

CONTAINER CLOSURE INTEGRITY TESTING

LIFE INSPIRED, QUALITY DRIVEN



The safety and efficacy of any pharmaceutical product is inextricably linked to its packaging. Container closure integrity testing at SGS ensures that your container's closure system will not compromise the sterility of the final drug product over the course of its shelf life.

While there is no one universally appropriate method for integrity testing all product-package configurations, SGS offers our clients can offer both deterministic testing, using the High Voltage Leak Detection (HVLD) equipment, and probabilistic testing using the Tracer Liquid method.

With over 20 years of experience, SGS designs and performs package integrity testing studies that satisfy regulatory authorities such as FDA and EMA. We will work with you to design and execute the study that will be most appropriate for your specific container configuration.

EXPERIENCE WITH CLOSURE SYSTEMS

- Bottles
- Stoppered and sealed vials
- Pre-filled syringes
- Cartridges/auto-injectors
- Pouches

TECHNIQUES INCLUDE

- High Voltage Leak Detection (HVLD)
 - Low voltage conductivity test method
 - Nondestructive
 - Quantitative and highly sensitive
 - USP<1207.2>
 - Appropriate for liquid-filled parenteral drug product glass vials, syringes, and reconstituted lyophilized cakes
- Dye Penetration by UVVis
 - Employs a dye solution under dynamic challenge conditions and utilizes UV-Vis analysis to determine if the container closure system remained intact during the challenge
 - Options for pressure and/or vacuum
 - Method development and validation available
 - Semi- Quantitative
- Elemental Solution Challenge with ICP Analysis
 - Level of ingress relative to standard and limit of detection
 - Client specific protocols
 - Semi - Quantitative

■ Oxygen Headspace

- Uses Frequency Modulated Spectroscopy (FMS) to measure the oxygen in the headspace above a drug product
- Nondestructive
- Appropriate for optically transparent containers

■ Dye Penetration by Visual

- Exposes the product's container to a dye solution under dynamic challenge conditions and utilizing a visual analysis to determine if the container closure system remained intact during the challenge
- Options for pressure and/or Vacuum
- Probabilistic

■ Microbial Challenge

- Immersion of the product's container (filled with sterile media) into a microbial solution and incubating to determine if the container closure system remained intact during the challenge
- Options for pressure, vacuum, and/or temperature cycling
- Probabilistic

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SGS Life Sciences enables the medical and health innovators of the world to deliver life-changing solutions in the quickest, safest and most efficient way, helping improve the lives of many. We provide the highest quality services, reliable expertise and guidance through our network of labs conveniently located around the globe.

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WHEN YOU NEED TO BE SURE

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