Stopper Compression Analysis

This service provides critical information necessary to insure robust seal integrity and repeatable capper set up. A stoppered vial is a universal parenteral drug container closure system. The system however should not be considered integral until the rubber stopper is crimped firmly in place with sufficient compression against the vial, assuring all potential leakage is cut off at the seal interface. Analysis of this seal integrity should be a critical aspect of the packaging development, evaluation and qualification.

THE SERVICE

A parenteral vial container closure system is made integral by compressing the flange of a rubber stopper against the sealing surface of a vial (finish crown) and securing it in place with a crimped aluminum ferrule or seal. The elastomeric properties of the rubber maintain a force that effectively seals the vial. Our experienced technicians analyze your specific container closure system and determine the optimal compression percentage to achieve leak rate cut off. This value is then correlated to Residual Seal Force (RSF) and verified by a standard leak testing method.

The RSF value is the measured stress the compressed rubber closure flange continues to exert on the vial-sealing surface after application (crimping) of an aluminum ferrule.

RSF is the measurable stress a compressed elastomeric closure flange continues to exert on the vial land surface after the application of an aluminum seal (crimping). By correlating RSF values for each set of vials to the compression calculation for those vials, RSF can then be used as an indirect test method to estimate closely the elastomeric closure compression. RSF values may be used in effectively setting up vial cappers and for monitoring the crimping process. With an understanding of compression and leak rate cut-off RSF can be further used as a predictor of leakage risk (Orosz, 2010). The FDA recognizes the use of RSF as a predictor of seal integrity.

Genesis provides a complete report which includes all the test procedures used and data collected. This information can then be used to develop your vial sealing SOP's.

The report includes:

- Stopper Flange Compression Analysis
- Levels of Compression Graphics
- Compression and Residual Seal Force Data
- Residual Seal Force Measurements
- Helium Leak Testing
- Discussion and Recommendations
- References
- Stopper Compression Measurement Procedure
- Residual Seal Force Measurement Procedure
- Package Component Specifications

To learn more about this service please contact Genesis Sales at 610-458-4900 or visit our web site at www.gen-techno.com.