



# Container Closure Integrity and CCI Testing

## Container Closure Integrity (CCI)

One of the most important concerns of a parenteral drug manufacturer is ensuring integrity of the final packaged product. West elastomeric closures play an essential role in maintaining that integrity. At the rubber-to-glass interface, the rubber conforms to the shape of the glass, accommodating any imperfections in the glass surface. An airtight seal occurs when the rubber is compressed and held in contact with the glass. Such is the case when inserting a plunger into a slightly smaller syringe barrel or securing a serum stopper onto a vial using a crimped aluminum seal. For more information, request technical support bulletin 2003/006.

## West Analytical Services/Helium Leak Detection Test

West Pharmaceutical Services, Inc. utilizes a Seal Integrity Monitoring System (SIMS™) for leak detection. The system is based on a helium mass spectrometer leak detector equipped with a custom fixture for the particular vial size to be tested. The instrument is calibrated against an NIST-traceable standard leak. The test measures the rate of helium leak from the vial as well as the actual percent of helium that is filled within the vial. The instrument is specific for helium detection and does not detect any other molecular species. The test as used in our laboratories is unique in that it can measure the leak rate, as well as the percent of helium remaining in a pre-filled sample. A helium detector has high sensitivity while being reliable and quantitative. West Pharmaceutical Services can provide this testing through its West Analytical Services. Additionally, West can assist with the development of sealing optimization/validation protocols. For more information, request technical support bulletin 2003/020.

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