



Packaging and Device/Combination Product Testing

Create. Execute. Interpret.

Understanding product performance as it relates to regulatory agencies, device manufacturers and end users can be a challenge. West's dedicated packaging and performance testing group works with customers to develop custom protocols specific to their needs – and the needs of the combination drug product. We partner with clients and understand the current regulations and standards to create and execute and the proper study design and interpret the results.

With expert knowledge of the market and customization of testing designed with regulatory need in mind, our experts can help reduce both launch schedule risk and risk to the patient. Studies cover a variety of administration and delivery systems, and all related components and devices.

Ready to Fill and Prefilled Glass and Advanced Polymer Syringes and Cartridges (ISO 11040 and 11608 Series)

- Break Loose, Extrusion and Lubrication Quantity
- Deliverable and Residual Volume
- Liquid Leakage Beyond Plunger and Fluid Pressure
- Luer Lock Adaptor Collar and Tip Cap Pull-off Force and Torques
- Luer Cone Breakage Resistance
- Luer Connectivity
- Tip Cap Closure System Forces and Torques
- Needle Penetration and Pull-out Forces
- Burst Resistance
- Flange Breakage Resistance
- Performance Related Shelf Life and Storage
- Technical Investigations and Failure Root Cause Analysis

Glass and Advanced Polymer Vial Containers and Vial Adapters and other Transfer Devices

- Residual Seal Force
- Spike Penetrability
- Deliverable and Residual Volume
- Fragmentation
- Spike Retention and Sealing Capacity
- Delamination Analysis Electron Microscopy (ISO-7 Lab)

Regulatory and Custom Testing Collaboration

- Understanding of Global Standards and Regulatory Expectations to Match Client Needs
- Utilize Current or Create and Validate New Custom Methods
- Execute GMP Lab Testing to Create Analysis Reports
- Interpretation, Consultation and Observations of Results through Subject Matter Experts

Contact the **West Analytical Services** team today to customize your packaging and performance tests to meet the needs of your drug product – and make the most to market fast. WestAnalyticalServices.com

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