

## Sterile Vial Integrity Testing



Sterile vials are often produced in large numbers in a batch process. Fluorescence has traditionally been used to identify vials which are evacuated during the vacuum cycle(s) during autoclaving, hence identifying those with leaks.

There are two electronically monitored alternative solutions and both alternatives can be validated and calibrated, allowing proven identification of quantified leaks. Vial closure integrity can be detected by a pressure decay method or a trace gas method.

### Vacuum Testing

In pressure testing, the vials are placed in a chamber that closely fits the vial profile. The chamber is subjected to a vacuum and leakage from the vial into the vacuum is measured as a pressure increase. This is analogous to pressure decay testing, where a positive pressure is applied inside the product. This method is best suited to audit testing as the volume of the test chamber significantly influences the test time and sensitivity. Hence testing vials individually is most efficient.

Testing can be carried out to ASTM F2338-05, Standard Test Method for non destructive Detection of Leaks in Packages by Vacuum Decay Method (Sterility).

### Tracer Gas Testing

If 100% testing is required the tracer gas method is often the best solution. A variety of gases can be used for the testing of packaging. The essential requirement for the gas is that it should have low abundance in the atmosphere. Hydrogen fits the bill extremely well and offers the added advantage of having very low viscosity. It is a perfect gas for detecting micron-sized leaks, with low consumable costs. A non-explosive mixture of 5% hydrogen in nitrogen is used.

Ampoules and vials are sealed in an the tracer gas-enriched atmosphere. Gas detection equipment is then used further down the production line. This equipment can very accurately detect tiny leaks and identify which product is at fault. Alternatively, vials can be produced in normal ambient atmosphere and then stored in a pressurised, hydrogen-enriched chamber prior to testing. Both methods are sensitive and produce accurate results.

Tracer gas options from MET include: Carbon Dioxide, Helium and Hydrogen. Carbon dioxide is a popular method and can be used as an in-line method.

Validation and calibration is achieved using manufactured leaks of known size.