products

- 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

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