



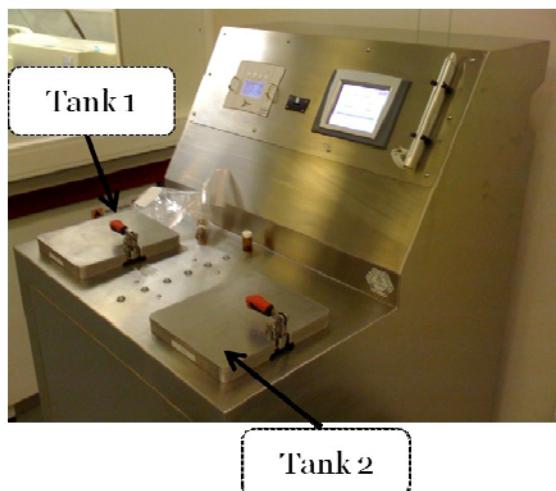
Helium Leak Testing for Pharmaceuticals Packaging

Industrial sealing control methods differ depending on the products being packaged, and many have reached their limits. For example, the most widely used method of leak testing in the packaging industry uses a destructive method. This means when a sample is tested, it cannot be returned to the production line. In reality, the result is: That **was** a good package. This is a very expensive process since it means a loss of finished, shippable product. In the pharmaceutical field, the most common test is visual, utilizing an “immersion test” with methylene blue. Once a pharmaceutical is exposed to this test, it must be destroyed. Again, a costly source of lost revenue. The concerns with profit and productivity issues are pushing manufacturers to re-evaluate quality control testing at the end of the production lines.

The Helium Technology to Improve Quality

Recently a new technology has emerged: Tracer gas leak detection. Previously used extensively for leak detection in the HVAC industry, underground water leak detection, and fuel tank sealing control in aircraft, it has recently been adapted to improve the quality of packaging, particularly in the pharmaceutical industry.

Manufacturers of leak detectors developed automated leak test benches specifically dedicated to non-destructive checks using helium leak testing for pharmaceutical packaging.



Helium leak tester for pharmaceuticals packaging : The Trace900

Why using helium? The helium molecule is the smallest of all gases, and is totally nonreactive to any materials or chemicals. It allows clean, very sensitive and non-destructive testing. The test cycle usually has four steps:

- The product is exposed to vacuum to check the soundness of packaging closures (tank1).
 - The product is over-pressured with helium – the “bombing” process (tank1).
 - The product is transferred in the test chamber (tank 2).
 - The product is exposed to a vacuum (tank 2). If a product is defective, the helium introduced by the “bombing” process escapes into the test chamber. The tracer gas is easily and quickly detected.
- Defect-free products are returned to the production line for distribution.



Informations about Helium



- Helium is an inert chemical element
- Helium is non-hazardous, non-flammable, and non-explosive.
- Helium is an industrial gas, is reasonably priced. It is available in medical grade and other degrees of purity.
- Helium is easy to get.

Leaks Relevant to the Pharmaceutical Industry: FAQ

What are the risks associated with these leaks?

The main risk is the penetration of external agents into the package, such as air, moisture, bacteria, viruses, etc.

What are some consequences of these leaks?

The consequences of leaks in packaging are:

- Degradation of active ingredients and their medicinal/chemical properties.

Example: Effervescent tablets losing their fizz.

- Modification of active ingredients and their medicinal/chemical properties.

Example: A compound which would be neutralized in contact with moisture and become ineffective as a cure. DANGER

What are the benefits of leak detection for the manufacturer?

In Research and Development

Validating selected materials for packaging.

Allowing fine tuning of procedures to improve quality.

Ensuring compliance before shipping product to the public.

In Production

Helping to detect drifts in sealing tool settings.

Traceability for the customer of the production quality.

Giving management peace of mind regarding quality and production control.