



USP <382>: Elastomeric Component Functional Suitability in Parenteral Product Packaging/Delivery Systems GMP Testing Services

The United States Pharmacopoeia (USP) has added Chapter <382> and its supporting chapter <1382> due to changes to Chapter <381>. The new chapters address the fitness-for-intended-use functional suitability requirements of packaging/delivery systems that are intended for parenteral dosage forms, which include primary packaging components that are partially or completely made of elastomeric material. Elastomeric components, when properly fitted with dimensionally compatible packaging/delivery systems, are intended to protect and contain the system's contents while enabling safe and effective product access at the time of use. Utilizing West's expertise and technology, our Analytical Services team is prepared to provide testing for all four of the new USP test sections.

System Integrity USP <1207>



- System closure integrity per USP <1207>
- Fragmentation of vial stopper and cartridge seals

Needle and Spike Access Functionality



- Penetrability using needles and spikes
- Needle self-seal of vial and cartridge systems
- Spike retention and sealability of vial systems

Plunger Functional Suitability



- Break-loose and extrusion forces of plungers
- Seal integrity and leakage of plungers

Tip Cap and Needle Shield Functionality

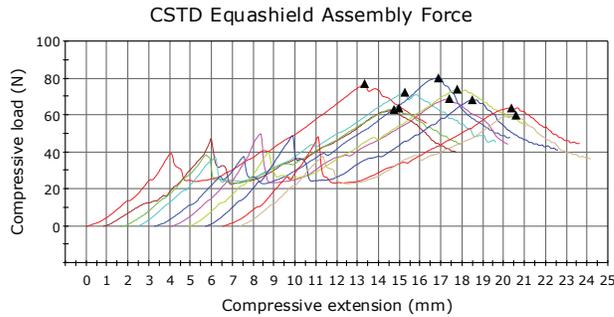


- Tip cap and needle shield retention forces sensitive drugs.



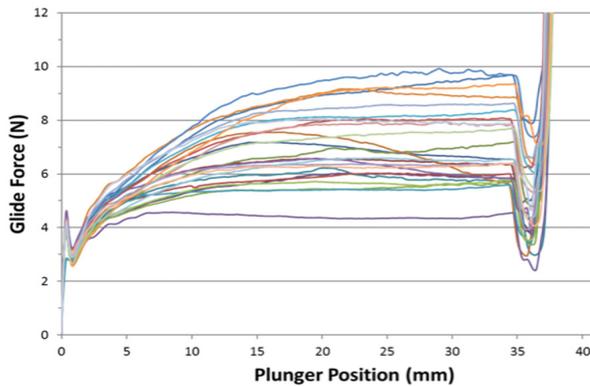
Testing Capability Example 1

West investigates transfer device spikes to determine vial system suitability by testing stopper push-in and both penetrability and attachment forces.



Testing Capability Example 2

West conducts testing to understand drug and interfacing components functionality to determine short and long-term compatibility.



Testing Capability Example 3

Fill-finish aspects of a system has direct influence on fundamental performance. West performs system functional performance assessment outcome with representative fill-finish processing including vial, cartridge and syringe stoppering.



Our Capabilities Include:

- Combination Product Testing
- On-Body Delivery Systems Testing
- Auto and Pen Injector Systems Testing
- Syringe and Cartridge Performance Testing
- Syringes with Safety Systems Testing
- Vial System Performance Testing
- Combination Product Stability Performance Testing
- Extractables and Leachables Testing
- Container Closure Integrity Testing
- Particle Load Testing Primary and Secondary Packaging
- Custom Method Development



Contact West today for more information at WestAnalyticalServices.com

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