LVA
VACUUM DETECTION MACHINE
FOR LYOPHILIZED / FREEZE DRIED PRODUCTS
Bonfiglioli Engineering, the leading supplier of Leak Detection Systems announces the LVA, a totally precise way to perform 100% vacuum detection. Using an optical-based headspace sensing system. It is now possible to directly measure pressure, oxygen and moisture in the headspace of parenteral drug products.

**Measurement Process**

Light from a near-infrared semiconductor laser is tuned to match the internal vibrational frequency of a target molecule. The light is passed through the headspace region of a sealed container and some of the laser energy is absorbed by the target molecules. The laser is scanned in frequency and a photodetector records an absorption profile. The laser absorption signal contains information about the headspace gas concentration and the total headspace pressure. The measurement method also incorporates a high sensitivity detection technique known as TDLAS (Tunable Diode Laser Absorption Spectroscopy).

This laser absorption technique solves the drawbacks of the spark test method. Headspace pressure measurements can be made over the full range (0 – 1 atm). Since the laser light simply passes through the headspace of the vial, there is no affect on the product.

The LVA machine measures the actual vacuum level in the headspace of each container that passes through the optical head. Unlike systems that indirectly determine leaks by measuring oxygen ingress, it can, in real-time, monitor the actual pressure in the headspace of the container and report a quantitative value. The absolute pressure is measured by monitoring changes in peak width of the moisture absorption signal. The peak width is proportional to the pressure in the headspace of the container being measured. All lyophilized products contain some moisture in the headspace (0.1% to 5%) and provide sufficient signal for the laser technology to make the measurement. Pressure broadening, the term used to describe this physical characteristic allows the LVA to measure vacuum levels at rates up to 500 vials/minute with a single head.

**TECHNICAL SPECIFICATIONS**

- Non Destructive, Rapid and accurate analysis system
- Optical non-intrusive analysis
- Goes through glass vial walls
- Measurement possible through powdered vials
- No nitrogen purging necessary
- High Control sensitivity
- Vacuum Dynamic Range: from 0 to 1 bar
- Production speed: up to 500 vials/minute.
- Container sizes: from 1 ml up to 500 ml
- Container compatibility: tubing, moulded, amber or clear
- Fully validated system
- Autotest system for self checking
- LVA is configurable to comply with CFR21 part 11 and GMP norms